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Reflection paper on physical frailty: instruments for baseline characterisation of older populations in clinical trials

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Table of contents

List of Abbreviations

ADL: Activities of Daily Living

CGA: Comprehensive Geriatric Assessment

CHMP: Committee for Medicinal Products for Human Use

GEG: Geriatric Expert Group

ICH: International Conference on Harmonisation

PD: Pharmacodynamics

PK: Pharmacokinetics

ROC: Receiver Operating Characteristic

SPPB: Short Physical Performance Battery

Executive summary

Clinical Trials Regulation (EC) No 536/2014 requires a '*justification for the gender and **age** allocation of subjects and, if a specific gender or age group is excluded from or underrepresented in the clinical trials, an explanation of the reasons and justification for these exclusion criteria'.* It further states that *'in order to improve treatments available for vulnerable groups such as **frail** or older people, people suffering from multiple chronic conditions, and people affected by mental health disorders, medicinal products which are likely to be of significant clinical value should be fully and appropriately studied for their effects in these specific groups, including as regards requirements related to their specific characteristics and the protection of the health and well-being of subjects belonging to these groups'.*

Older persons are large medicines consumers for a number of chronic diseases, but despite this they have generally been excluded from clinical trials. The ICH topic E7 Studies in Support of Special Populations: Geriatrics Questions and Answers (EMA/CHMP/ICH/604661/2009) also advocates that '*it is very important to ensure, to the extent possible, that the population included in the clinical development program is **representative** of the target patient population'* and states that '*vulnerable geriatric patients at high risk of **adverse outcomes** (so-called "**frail**" geriatric patients)*' are considered '*particularly important to address in the planning of the clinical development program'*. The benefit-risk balance may be different for older patients, particularly for older patients with frailty, than for the younger adults usually enrolled in a clinical investigation.

Recognising that it is important to understand whether data on frail patients are available in a clinical development, the EMA Geriatric Medicines Strategy (EMA/CHMP/137793/2011) included the following action: *'The Agency should perform a search among available documentation and other scientific data to identify available and validated instruments/methods (e.g. scales) which can be used to examine effect and safety in "frail" patients'.* In 2011 the Committee for Medicinal Products for Human Use (CHMP) requested the Geriatric Expert Group (GEG) to perform such a search, and this Reflection paper document is the result of that work.

The scope of this document is to describe the recommended instruments to be applied for the baseline characterisation of physical frailty of patients aged 65 years and older enrolled in a clinical trial or other clinical investigation (e.g. registry). These instruments are proposed to supplement age, as delineated in ICH E7, as a demographic characterisation factor in order to support a better understanding of the benefit-risk of a medicine in the older population.

Subgroup analysis by baseline physical frailty parameters set *a priori* may allow investigating the association of results in subgroups with the overall results of the clinical trial (or observational study). Subgroups defined may be associated with a heterogeneous response to treatment, i.e. differential treatment efficacy and/or differential incidence of treatment-related adverse events. If any substantial

subgroup differences are anticipated between older subjects with or without physical frailty (e.g. concerning drug effects, dose adjustment or adverse events), it is expected to be *a priori* mentioned in the clinical trial protocol, and may be used as a stratification factor. As illustrated in the draft Guideline on the investigation of subgroups in confirmatory clinical trials (EMA/CHMP/539146/2013), cut-off points used to classify the physically frail and the non-frail subpopulation under investigation should generally be pre-specified and justified accordingly. Moreover, sensitivity analyses using different cut-offs should routinely be performed.

Research on frailty is currently an area in evolution, and several available instruments have been reviewed for this Reflection paper. The criteria that have been taken into account to identify the tools proposed in this document are: prognostic value of disability and mortality; validation status; feasibility of use across all therapeutic areas; ease of use; time required; ease of investigator's training; cost.

The Short Physical Performance Battery (SPPB) is identified as the instrument best fulfilling these criteria. If it is not feasible to assess baseline physical frailty by SPPB, then Gait Speed is an alternative instrument, but it should be noted that it is not as well validated and multifaceted as SPPB.
The other instruments were considered more difficult to routinely implement in a clinical trial context (see section 5).

This document should be read in conjunction with other EMA and ICH guidelines which may apply to this patient population (see section 3).

1. Introduction

Reasons for exclusion of older people from clinical trials often have been insufficiently justified, and have included predefined arbitrary upper age limits, as well as exclusion criteria including comorbidities or concomitant medications. This selection bias is even more evident for the older patients with frailty, who account for a significant proportion of older persons at risk of adverse outcomes.[1,2,3]

Frailty and multimorbidity (usually defined as the co-existence of two or more conditions in an individual, and also called comorbidity in the context of an index disease) are two distinct entities which are often closely related, since most pre-frail and frail older people suffer from multimorbidity. Usual medical diagnostic and therapeutic approaches focused on each single disease do not account for disease-disease interactions which may impair health and functional outcomes. While the knowledge of the multimorbidity status of a clinical trial population is needed to fully characterise the benefit-risk of a medicine in clinical practice, multimorbidity assessment is outside the scope of this document.

Better characterisation of this growing segment of the older population beyond age, following a standardized approach, might better inform the evaluation of efficacy and safety of medicines in the pre- and post-authorisation phase.[4,5,6] A standardized characterisation of physical frailty is potentially useful for risk stratification, in order to improve the description of the characteristics of older populations involved in clinical trials, and support the external validity of the benefit/risk conclusions. If such physical frailty scales were routinely introduced to define the baseline characteristics of the population enrolled in a clinical trial for a medicine with highly prevalent use in the older population, this would enhance the knowledge of whether the benefit-risk balance of the product can be assessed in a population representative of the full target population.

Important elements to be considered in the development of a new medicine for use in the older population include the recruitment of sufficient numbers of older patients in appropriate age ranges (particularly the very old patients) for Pharmacokinetics as well as PK/PD analyses; the use of an age-appropriate measure of renal function; awareness of, and openness to testing covariates reflecting biological rather than chronological age. The very old people often exhibit modified Pharmacodynamics sensitivity and thus exploration of the minimum effective dose is essential to improving tolerability.

2. Scope

This Reflection paper is intended to describe the recommended instruments for the characterization of the baseline physical frailty status of older patients (i.e. aged ≥ 65 years) enrolled in a clinical trial or other clinical investigation (e.g. registry), to supplement the requirements of ICH E7 Note for Guidance and Questions and Answers.

In order to ensure that the population included in the clinical trials is representative of the users of the medicinal product, older population characteristics are expected to be described beyond age, as the benefit-risk balance in older patients may depend on their physical frailty status.

3. Legal basis and relevant guidelines

The considerations of the effects of medicinal products of significant clinical value on older people in a clinical development program can be found in the Recital 14, 15, 19 and 35 of the Clinical Trials Regulation (EC) No 536/2014[i].

The presentation requirements for Modules 1 to 5 are found in the Annex I of Directive 2001/83/EC, as amended.

In addition, the following guidelines should be taken into account:

- Note for Guidance on Studies in Support of Special Populations: Geriatrics - CPMP/ICH/379/95 (ICH E7) and the Questions and Answers - EMEA/CHMP/ICH/604661/2009;
- Note for Guidance on Dose Response Information to Support Drug Registration - CPMP/ICH/378/95 (ICH E4);
- Note for Guidance on Statistical Principles for Clinical Trials - CPMP/ICH/363/96 (ICH E9);
- Note for Guidance on Population Exposure: The Extent of Population Exposure to assess Clinical Safety - CHMP/ICH/375/95 (ICH E1);
- Pharmacokinetic Studies in Man - EudraLex vol. 3, 3C C3A;
- Note for Guidance on the Investigation of Drug Interactions - CPMP/EWP/560/95;
- Guideline on good pharmacovigilance practices (GVP) Module V – Risk management systems - EMA/838713/2011 Rev 2.

These Guidelines have to be read in conjunction with the introduction and general principles and Part I and II of the Annex I to Directive 2001/83/EC as amended. Applicants should also refer to other relevant adopted EMA and ICH guidelines.

[i] Regulation (EU) No 536/2014 of the European Parliament and the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EEC.

4. The concept of frailty

Frailty is defined as a state of increased vulnerability resulting from aging and often disease associated decline in reserve and function across multiple physiologic systems such that the ability to cope with acute stressors is reduced, leading to increased risk of adverse health outcomes such as incident disability, cognitive decline, falls, hospitalization, institutionalization, or increased mortality. Older persons with frailty are also more vulnerable to clinically important adverse drug reactions. Hospital admissions related to medicines are especially frequent in older patients, and data suggest that many are potentially preventable.[7,8,9,10]

Frailty is a dynamic process with several phases that develops as a continuum, from fit to pre-frail, and then frail status. The prevalence of frailty increases with age in a non-linear pattern. It is more common in women, although frail women tend to survive longer than frail men[11].

Although there is a general agreement on the concept of frailty, a standardized assessment instrument to be used in clinical trials and research is still needed. Thresholds based on chronological age, which are the prevailing indicators, are not sufficient, as they do not offer a good estimate of biological age.

The main controversy arises around the precise identification of frailty, as different models have included the exploration of either physical, functional, cognitive, social functioning measures or any combination of these.[12,13,14,15,16] The use of different frailty models may lead to the identification of groups of frail older subjects which may not be identical in composition.[17]

It is recognised that a complete evaluation of frailty to support its management requires a multidimensional interdisciplinary Comprehensive Geriatric Assessment (CGA), which is the 'gold standard' in clinical practice, but due to complexity it is beyond the scope of this document. Domains assessed in a typical CGA include physical and cognitive function, nutritional status, multimorbidity, concomitant medications and socio-economic factors. CGA is of a comprehensive nature, making it the optimal instrument for patient management in clinical practice. It can potentially identify underlying causes of frailty and support the decision to start interventions in order to reverse it, and the identification of the 'fit' older people who do not require subsequent complete CGA is desirable. However, the limitations that might hinder the incorporation of CGA into every clinical trial include the time required for the assessment and the expertise of a geriatrician for good reproducibility, though CGA is an important categorisation tool in clinical trials performed in nursing homes or Geriatric Departments in hospitals. As such, attention has turned to the development of instruments which may correlate with CGA. For instance, the Multidimensional Prognostic Index (MPI)[18,19] is able to extract information from CGA to categorize frailty in three subgroups with excellent prognostic value.

Several frailty instruments have been tested and validated in epidemiological studies in the older population, while their applicability to other settings has been somewhat limited. The problems arising when using them in clinical settings were demonstrated in a Dutch study, where four common frailty instruments were investigated for their feasibility and effect on the selection of frail older patients among those consecutively admitted to an acute geriatric or old age psychiatry ward.[20] The prevalence of frailty in the older people was different using different criteria and the patient populations identified by these criteria only partially overlapped. The authors' conclusions were that '*the choice of the most appropriate frailty criterion should be based on the purpose, the outcome on which the criterion was originally validated, the quality of the validation process carried out so far, and the similarity of the current population to the validation group*'.

Physical performance measures appear to integrate the effects of multiple facets of health and aging, including fitness, emotional status, cognitive dysfunction, disease processes and nutritional status. These measures may offer advantages over self-report measures of functional limitation in terms of validity, reproducibility, sensitivity to change, applicability to cross national and cross-cultural studies, and the ability to identify a reduced physical performance in early stages in older subjects who are considered to have high levels of function as a consequence of the ceiling effect that is a limitation to the scales currently used to assess disability.[21]

5. Assessment of baseline physical frailty

Several studies compared the ability of different frailty scales as prognostic markers of adverse outcomes in older subjects, in particular disability and mortality. A common finding is that different frailty scales capture different but overlapping groups of older adults.[22] In general, the different scales can all be prognostic of these adverse outcomes, although the psychometric properties might be slightly different, in terms of sensitivity, specificity and area under the ROC curve. Nevertheless, the similar prognostic ability among different frailty scales suggests that the choice of an instrument should take into account the purpose of the research, information available and the ease of use. A major limitation of all these studies is that the frailty scales were usually adapted from the original definitions to use data available in each specific study.[23]

A number of validated scales with good correlation with higher risk of disability and mortality have been considered[6]. The criteria that have been applied for the choice of the recommended instruments are as follows:

- prognostic value of disability and mortality
- validation status
- feasibility of use across all therapeutic areas
- ease of use
- time required
- ease of investigator's training
- cost.

The scales proposed to be used in clinical trials to assess baseline physical frailty are:

- *Short Physical Performance Battery (SPPB)*
- *Gait speed.*

These tools can identify the increased vulnerability that is the hallmark of physical frailty, prognostic of disability and mortality in older subjects, and have been extensively used in clinical settings.[15,16,24,25,26] The SPPB is identified as the instrument fulfilling all of these criteria, and is recommended as the instrument of choice for the baseline characterization of physical frailty of older people enrolled in a clinical trial. Should it not be feasible to assess baseline physical frailty by SPPB, then Gait Speed is a possible alternative instrument, though not as well validated and as multifaceted as SPPB.

As an example, other instruments that were considered but found more difficult to implement in a clinical trial context were:

- The Canadian Study of Health and Aging (CSHA) Frailty Index (FI)[27] developed by Rockwood et al. as a measure of deficit accumulation, has the limitation of being very difficult to apply in clinical settings, as the 70-item scale is cumbersome.
- Fried criteria[28] also require more time, equipment and expertise than SPPB, and further limitations

are that it has been developed in a USA community-dwelling sample excluding older subjects with cognitive impairment, stroke and depression. Fried criteria may be difficult to easily apply to clinical trial populations as well, particularly with regard to the assessment of habitual physical activity and in those having the highest degree of health and functional impairment (e.g. hospitalized subjects, nursing home and assisted living residents).

Moreover, some therapeutic areas may have established instruments that are well validated in specific settings, such as several geriatric tools for older cancer patients including G8.[29] These instruments are not covered by this document, as they do not meet the criterion of general applicability across therapeutic areas. Should the sponsor of the clinical trial consider another validated scale, it could be used in addition to SPPB or Gait speed. Research into validation of alternative scales is encouraged.

5.1. Short Physical Performance Battery (SPPB)

The Short Physical Performance Battery (SPPB) assesses lower-extremity function by measures of three separate tests, i.e. standing balance, gait speed, and ability to rise from a chair.[21,30] A summary performance score is created by adding the scores for the tests of standing balance, gait speed, and repeatedly rising from a chair. The summary scores range between 0 and 12, with higher scores indicating better performance. The SPPB assessment takes 10-15 minutes.[21] It requires modest instrumentation (a chronometer and a tape floor mark for the distance to measure gait speed).

Summary score cut-offs have been defined based on subsequent risk of disability and mortality:[30,31,32]

SPPB 10-12 points	fit patient, normal
SPPB 8-9 points	pre-frail patient
SPPB ≤ 7 points	frail patient

Advantages:
Among easily-applied instruments, SPPB has the best prognostic value of adverse outcomes of long-term survival, mortality, hospitalization, disability, worsening mobility, falls, decline in function, decline in health related and acute medical events.

Limitations:
The test can have a floor effect, particularly in very sick patients or those with Activities of Daily Living (ADL) disability, who might be unable to do the performance test. [16,33]

5.2. Gait speed

Gait speed at usual pace is one of the tests of the SPPB, and in studies it has shown the same prognostic value of disability and mortality as the whole battery.[34,35,36,37] It has also proved to add meaningful information to the assessment of prognosis of older individuals undergoing cardiac surgery.[38,39] Walking requires strength, coordination and balance, thus placing demands on multiple organ systems, including the cardiovascular, respiratory, nervous, and musculoskeletal systems. A slowed gait may reflect both impairment of these systems as well as the additional effort required to walk.

Gait speed is measured over short distances, usually using a 2.43-meter (8 feet) to 6-meter walking course with a simple protocol. [40,41] Most evidence for use comes from large epidemiological studies using 4- or 6-meter walking distances[42] with standardisation to 4 meters[43], thus the 4 meters distance is recommended as the standard assessment. In addition, it is more practical for use both in the home context and at the clinic.[34] As mentioned for the SPPB, it requires modest instrumentation (a chronometer and a floor mark).

Gait speed cut-offs have been defined based on their relation with a risk of negative health outcomes (persistent lower extremity limitation, hospitalization and death): [30,40,41]

<0.4 m/s	very high risk of negative health outcomes
0.4 – 0.99 m/s	high risk of negative health outcomes
≥ 1 m/s	low risk of negative health outcomes

Advantages:
It is a simpler test than the whole battery of SPPB, and in some studies it has shown the same prognostic value, principally for mortality but also for incident disability. Gait speed could be considered a simple and accessible summary indicator of vitality because it integrates both known and unrecognised impairment of multiple organ systems, many of which affect survival. [44] In addition, decreasing mobility may induce a vicious circle of reduced physical activity and de-conditioning that has a direct negative effect on health and survival.[37]

Limitations:
It is not as well validated and as multifaceted as SPPB.

6. Conclusion

Clinical Trials Regulation (EC) No 536/2014 and ICH E7 Note for Guidance and Questions and Answers indicate that clinical trials should recruit patients that represent the target population which will use a medicinal product. This document provides the recommended instruments to characterise older patients by their baseline physical frailty status.

These instruments are intended for use in pre- and post-authorisation studies across all therapeutic areas, to support the inclusion of a representative population in the clinical trial development program as required by the epidemiology of the disease.

The SPPB is the preferred option for routine use in clinical trials to characterize baseline physical frailty, as it has the best prognostic value of disability and mortality. In situations where it is not possible to assess baseline physical frailty by the SPPB instrument, the Gait Speed is an alternative choice, although not as multifaceted and as well validated as the SPPB. Other disease-specific validated scales could be used in addition for specific populations, to refine the subgroup of older patients with physical frailty and discriminate motor performance due to frailty itself and impairment related to the disorder.

7. Annex. SPPB and Gait speed

(Guralnik JM et al. 1994)

Study ID _____ Date _____ Tester Initials _____

Scoring for Complete Short Physical Performance Battery

Test Scores
Total Balance Test score _____ **points**
Gait Speed Test score _____ **points**
Chair Stand Test score _____ **points**

Total Score _____ **points (sum of points above)**

SHORT PHYSICAL PERFORMANCE BATTERY PROTOCOL AND SCORE SHEET

All of the tests should be performed in the same order as they are presented in this protocol. Instructions to the participants are shown in bold italic and should be given exactly as they are written in this script.

1. BALANCE TESTS
The participant must be able to stand unassisted without the use of a cane or walker. You may help the participant to get up.

Now let's begin the evaluation. I would now like you to try to move your body in different movements. I will first describe and show each movement to you. Then I'd like you to try to do it. If you cannot do a particular movement, or if you feel it would be unsafe to try to do it, tell me and we'll move on to the next one. Let me emphasize that I do not want you to try to do any exercise that you feel might be unsafe.

Do you have any questions before we begin?

A. Side-by-Side Stand

1. ***Now I will show you the first movement.***
2. (Demonstrate) ***I want you to try to stand with your feet together, side-by-side, for about 10 seconds.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the side-by-side position.
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say, ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.
9. If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

Study ID _____ Date _____ Tester Initials _____

B. Semi-Tandem Stand

1. ***Now I will show you the second movement.***

2. (Demonstrate) ***Now I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.***

3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***

4. Stand next to the participant to help him/her into the semi-tandem position

5. Supply just enough support to the participant's arm to prevent loss of balance.

6. When the participant has his/her feet together, ask ***"Are you ready?"***

7. Then let go and begin timing as you say ***"Ready, begin."***

8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.

9. If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

C. Tandem Stand

1. ***Now I will show you the third movement.***

2. (Demonstrate) ***Now I want you to try to stand with the heel of one foot in front of and touching the toes of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.***

3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***

4. Stand next to the participant to help him/her into the tandem position.

5. Supply just enough support to the participant's arm to prevent loss of balance.

6. When the participant has his/her feet together, ask ***"Are you ready?"***

7. Then let go and begin timing as you say, ***"Ready, begin."***

8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.

Study ID _____ Date _____ Tester Initials _____

2. GAIT SPEED TEST

Now I am going to observe how you normally walk. If you use a cane or other walking aid and you feel you need it to walk a short distance, then you may use it.

A. First Gait Speed Test

1. ***This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store.***

2. Demonstrate the walk for the participant.

3. ***Walk all the way past the other end of the tape before you stop. I will walk with you. Do you feel this would be safe?***

4. Have the participant stand with both feet touching the starting line.

5. ***When I want you to start, I will say: "Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***

6. Press the start/stop button to start the stopwatch as the participant begins walking.

7. Walk behind and to the side of the participant.

8. Stop timing when one of the participant's feet is completely across the end line.

B. Second Gait Speed Test

1. ***Now I want you to repeat the walk. Remember to walk at your usual pace, and go all the way past the other end of the course.***

2. Have the participant stand with both feet touching the starting line.

3. ***When I want you to start, I will say: "Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***

4. Press the start/stop button to start the stopwatch as the participant begins walking.

5. Walk behind and to the side of the participant.

6. Stop timing when one of the participant's feet is completely across the end line.

Study ID _____ Date _____ Tester Initials _____

GAIT SPEED TEST SCORING:

Length of walk test course: Four meters ❒ Three meters ❒

A. Time for First Gait Speed Test (sec)

1. Time for 3 or 4 meters __ __.__ __sec
2. If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not walk unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (Specify) _____	6
Participant refused	7
Complete score sheet and go to chair stand test	

3. Aids for first walk.....None ❒ Cane ❒ Other ❒

Comments:_____
_____
_____

B. Time for Second Gait Speed Test (sec)

1. Time for 3 or 4 meters __ __.__ __ sec
2. If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not walk unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (Specify)	6
Participant refused	7

3. Aids for second walk..... None ❒ Cane ❒ Other ❒

What is the time for the faster of the two walks?
Record the shorter of the two times __ __.__ __ sec
[If only 1 walk done, record that time] __ __.__ __ sec

If the participant was unable to do the walk: ❒ **0 points**

For 4-Meter Walk:		**For 3-Meter Walk:**	
If time is more than 8.70 sec:	❒ **1 point**	If time is more than 6.52 sec:	❒ **1 point**
If time is 6.21 to 8.70 sec:	❒ **2 points**	If time is 4.66 to 6.52 sec:	❒ **2 points**
If time is 4.82 to 6.20 sec:	❒ **3 points**	If time is 3.62 to 4.65 sec:	❒ **3 points**
If time is less than 4.82 sec:	❒ **4 points**	If time is less than 3.62 sec:	❒ **4 points**

Study ID _____ Date _____ Tester Initials _____

3. CHAIR STAND TEST

Single Chair Stand

1. ***Let's do the last movement test. Do you think it would be safe for you to try to stand up from a chair without using your arms?***

2. ***The next test measures the strength in your legs.***

3. (Demonstrate and explain the procedure.) ***First, fold your arms across your chest and sit so that your feet are on the floor; then stand up keeping your arms folded across your chest.***

4. ***Please stand up keeping your arms folded across your chest.*** (Record result).

5. If participant cannot rise without using arms, say ***"Okay, try to stand up using your arms."*** This is the end of their test. Record result and go to the scoring page.

Repeated Chair Stands

1. ***Do you think it would be safe for you to try to stand up from a chair five times without using your arms?***

2. (Demonstrate and explain the procedure): ***Please stand up straight as QUICKLY as you can five times, without stopping in between. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. I'll be timing you with a stopwatch.***

3. When the participant is properly seated, say: ***"Ready? Stand"*** and begin timing.

4. Count out loud as the participant arises each time, up to five times.

5. Stop if participant becomes tired or short of breath during repeated chair stands.

6. Stop the stopwatch when he/she has straightened up completely for the fifth time.

7. Also stop:
   - If participant uses his/her arms
   - After 1 minute, if participant has not completed rises
   - At your discretion, if concerned for participant's safety

8. If the participant stops and appears to be fatigued before completing the five stands, confirm this by asking ***"Can you continue?"***

9. If participant says "Yes," continue timing. If participant says "No," stop and reset the stopwatch.

Study ID _____ Date _____ Tester Initials _____

SCORING

Single Chair Stand Test

		YES	NO	
A.	Safe to stand without help	❒	❒	
B.	Results:			
	Participant stood without using arms	❒		→ Go to Repeated Chair Stand Test
	Participant used arms to stand	❒		→ End test; score as 0 points
	Test not completed	❒		→ End test; score as 0 points

C. If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not stand unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (Specify) _____	6
Participant refused	7

Repeated Chair Stand Test

		YES	NO
A.	Safe to stand five times	❒	❒

B. If five stands done successfully, record time in seconds.

Time to complete five stands __ __.__ __ sec

C. If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not stand unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (Specify)	6
Participant refused	7

Scoring the Repeated Chair Test

Participant unable to complete 5 chair stands or completes stands in >60 sec:	❒ 0 points
If chair stand time is 16.70 sec or more:	❒ 1 points
If chair stand time is 13.70 to 16.69 sec:	❒ 2 points
If chair stand time is 11.20 to 13.69 sec:	❒ 3 points
If chair stand time is 11.19 sec or less:	❒ 4 points

Short Physical Performance Battery

1. Balance Tests

Side-by-Side Stand
Feet together side-by-side for 10 sec

< 10 sec (0 pt) → Go to 4-Meter Gait Speed Test

10 sec (1 pt)

Semi-Tandem Stand
Heel of one foot against side of big toe of the other for 10 sec

< 10 sec (+0 pt) → Go to 4-Meter Gait Speed Test

10 sec (+1 pt)

Tandem Stand
Feet aligned heel to toe for 10 sec

10 sec (+2 pt)
3-9.99 sec (+1 pt)
<3 sec (+0 pt)

2. Gait Speed Test

Measures the time required to walk 4 meters at a normal pace (use best of 2 times)

<4.82 sec	4 pt
4.82-6.20 sec	3 pt
6.21-8.70 sec	2 pt
>8.7 sec	1 pt
Unable	0 pt

3. Chair Stand Test

Pre-test
Participants fold their arms across their chest and try to stand up once from a chair

unable → Stop (0 pt)

able

5 repeats
Measures the time required to perform five rises from a chair to an upright position as fast as possible without the use of the arms

≤11.19 sec	4 pt
11.20-13.69 sec	3 pt
13.70-16.69 sec	2 pt
>16.7 sec	1 pt
>60 sec or unable	0 pt

8. References

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