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ORIGINAL ARTICLE

The prevalence of frailty and related factors in community-dwelling Turkish elderly according to modified Fried Frailty Index and FRAIL scales

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Abstract
Aim The purpose of this study is to determine the prevalence of frailty with the Fried Frailty Index (FFI) and FRAIL scales (Fatigue, Resistance, Ambulation, Illness, Low weight) and also its associated factors in the community-dwelling Turkish elderly.
Methods This is a cross-sectional population-based study in an urban area with a population of over 1,200,000. We sampled 1/100 of the elderly population. Frailty prevalence was assessed with a modified version of the FFI and FRAIL scale. Nutritional status was assessed by Mini Nutritional Assessment. Cognitive function was assessed by Mini-Mental State Examination. Depressive mood was assessed by GDS. Functional capacity was assessed by the instrumental activities of daily living scale. Falls and fear of falling were noted. Uni- and multivariate analyses were done to determine associated factors for frailty.
Results A total of 906 community-dwelling elderly were included, in whom the mean age and standard deviation (SD) of age were 71.5 (5.6) years (50.6 % female). We detected frailty (female 30.4 %, male 25.2 %), pre-frailty and non-frailty prevalence with FFI as 27.8, 34.8, and 37.4 %, respectively. The prevalence of frailty (female 14.5 %, male 5.4 %), pre-frailty and non-frailty with the FRAIL scale was detected as 10, 45.6, and 44.4 %. Coexisting associated factors related with frailty in both models were found as depressive mood, cognitive impairment, and malnutrition in multivariate analysis.
Conclusions According to both scales, frailty was strongly associated with cognitive impairment, depressive mood, and malnutrition in the community-dwelling Turkish elderly population.

Keywords Community dwelling · Elderly · Frailty

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Introduction

Frailty, which is a significant geriatric syndrome in which vulnerability to stressors is increased due to multiple body systems impairment is considered to be more prevalent with increasing age [1]. It is a significant problem since it may lead to functional decline and increased hospitalization, institutionalization and mortality [2]. The prevalence of frailty is difficult to determine due to disparity in how frailty is defined. Frailty is determined according to assessment in three domains: functionality, deficit accumulation, and biology [3]. The biological model of frailty was proposed by Fried and her colleagues and is based on

five components: weight loss, exhaustion, low energy expenditure, slowness and weakness in the Cardiovascular Health Study (CHS) scale [4]. Another scale produced by the International Academy of Nutrition and Aging, the FRAIL scale (FRAIL: Fatigue, Resistance, Ambulation, Illness, Low weight) was recently developed as a simple measure that combines components of functionality, deficit accumulation, and biology [3]. It is an easy to use scale which can be administered in a relatively short time but depends on the self reports of patients. On the other hand, the FFI, which is the most frequently used scale to describe frailty and can be considered as a more objective measure, needs a comparatively long time and staff education so it may not be practical in a busy clinic setting. Hand grip and walking speed can be mentioned as objective measures while weight loss and exhaustion are self-reported items in FFI.

A recent systematic review including 21 community-based studies, in which different definitions of frailty are used, shows that the prevalence of frailty is 4–59.1 % [5]. However, the prevalence of frailty in the Turkish elderly population has not been determined yet.

The aim of this study is to determine the prevalence of frailty as described by two frequently used scales and to determine the factors associated with frailty in the community-dwelling Turkish elderly.

Methods

We used the data of the Kayseri Elderly Health Study (KEHES) which was conducted from August 2013 to December 2013. It is a cross-sectional population-based study which included at least 1 % of the community-dwelling elderly in Kayseri, where 88 % of the general population lives in the urban area. This is one of the leading industrialized metropolitan cities in Turkey and receives a great deal of immigration from all other regions of Turkey. A total of 21 Family Health Care Centers [Aile Sagligi Merkezi (ASM)] were chosen. The distribution of these health centers were stratified according to socio-economical level. In each ASM, all the family physicians who was employed in that health center were requested to randomly choose six elderly people (three male and three female) who were aged 65–74, 75–84 and older than 85 years from their patient list. Each 40th person in their elderly patient's list, from each age group, as defined above, was invited to participate in the study. Any elderly individual who was older than 60 years and who requested to participate was also included. A history of any malignancy (including cured), being bedridden, and refusal to participate were regarded as exclusion criteria. All other community-dwelling elderly who accepted the invitation of their family physician were recruited. A face-to-face interview was conducted and physical measurements were taken.

The FFI was originally composed of five criteria: unintentional weight loss, weakness, self-reported exhaustion, slow walking speed and low physical activity. Frailty was assessed according to the modified version of the FFI in which physical activity is not included as in some other studies [6, 7]. The modified FFI has 4 domains, which are weight loss, exhaustion, walking speed, and grip strength. Weight loss (shrinking) is assessed by self-reported weight loss in the previous 12 months. Subjects with unintentional weight loss of >4.5 kg (10 lbs) are categorized as positive (yes = 1, no = 0). Exhaustion is assessed by individual response to the question "Do you feel full of energy?" (yes = 1, no = 0) which is taken from the Geriatric Depression Scale (GDS) [7–9]. Slowness is assessed by a 4-m walking test in which ≥75th percentile of 4-m walking speed (≥5.67 s/m for females and ≥4.67 s/m for males) is considered as the cut-off point for slowness (≥75th percentile = 1, <75th percentile = 0). Weakness is assessed as grip strength ≤25th percentile (≤25.6 kg for females and ≤14.7 kg for males), it is scored as 1 or 0 (≤25th percentile = 1, >25th percentile = 0). The elderly are classified as non-frail if the total score is 0, pre-frail if the total score is 1 and frail for scores ≥2.

In the FRAIL scale there are five domains: fatigue, resistance, ambulation, illnesses and weight loss [10]. Fatigue is assessed by the response of the elderly person to the question "How often have you felt tired in the previous 4 weeks" The score is noted as one if they say they felt tired often or most of the time; otherwise the score is zero. Resistance is assessed if they self-report that they had difficulty in walking up 10 steps alone without resting and without aid (yes = 1, no = 0). Ambulation is assessed by self-report that they had difficulty in walking several hundred yards alone and without aid (yes = 1, no = 0). Illness was scored as 1 for respondents who reported having five or more illnesses. These five diseases are derived from the following list: hypertension, diabetes mellitus, chronic obstructive lung disease, angina, myocardial infarction, congestive heart disease, asthma, arthritis, stroke, renal disease, cancer (other than small skin cancers). Weight loss is assessed by 5 % or more loss in body weight within the previous 12 months (yes = 1, no = 0). In this scale fatigue and weight loss represent biological factors, resistance and ambulation represent function, and illness represents deficit accumulation. The elderly are classified as non-frail if the total score is 0, pre-frail if the total score is 1–2 and frail for scores ≥3.

Demographic data including age, gender, marital status, smoking, income, length of education, living alone or not and vocation were obtained. Income was categorized as low,

moderate, or good. Since a variety of jobs were done by males, most of whom were retired, and almost all females were housewives, we categorized vocation as housewife and others. Falls and fear of falling were evaluated as to whether absent or present during the last year.

Nutritional status was assessed by the Turkish version of the Mini Nutritional Assessment long form (MNA) [11]. The MNA was developed by Guigoz et al. [12] and is the most well-established and widely applied nutritional assessment tool used in the geriatric population [13]. MNA scores were classified into three categories: <17 as malnutrition (MN), 17–23.5 as at malnutrition risk (MNR) and ≥23.5 as well nourished. Depressive mood was assessed using GDS [9]; its cut-off point was 14 for the Turkish version [14]. Cognitive function was assessed by the Turkish version of the Mini-Mental State Examination (MMSE) [15]. Cognitive impairment was defined, according to the last school that the subjects graduated from, as the MMSE score of less than 24/30 in the illiterate and 25/30 in the literate [16]. Functional capacity was assessed by the instrumental activities of daily living (IADL) scale. The IADL scale is based on the eight levels of self-performance including using the telephone, shopping, cooking, housekeeping, laundry, transportation, ability to take his/her medications and financial management [17].

Four-meter walking speed was noted during participants' usual gait speed (sec) over a 4-m long course. Muscle strength was assessed by hand grip strength (HGS), which was measured with a dynamometric instrument (Takei TKK 5401 Digital Handgrip Dynamometer, Niigata-City, Japan). All participants were instructed to stand upright, with arms placed by their sides, and to squeeze the dynamometer in the dominant hand. The HGS score is calculated as the mean of three trials.

Consent was received from the elderly subjects themselves or their proxy and ethical approval was given by Erciyes University Institutional Board.

Comparisons between the frail/pre-frail and non-frail were performed by the Chi square test (categorical variables) and the independent sample *t* test (continuous variables). The *p* values <0.05 were considered to be statistically significant. Age-adjusted correlation between FRAIL and FFI was calculated. We performed uni- and multivariate logistic regression analyses in which the independent variable for the FFI and FRAIL scales were classified into two groups as frail/pre-frail and non-frail. Independent variables in univariate analysis were age, gender, marital status, vocation, income, education level, living alone, depression, cognitive impairment, nutritional status, falls, fear of falling and IADL. These independent variables were checked for frailty (frail/pre-frail) in univariate analysis and later each of these parameters was checked in multivariate analysis (backward Wald) to eliminate related independent risk factors among these parameters. We plan to discuss the significance of independent variables in multivariate analysis which are common in both the FRAIL scale and FFI.

Results

A total of 906 community-dwelling elderly were recruited. However, we failed to calculate frailty in 1.0 and 6.0 % of the elderly for FRAIL and FFI, respectively, because of missing data. The mean and standard deviation (SD) of age were 71.5 and 5.6 years; 50.6 % of the subjects were female and 49.4 % were male. Of the total, 70.8 % of the study sample were aged 60–74 years, and 29.2 % were ≥75 years. Also, 53.2 % of the elderly in the 60–74 years age group were female and 46.8 % of them were male. In the elderly who were ≥75 years, 44.2 % of them were female and 55.8 % of them were male. In the 60–74 age group, we found that frailty was significantly high in female gender but there was not a significant difference in the ≥75 age group. The exhaustion component of the FFI was significantly high in female gender in the 60–74 age group. Independent of age group and gender, the prevalence of frailty was 27.8 %, that of pre-frailty was 34.8 %, and non-frailty was 37.4 % according to FFI (Table 1). Independent of age group and gender, the prevalence of frailty was 10 %, that of pre-frailty was 45.6 %, and non-frailty was 44.4 % according to FRAIL. In the FRAIL scale, we found a significant difference between each gender both in the 60–74 years group and ≥75 years age group where the gender specific ratio of frailty was about 4 times higher in the 60–74 years age group and 2 times higher in ≥75 years age group in favor of females. In the 60–74 years group fatigue, ambulation and resistance were found to be about two times higher in females but in ≥ the 75 years age group, fatigue was about 1.5 times higher and ambulation was about two times higher in females. A comparison of age- and gender-specific prevalence of frailty detected with the FFI and FRAIL scales are shown in Table 1. The age-adjusted correlation between FRAIL and FFI for females and males was 0.36 and 0.37, respectively.

In the examination of frail, pre-frail and non-frail status for FFI, we found that female gender, ≥75 years of age, being illiterate, living alone, having a low income, depressive mood, cognitive impairment, malnutrition, falls or fear of falling and decline in daily activity (IALD) were all associated with increased frailty. Smoking and being a housewife was associated with normality or pre-frailty rather than frailty.

In the examination of frail status by the FRAIL scale: female gender, ≥75 years, being illiterate and low income were associated with increased frailty. Smoking and being

Table 1 Comparison of age and gender specific prevalence of frailty for Turkish community-dwelling elderly according to two different scales

Models	60–74 age		*p* values	≥75 age		*p* values
	Female *n* (%)	Male *n* (%)		Female *n* (%)	Male *n* (%)	
Frailty (FFI)						
Frail	80 (24.7)	47 (16.5)		50 (48.5)	59 (43.4)	
Pre-frail	126 (38.9)	104 (36.5)	0.01	28 (27.2)	37 (27.2)	0.634
Non-frail	118 (36.4)	134 (47.0)		25 (24.3)	40 (29.4)	
FFI components						
Weight loss (>4.5 kg)	34 (10.0)	33 (11.0)	0.660	11 (9.4)	26 (17.6)	0.057
Exhaustion	154 (45.4)	87 (29.1)	<0.001	65 (56.0)	70 (47.3)	0.159
Walking speed	64 (19)	57 (19.3)	0.947	51 (45.9)	53 (36.8)	0.141
Grip strength	69 (20.8)	50 (6.9)	0.215	42 (38.5)	60 (41.4)	0.647
Frailty (FRAIL)						
Frail	42 (12.4)	9 (3.1)		24 (20.7)	15 (10.2)	
Pre-frail	188 (55.5)	107 (36.3)	<0.001	59 (50.9)	55 (37.4)	<0.001
Non-frail	109 (32.2)	179 (60.7)		33 (28.4)	77 (52.4)	
FRAIL scale components						
Fatigue	185 (54.3)	74 (24.7)	<0.001	63 (53.8)	43 (29.1)	<0.001
Resistance	50 (14.7)	21 (7.1)	0.004	25 (21.4)	21 (14.3)	0.132
Ambulation	110 (32.4)	44 (14.9)	0.001	51 (44.0)	30 (20.4)	<0.001
Illnesses (more than five)	15 (4.4)	7 (2.3)	0.152	6 (5.1)	4 (2.7)	0.304
Weight loss (more than 5 %)	30 (8.8)	27 (9.0)	0.928	13 (11.1)	28 (18.9)	0.081

a housewife, falls or fear of falling, depressive mood, cognitive impairment and functional decline in IALD were associated with no-frailty or pre-frailty. Table 2 shows the characteristics of community-dwelling frail, pre-frail and non-frail elderly.

In univariate logistic analysis age, gender, marital status, income, living alone, vocation, education level, falls, fear of falling, depressive mood, cognitive impairment, nutritional status and IADL were all found as significant for frailty. Among these dependent variables age, smoking, depressive mood, malnutrition and cognitive impairment, according to FFI, and gender, falls, fear of falling, depressive mood, malnutrition and cognitive impairment, according to FRAIL, were found as significant independent variables influencing frailty (Tables 3, 4).

Discussion

To our knowledge, this is the first study to report the prevalence of frailty in the Turkish community-dwelling elderly. Although many methods have been proposed, there is not as yet a universal criterion to determine frailty. Two well-known scales, the FRAIL and the FFI, were used together in this study [3]. The age-adjusted bivariate correlation between the FRAIL scale and the FFI in each gender was calculated as 0.36 and 0.37, respectively, for females and males. We found the prevalence of frailty was 28.7 and 10 %, respectively, for the FFI and FRAIL scale. We consider that the FRAIL scale depends on self-reported estimation, while FFI estimation depends on relatively objective measures. The FFI parameters handgrip and walking speed are direct indicators of muscle function. The self-reported character of the FRAIL scale may lead to underestimation of frailty by the elderly. Personal or cultural differences in their perception of health may lead the elderly to overestimate their health status [18, 19]. In our culture, even a severely ill individual may respond that he/she is very well when asked how his/her health is? Thus, the cut offs for frailty for these two scales could be adjusted according to different cultural characteristics. FFI scores may be considered as objective measures for frailty; on the other hand, FRAIL may underestimate frailty because of the traditional verbal behavior of the Turkish elderly. In our culture, the perception of illness used to be underestimated because the cause of illness may be related with mystic reasons, which may have alleviated the severity of perception of illness [20]. In contrast, we should state that there is a weak bivariate correlation between these two scales.

The prevalence of frailty in the community-dwelling elderly in ten countries in Europe (the SHARE Study, in

Table 2 Characteristics of community-dwelling frail, pre-frail and non-frail elderly

	Fried *n* (%)			*p*	FRAIL Scale *n* (%)			*p*
	Frail	Pre-frail	Non-frail		Frail	Pre-frail	Non-frail	
Gender								
Female	130 (30.4)	154 (36.1)	143 (33.5)	<0.05	66 (14.5)	247 (54.3)	142 (31.2)	<0.001
Male	106 (25.2)	141 (33.5)	174 (41.3)		24 (5.4)	162 (36.7)	256 (57.9)	
Age								
60–74	127 (20.9)	230 (37.8)	252 (41.4)	<0.001	51 (8.0)	295 (46.5)	288 (45.4)	0.009
≥75	109 (45.6)	65 (27.2)	65 (27.2)		39 (14.8)	114 (43.3)	110 (41.8)	
Length of education								
Illiterate	152 (35.2)	150 (34.6)	131 (30.2)		72 (15.5)	237 (50.9)	157 (33.6)	
1–8 years	77 (23.3)	119 (36.0)	135 (40.8)	<0.001	16 (10.3)	147 (42.4)	184 (53.0)	<0.001
>8 years	7 (8.3)	26 (31.0)	51 (60.7)		2 (2.4)	25 (29.8)	57 (67.9)	
Living alone	43 (37.7)	38 (33.3)	33 (28.9)	0.025	18 (14.4)	72 (57.6)	35 (28.0)	<0.001
Income								
Low	73 (30.5)	96 (40.2)	70 (29.3)		31 (12.4)	131 (52.2)	89 (35.5)	
Moderate	115 (27.8)	130 (31.5)	168 (40.7)	0.031	42 (9.5)	187 (42.2)	214 (48.3)	0.011
Good	45 (24.2)	66 (35.5)	75 (40.3)		14 (7.3)	86 (44.8)	92 (47.9)	
Vocation								
House wife	122 (31.5)	139 (35.9)	126 (32.6)	0.032	62 (15.0)	226 (54.6)	126 (30.4)	<0.001
Current smoking	52 (24.2)	66 (30.7)	97 (45.1)	<0.001	14 (6.1)	89 (38.9)	126 (55.0)	<0.001
Falls	76 (37.4)	69 (34.0)	58 (28.6)	0.001	33 (15.4)	113 (52.8)	68 (31.8)	<0.001
Fear of falling	128 (39.3)	98 (30.1)	100 (30.7)	<0.001	53 (14.8)	193 (54.1)	111 (31.1)	<0.001
Depressive mood	90 (45.2)	76 (38.2)	33 (16.6)	<0.001	50 (22.4)	131 (58.7)	42 (18.8)	<0.001
Cognitive impairment	88 (40.9)	80 (37.2)	47 (21.9)	<0.001	44 (18.9)	121 (51.9)	68 (29.2)	<0.001
Nutritional status								
Malnutrition	14 (63.6)	7 (31.8)	1 (4.5)		12 (42.9)	14 (50.0)	2 (7.1)	
Malnutrition of risk	122 (37.2)	133 (40.5)	73 (22.3)	<0.001	49 (13.8)	200 (56.3)	106 (29.9)	<0.001
Normal nutrition	88 (19.9)	137 (30.9)	218 (49.2)		26 (5.7)	180 (39.5)	250 (54.8)	
IADL, dependent	66 (47.1)	46 (32.9)	28 (20)	<0.001	33 (21.5)	77 (50.0)	43 (28.5)	<0.001

which the FFI was used) showed local differences [19]. In comparison with the SHARE Study, the prevalence of frailty (28.7 %) in our study was similar to that of Spain (27.3 %), but pre-frailty prevalence in Spain was higher than in ours (34.8 vs. 50.9 %). The prevalence of frailty in Sweden, Denmark, the Netherlands, Germany, Austria, Switzerland and France was 8.6, 12.4, 11.3, 12.1, 10.8, 5.8 and 15.0 %, respectively, which is very low when compared with our study. In the Mediterranean region, frailty prevalence in Greece was 14.7 % but in Italy, it was 23.0 %; so even in similar regions, frailty prevalence may differ. The prevalence of pre-frailty in our study was similar to the pre-frailty prevalence in Denmark, the Netherlands and Germany of 38.4, 38.5 and 34.6 %, respectively; however, it was lower than the pre-frailty prevalence in Sweden, Austria, Switzerland, Italy, France and Greece of 45.3, 40.7, 46.5, 45.6, 43.6 and 44.9 %, respectively. Although in both studies (SHARE and the present study) FFI was used, in our study the physical activity domain could not be used because of unavailable data for physical activity. However, since the cut-off for pre-frailty and frailty is only one point higher in original the FFI we may conclude that the modified FFI scale does not underestimate pre-frailty and frailty. Considering that it is challenging to assess physical activity in the elderly, measuring physical activity as a domain in FFI should be done cautiously [21].

In two other similar studies which used similar methods (modified FFI criteria: identical to the criteria in our study) to us to detect the prevalence of frailty and pre-frailty, Fernando et al. found the prevalence of frailty and pre-frailty as 27.8 and 47.3 %, respectively; while Ottenbacher et al. found the prevalence rates of 7.6 and 47.6 %, respectively [6, 7].

The difference for prevalence both in frailty and pre-frailty may be related to nutritional status, socio-economic

Table 3 The odds ratio of frailty (FRAIL) for associated factors detected in multivariate analysis

Variables	Odds	95 % Cl	
		Lower	Upper
Gender			
Female	1		
Male	0.456	0.333	0.626
Malnutrition	1		
Malnutrition risk	0.311	0.069	1.392
Normal nutrition	0.148	0.033	0.663
Cognitive impairment			
Absent	1		
Present	1.703	1.174	2.470
Depression			
Absent	1		
Present	2.353	1.528	3.625
Fall			
Absent	1		
Present	1.519	1.028	2.245
Fear of falling			
Absent	1		
Present	1.452	1.029	2.048

Table 4 The odds ratio of frailty (FFI) for associated factors detected in multivariate analysis

Variables	Odds	95 % Cl	
		Lower	Upper
Age	1.052	1.020	1.086
Current smoking	1		
Non smoker	1.584	1.082	2.320
Ex smoker	0.697	0.385	1.261
IADL			
Dependent	1		
Independent	0.569	0.339	0.954
Depressive mood			
Absent	1		
Present	2.327	1.461	3.708
Cognitive impairment			
Absent	1		
Present	1.653	1.083	2.521
Nutritional status			
Malnutrition	1		
Malnutrition risk	0.301	0.039	2.354
Normal nutrition	0.117	0.015	0.915

level and the frequency and intensity of physical and leisure activities. Other than the above-mentioned characteristics, age is found as an independently variable which significantly increases the prevalence of frailty [22, 23]. The cause of this finding may be related with the increases in sarcopenia prevalence especially in older age [24]. In addition, the cause of differences in the frailty score may be related to modifications applied to the Fried criteria in the definition of exhaustion, walking speed and grip strength.

It was reported that females are more likely to be frail than males in other studies. In our study, frailty was more prevalent in females (24.7 and 16.5 %, respectively, in females and males). Frailty prevalence was reported as 8.5 % for females and 4.1 % for males in the United Kingdom, and as 8.7 % in females and 4.3 % in males in France [18, 25]. The female to male frailty prevalence ratio both in the UK and France was similar to ours. On the other hand, the general prevalence for each gender was about two to four times higher in our population. The gender-specific difference in favor of females can be explained by high depressive mood, cognitive impairment, higher malnutrition, high dependency (IADL), relatively short duration of education, and low income in females.

To our knowledge, there are only few studies about the prevalence of frailty and pre-frailty. Hyde et al. [26] reports the prevalence of frailty and pre-frailty as 15.2 and 46.2 %, respectively, in male gender with the FRAIL scale. In our study, frailty prevalence was particularly low (5.4 %), while pre-frailty prevalence was 9.5 % lower than in Hyde et al.'s study. These differences can be explained by the high mean age in the study made by Hyde et al. In another study, the non-gender-specific prevalence of frailty was lower (6.4 vs. 10 %) and the prevalence of pre-frailty was lower than in ours (42.0 vs. 45.6 %) [3].

Although both the FFI and FRAIL scale demonstrated the strongest prediction for new onset disability and mortality, each has specific characteristics [3]. The FFI is time-consuming but provides a relatively objective measure. The FRAIL scale depends on self-report and can be administered easily.

The prevalence of frailty in our study group, which was calculated by the FRAIL scale and FFI, was similar to studies from abroad. On the other hand, the absence of physical activity in our study may have caused us to under or over-estimate frailty prevalence in our study. The relatively small sample size for elderly subjects $\geq$85 years should be mentioned as another limitation of our study. Although neither the FFI nor the FRAIL scale make cognitive assessment, in both scales we detected that cognitive impairment is one of the significant parameters leading to frailty.

Conclusion

Frailty is a geriatric syndrome which significantly influences mortality and disability. This study determined the prevalence and associated factors which influence frailty

with the FFI and FRAIL scale in the Turkish elderly. In addition, we conclude that, according to these two reliable scales, depressive mood, cognitive impairment, and malnutrition may be considered as risk factors for frailty. Thus, any impairment in these three domains should alert physicians to establish early precautions to prevent or slow the progression of frailty.

Conflict of interest The authors report no conflict of interest.

Human and Animal Rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the author.

Informed consent Informed consent was obtained from all individual participants included in the study.

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