Sensitivity, Specificity, Positive and Negative Predictive Values of a Postal Mail Self-Screening Tool for Frailty in French Older Adults

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Abstract

BACKGROUND: Frailty has emerged as one of the major risk factors of loss of autonomy and it can be reverted through early and appropriate interventions. A wide range of available frailty screening tools are administered, mainly in clinical settings. However, few frailty instruments are self-administered.
OBJECTIVES: The aim of this study was to determine the diagnostic test accuracy of a modified self-administered questionnaire derived from the Study of Osteoporotic Fractures (SOF) index against the Fried frailty phenotype in identifying frailty.
DESIGN: Observational, multicenter, diagnostic test accuracy study.
PARTICIPANTS: Participants aged 70 and over, living at home or in community-dwelling (n=5134) in two centers in France were contacted.
MEASUREMENTS: Participants were mailed self-administered questionnaires derived from the SOF index. Responders who accepted the home evaluation were assessed by trained nurses, blinded to results of the questionnaire, using the Fried frailty phenotype as the reference method.
RESULTS: The questionnaire was sent to 5134 participants, of which 1878 (36.6%) met inclusion criteria and returned the questionnaire. Fried frailty assessments were obtained in 691 (35.4%) participants. A total of 639 subjects had a complete evaluation on both the self-administered questionnaire and the Fried phenotype. Mean age was 78.9 (standard deviation [SD]: 5.95) years and 359 (56.2%) participants were women. According to the questionnaire, 159 (24.9%) subjects were considered frail, 172 (26.9%) pre-frail, and 308 (48.2) robust. With the home evaluation, Fried frailty phenotype results were respectively, 114 (17.8%), 295 (46.2%) and 230 (36%). The self-administered questionnaire presented a sensitivity of 66.6% (95% CI: 57.2-75.2) and a specificity of 84.2% (95% CI: 80.8-87.2).
CONCLUSIONS: A self-administered questionnaire can be used in elders and represents an opportunity for empowering them in the management of their health in the context of frailty.

Key words: Frailty, self-assessment, diagnostic accuracy.

Introduction

The physical frailty phenotype, first described by Fried and colleagues (1) has been described as a state of increased vulnerability to stressor events, resulting from the accumulation with age of deficits in multiple physiological systems. These deficits cause a decrease in the body's functional reserves and in its ability to cope with a stressful situation (1-5). Worldwide yearly incidence of frailty among community dwelling adults above 60 years old is estimated to be 4.3% (3). Frailty syndrome has severe consequences, with several prospective studies and meta-analyses showing an increased risk of adverse health outcomes, such as falls, disability, hospitalization, institutionalization, and death (6-13). A few studies have also indicated that frailty is also associated with increased healthcare costs (14-15). However, recent clinical trials have shown that frailty syndrome is potentially reversible if early preventive and rehabilitative interventions are implemented (2).

Being common, costly, severe and potentially reversible with an appropriate early intervention makes the frailty syndrome an almost perfect candidate for a population screening according to the World Health Organization classical criterias (31). However, to the best of our knowledge only England has implemented a kind of systematic frailty screening (32). A recent qualitative meta-synthesis showed that some of the main reasons caregivers, healthcare providers and elderly adults give for the absence of screening are the lack of a proper tool and of a screening pathway. Indeed among the self-screening tools developed very little have correct diagnostic properties evaluated against an appropriate reference standard (17, 23).

The Study of Osteoporotic Fractures (SOF) index is a rapid and validated easy-to-apply screening tool to assess frailty phenotype in the older population in clinical practice. It includes 3 items: weight loss, inability to rise from a chair five times without using the arms and reduced energy. It is established as a predictor of adverse health outcomes based on assessments conducted in clinical settings (7, 18). Ruiz and colleagues have recommended the SOF scale to be incorporated in primary care settings for the identification of patients who may require referral for comprehensive geriatric assessment (19). Because of its simplicity and proximity with the original items of the Fried criteria, and its shortness, we believed the SOF to be a good candidate for an adaptation destined for self-screening by postal mail. Indeed postal mail is the favorite way of communication reported by older adults and would enable medico-social organizations to have a simple, and reliable self-administered screening tool to detect frailty in

Table 1. Questionnaire derived from the SOF index

Items	Questions	Answer	Score
Weight loss	In the past year, have you lost 5% or more of your usual weight?	Yes Non	1 0
Inability to rise from a chair five times without using the arms	Can you rise from a chair five times without using the arms?	Yes No	0 1
Exhaustion	Do you feel without energy, much more tired than usual?	Yes Non	1 0

the elderly people. This pragmatic approach would promote subjects' empowerment in the management of their health, hence complementing the treating physician's role in primary prevention.

The main objective of this study is therefore to assess in elderly subjects aged 70 years and over, the diagnostic test accuracy in detecting frailty of a modified self-administered SOF index, sent by postal mail against the Fried frailty phenotype evaluated by a healthcare professional. Another objective is to assess the diagnostic accuracy of the self-administered questionnaire against the Fried phenotype in detecting both frailty and pre-frailty.

Methods

Study design, setting and participants

We conducted a multicenter, observational, diagnostic cross sectional study. It included 5134 participants aged 70 and over, living at home or in community-dwelling, from Paris and Toulouse areas. Participants were randomly selected from the French National Old-Age-Insurance Fund (Caisse Nationale d'Assurance Vieillesse "CNAV"). The CNAV is the main public pension fund in France covering more than 80 percent of pensioners. Using their records, the CNAV produced a sample representative of the general French population in terms of age and sex.

Participants were excluded from the study if they were institutionalized, received the personalized allowance for autonomy or had been previously enrolled in other frailty studies. Excluding participants receiving the personal allowance for autonomy allowed us to exclude older adults with identified dependence, thus excluding subjects with identified cognitive impairments.

In September 2019, 5134 participants received a postal letter from the CNAV explaining the study objectives and a separate modified self-administered questionnaire derived from the SOF index to be filled in and sent back in a pre-paid envelope to the International Longevity Centre France (ILC-France), the coordinating site. After 4 weeks, a reminder was sent to the 3866 non-responders. A pilot study, initially conducted in 300 subjects from Paris, provided a response rate of 46% with the mailing approach (unpublished data).

Participants who accepted the home assessment were examined by trained nurses, blinded to the results of the self-administered questionnaire, using the Fried frailty phenotype as the reference measure of frailty. Participants also received information related to preventive actions (individual or collective sessions) organized as part of the healthy ageing promotion programs (eg: physical activities, cognitive training, nutritional advice etc...).

When a frail or pre-frail individual was identified by the nurse and with the participant's consent, ILC-France liaised directly with the geriatric platform of Paris or Toulouse to ensure a tailored loss of autonomy prevention plan was implemented in collaboration with the subject's treating physician.

All participants gave written informed consent prior to conducting the Fried frailty phenotype assessment. This study was approved by the independent ethics committee, "Comité de protection des personnes Ile de France 7", Approval Number: 19.01.21.51235.

Measurements

Sociodemographic characteristics

Age, sex, marital status, and educational level were collected.

Frailty self-administered questionnaire derived from the SOF index

The SOF index was adapted to be used for self-diagnosis rather than clinical use, therefore items were transformed into simple questions. Some examples of what a 5% percent weight loss would represent depending on the person's original weight were added.

The adapted SOF consisted of three items (Table 1): weight loss, inability to rise from a chair five times without using the arms and exhaustion.

Participants were considered "Robust" if none of the above criteria were found, "Pre-frail" when one criterion was reported and "Frail" if at least two criteria were met.

Fried frailty phenotype assessment

Frailty defined by the Fried frailty phenotype was based on the presence of 3 or more of the following 5 criteria: unintentional weight loss, low physical activity level, self-reported exhaustion, muscle weakness and slow walking speed (Table 2).

Subjects were scored "Robust" when none of the criteria was fulfilled, "Pre-frail" if they met 1 to 2 criteria and "Frail" if at least 3 criteria were present.

Table 2. Fried frailty phenotype

Items	Questions	Answers	Score
Weight loss	In the past two years, have you lost 5% or more of your usual weight?		
Exhaustion	How often over the last week, you felt that everything you did was an effort, or you could not get going*: - often (more than 3 times a week) or most of the time?	Yes No	1 0
Low physical activity level	What is your physical activity level? No physical activity or rather sedentary: short walks or physical activities of light intensity?	Yes No	1 0
Muscle weakness	Dominant hand grip strength measurement in kilograms using a calibrated hydraulic hand dynamometer (Jamar Hand Dynamometer), categorizations were stratified by sex (≤ 29 kg for males and ≤ 17 kg for females)- hand grip strength measurements below the threshold?	Yes No	1 0

*: Using the Center for Epidemiological Studies-Depression scale 20; **: The pedestrian crossing is calculated for a walking speed of 1m/sec.

Outcome assessment

Measures of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) were used to determine the ability of the self-administered questionnaire to identify frail subjects compared to the Fried frailty phenotype.

Postal response as well as the home assessment acceptance's rates were evaluated.

Statistical analysis

Sample size and confidence intervals calculations were done using the Clopper-Pearson exact formula for proportion confidence intervals (21, 22). The pilot study estimated a sensitivity of 85% and a specificity of 60% for the self-administered questionnaire. Aiming at a 95% confidence interval with a width equal or inferior to 0.15 and assuming the frailty prevalence is 20% according to Fried criteria, the estimated number of required participants is 495 for sensitivity and 388 for specificity. We therefore used the highest of the two numbers (i.e 495 for sensitivity) as the number we aimed to recruit. Results from the pilot study indicated that about 50% of participants would return the self-completed questionnaire. And that among responders, only 20% would accept the home assessment by the nurse. Therefore, we sent questionnaires to more than 4950 candidates (5134) aiming at recruiting 495 participants with both self-screening and home assessment."

Quantitative variables were described as mean and standard deviation or median and interquartile ranges (IQR), qualitative variables were described as number and percentage.

Sensitivity, specificity, PPV and NPV were calculated using a contingency table with frailty defined by the Fried criteria as the gold standard and frailty defined by the self-administered questionnaire as the candidate values. We also estimated frailty diagnosis rates both on all invited subjects to participate and responders. For the secondary outcome, the same procedure was applied to identify both frailty and pre-frailty defined with Fried criteria as the gold standard and frailty, or pre-frailty defined with the self-administered questionnaire as the candidate values.

Attrition bias was assessed by comparing subjects who only completed the self-administered questionnaire and those who had both evaluations according to sex, age stratification and each modified SOF criterion using Chi2 tests.

To assess whether there were some predictors associated with the diagnostic questionnaire performance, a multivariate regression was performed on frail subjects identified by the Fried criteria, using frailty identified by the self-administered questionnaire as outcome and sex, age, marital status, educational level (high school level or above versus others) and duration time between the self-assessment and Fried evaluations as explaining variables.

A sensitivity analysis was conducted on subjects evaluated before the first Covid-19 lockdown implementation in France in March 2020 as it might have modified the way of evaluating patients as well as delayed the nurses evaluation.

Finally, due to the potential impact of the delay between the two evaluations we calculated NPV, PPV, sensitivity and specificity separately for participants above or below the median delay and above or under third quartile delay.

Results

Of the 5134 participants, 1950 (37.9%) completed the self-administered questionnaire and 1878 (36.6%) responders fulfilled the study selection criteria. Among responders, 1745 (92.9%) participants completed all 3 questions, 1824 (97.1%), 1854 (98.7%), and 1806 (95.9%) participants replied respectively to the questions related to weight loss, subject's inability to rise from a chair, and reduced energy level.

Trained nurses conducted frailty assessments at home for 691 participants using the Fried frailty phenotype (figure1), representing 35.4% of all responders and 13.5% of the initial sample. A total of 639 subjects had a complete evaluation on both the self-administered questionnaire and the Fried phenotype, corresponding to 12.4% of the initial sample. Characteristics of these participants are reported in table 3.

Mean age was 78.9 (standard deviation [SD]: 5.95) years, 359 (56.2%) were women, 317 (49.9%) participants had a university educational level, 107 (16.9%) had a high school level and 161 (25.5%) reached the lower secondary level.

According to the self-administered questionnaire, 159 (24.9%) participants were considered frail, 172 (26.9 %) pre-frail, and 308 (48.2%) robust. The most frequently reported item was exhaustion, encountered in 256 (40.1%) participants.

According to the Fried frailty phenotype, 114 (17.8%) participants were frail, 295 (46.2%) prefrail and 230 (36%) robust. The most frequently reported frailty items were low physical activity (35.7%), muscle weakness (34.4%), and exhaustion (28.8%).

Table 3. Characteristics of 639 participants

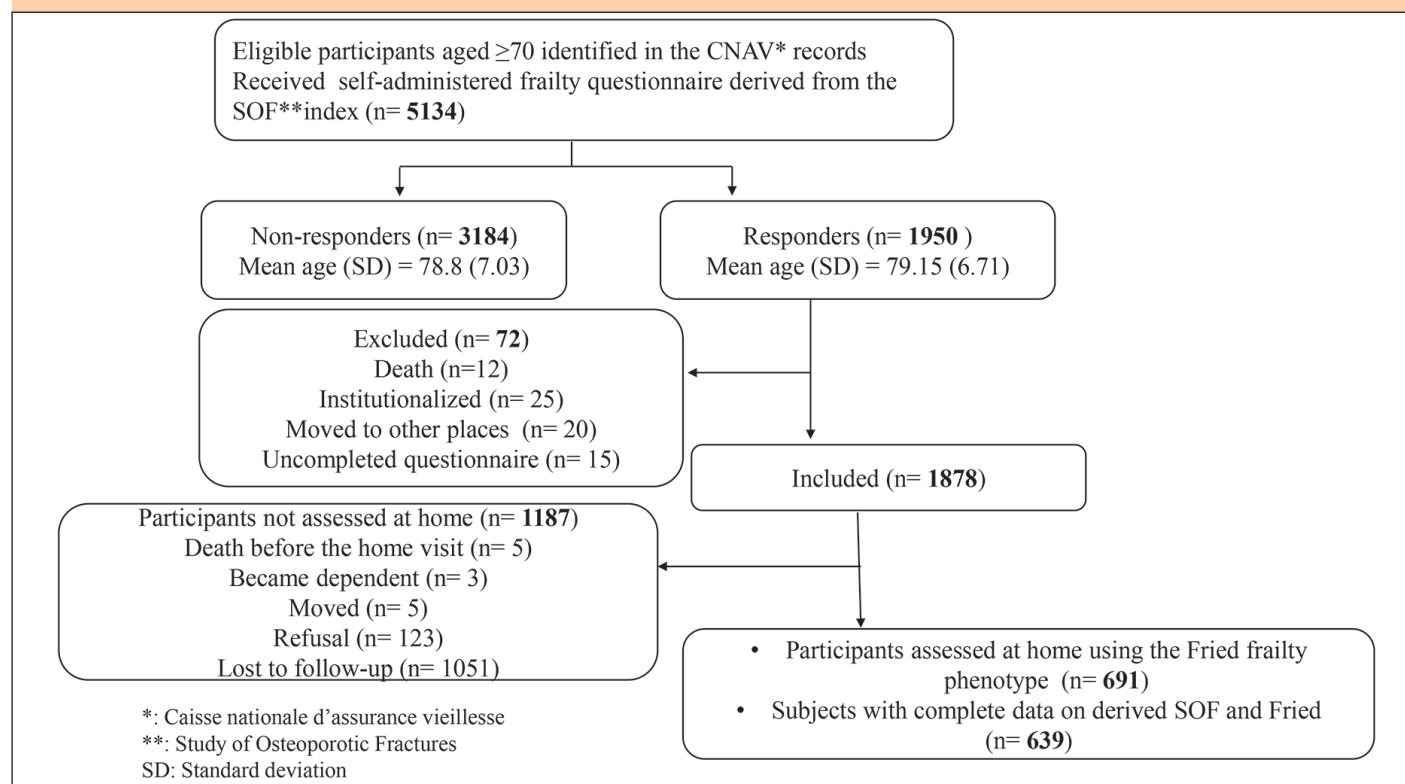| Variables	Participants, Mean (SD) or n (%)
Age	78.9 (5.95)
Sex, Female	359 (56.2)
Median time in days between the SOF and Fried frailty evaluations (IQR)	106 (103)
Marital status	
Single	97 (15.3)
Married	274 (43.3)
Divorced	120 (19)
Widowed	132 (20.9)
Cohabitation	10 (1.6)
Educational level	
Illiterate	14 (2.2)
Primary school	36 (5.7)
Lower secondary	161 (25.4)
Upper secondary	107 (16.9)
University	317 (49.9)
Individual self-administered questionnaire items	
Unintentional weight loss	155 (24.3)
Inability to rise from a chair 5 times without using arms	130 (20.3)
Reduced energy	256 (40.1)
Individual Fried frailty items	
Unintentional weight loss	122 (19.1)
Exhaustion	184 (28·8)
Low physical activity level	228 (35.7)
Slowness	86 (13.5)
Weakness	220 (34.4)
Frailty status by self-administered questionnaire	
Frail	159 (24.9)
Prefrail	172 (26.9)
Robust	308 (48.2)
Frailty status by Fried frailty phenotype	
Frail	114 (17.8)
Prefrail	295 (46.2)
Robust	230 (36)

IQR: interquartile range

Comparison between participants who accepted both evaluations (n=691) and those who only completed the self-administered questionnaire (n=1187) indicated that women, participants aged between 80-84 and those reporting a weight loss were more likely to be evaluated at home by the nurses (p-values <0.05). Results are shown in table 4.

Table 5 displays the comparison of results from the self-administered questionnaire and the Fried frailty phenotype. The self-administered questionnaire presented a sensitivity of 66.6% (95% CI: 57.2-75.2), a specificity of 84.2% (95% CI: 80.8-87.2), a PPV of 47.8% (95% CI: 39.8-55.9) and a NPV of 92.1% (95% CI: 89.3-94.3) in identifying frail participants. The detection rate of frailty was 4.04% (95% CI: 3.2-5) in included responders (n=1878), and 1.48% (95% CI: 1.17-1.84) in the overall sample (n=5134), respectively. Using logistic regression analyses, we observed that age, gender, marital status, educational level, or duration time between the self-administered questionnaire and Fried evaluation did not affect the self-administered questionnaire in identifying frail participants.

We conducted a separate analysis among 493 subjects assessed at home prior to the first COVID-19 lockdown implementation in France between March 17 and May 11, 2020, to avoid measuring variability secondary to the lockdown. During that period, all home visits were put on hold, however nurses maintained participant contact through telephone calls. Similar results as the primary analysis were found with a sensitivity and a specificity of 64.4% (95% CI: 53.7-74.3), and 85.4% (95%CI: 81.5-88.7), respectively (table 6).

Sensitivity, specificity, NPV and PPV were very similar in patients above or below the median or third quarter delay between evaluations (Supplementary Table 1 and 2).

Figure 1. Flowchart of subjects selection and frailty assessment

Eligible participants aged ≥70 identified in the CNAV* records
Received self-administered frailty questionnaire derived from the
SOF**index (n= **5134**)

Non-responders (n= **3184**)
Mean age (SD) = 78.8 (7.03)

Responders (n= **1950**)
Mean age (SD) = 79.15 (6.71)

Excluded (n= **72**)
Death (n=12)
Institutionalized (n= 25)
Moved to other places (n= 20)
Uncompleted questionnaire (n= 15)

Included (n= **1878**)

Participants not assessed at home (n= **1187**)
Death before the home visit (n= 5)
Became dependent (n= 3)
Moved (n= 5)
Refusal (n= 123)
Lost to follow-up (n= 1051)

- Participants assessed at home using the Fried frailty phenotype (n= **691**)
- Subjects with complete data on derived SOF and Fried (n= **639**)

*: Caisse nationale d'assurance vieillesse
**: Study of Osteoporotic Fractures
SD: Standard deviation

Table 4. Comparison between participants who only completed the questionnaire and those assessed at home

	Completed SOF only, n (%) N = 1187	Assessed at home by the nurse n (%) N = 691	p-value
Sexe Female	734 (61.8)	395 (57.2)	0.038
Age, N	1187	691	0.001
70-74	380 (32)	227 (32.9)	
75-79	303 (25.5)	181 (26.2)	
80-84	225 (18.9)	157 (22.7)	
85-89	167 (14.1)	95 (13.7)	
> 90	112 (9.5)	31 (4.5)	
Weight loss per questionnaire	228 (19.8)	162 (24.1)	0.035
Inability to rise from a chair per questionnaire	262 (22.4)	141 (20.7)	0.431
Exhaustion per questionnaire	437 (38.2)	272 (41)	0.262

The self-administered questionnaire presented a sensitivity of 65.5% (95% CI: 60.7-70.1), a specificity of 72.6% (95% CI: 66.4-78.3), a PPV of 80.9% (95% CI: 76.3-85.1) and a NPV of 54.2% (95% CI: 48.5-59.9) in identifying frail or prefrail subjects (secondary endpoint) as reflected in table 7.

Discussion

In the present study, the self-administered questionnaire derived from the SOF index provided a sensitivity of 66.6% and a specificity of 84.2% in detecting frailty against the Fried frailty phenotype.

Our results are within the ranges described in a recent systematic review on the diagnostic accuracy of self-reported/administered screening instruments to identify frailty in community-dwelling (17).

Sensitivity values were between 20.3-100% while specificity ranges varied from 60.5 to 95.6%. When comparing self-administered frailty instruments against the Fried phenotype, the authors indicated a sensitivity of 100% (95% CI: 34-100) and a specificity of 80% (95% CI: 67-89) for the Groningen Frailty Indicator (GFI), however the sample size was small (n=52) with wide confidence intervals. Hoogendijk and colleagues (23) reported a sensitivity of 57% and a specificity of 72% for the GFI, PRISMA-7 displayed a sensitivity of 86% and a specificity of 83%, and Self-rated health showed a sensitivity of 85% and a specificity of 73% (n=102). The Tilburg Frailty Indicator presented a sensitivity of 79.4% and a specificity of 60.5% (n=267) whereas the Frailty Postal Questionnaire showed a sensitivity of 75% and a specificity of 69% (n=1037) (24-26).

Table 5. Comparison of results from the self-administered questionnaire and the Fried phenotype in detecting frailty

	Frail per Fried phenotype	Robust or Prefrail per Fried phenotype
Frail per self-administered questionnaire	76	83
Robust or Prefrail per self-administered questionnaire	38	442

Sensitivity: 66.6% (95% CI: 57.2-75.2); Specificity: 84.2% (95% CI: 80.8- 87.2); PPV: 47.8% (95% CI: 39.8- 55.9); NPV: 92.1% (95% CI: 89.3- 94.3)

Table 6. Comparison of results from the self-administered questionnaire and the Fried phenotype in detecting frailty prior to the first COVID-19 lockdown.

	Frail per Fried phenotype	Robust or Prefrail per Fried phenotype
Frail per self-administered questionnaire	58	59
Robust or Prefrail per self-administered questionnaire	32	344

Sensitivity: 64.4% (95% CI: 53.7-74.3); Specificity: 85.4% (95% CI: 81.5- 88.7); PPV: 49.6% (95% CI: 40.2- 58.9); NPV: 91.5% (95% CI: 88.2- 94.1)

Table 7. Comparison of results from the self-administered questionnaire and the Fried phenotype in detecting frailty or pre-frailty

	Frail or Pre-frail per Fried phenotype	Robust per Fried phenotype
Frail or Pre-frail per self-administered questionnaire	268	63
Robust per self-administered questionnaire	141	167

Sensitivity: 65.5% (95% CI: 60.7-70.1); Specificity: 72.6% (95% CI: 66.4-78.3); PPV: 80.9% (95% CI: 76.3-85.1); NPV: 54.2% (95% CI: 48.5-59.9)

These results illustrate high heterogeneity related to the diagnostic test accuracy of the frailty tools, the study designs, the sample sizes, the frailty prevalence, and settings.

A separate analysis was also conducted among participants evaluated prior to the first Covid-19 lockdown to avoid measuring variability attributable to the lockdown effect. Results showed similar findings as the primary analysis in terms of sensitivity and specificity.

Clegg and colleagues (28) suggested a two-step assessment of frailty using first a score with high sensitivity and then a score with high specificity. Because of its relatively low sensibility but high specificity the modified SOF that we used would be better suited used as a second step following the Frailty Postal Questionnaire allowing for a full postal diagnosis.

The screening procedure through the postal questionnaire enabled participants to use a simple, and quick self-administered tool to detect frailty themselves at home, hence empowering the participants in the management of their health. A response rate of 38% in our study population can be considered satisfactory compared to previously reported response rates (29). Such approach addresses the request from the patient group consumer outlined in the clinical practice guidelines for identification and management of physical frailty issued by the task force of the International Conference of Frailty and Sarcopenia (27).

This study has some limitations. Like the home evaluations, items included in the self-administered questionnaire assessed weight loss, muscle weakness and exhaustion which are part of the Fried criteria. However, there is evidence to indicate that these 3 components reflect impairment in physiologic domains most frequently mentioned in the frailty literature (7). In order to reduce bias, nurses were blinded to the results of the self-administered questionnaire and were instructed not to discuss with the participants of these results during the Fried evaluations.

There was a relatively long median delay of 106 days between both evaluations. However there was no difference in sensitivity or specificity between participants evaluated with a delay over or under that threshold. Participants who accepted the Fried evaluations at home belonged to people with a high level of education (49.9% with a university level and 16.9% with an upper secondary school level). As a result, there is an under-representation of subjects with low educational level and these data cannot be used to draw a conclusion in this population. This raised the question about how low educated participants could be reached for frailty assessment as some evidence indicates that higher frailty prevalence is observed among them (30). Future studies are needed to get more insights on potential motivators, barriers, and optimal strategies to engage this population in frailty detection and early intervention programs.

In addition, the attrition bias indicated that women, participants aged between 80-84 and those reporting a weight loss on the self-administered questionnaire were more likely to be evaluated at home by the trained nurses.

In conclusion, the present study confirms that the self-administered questionnaire adapted from the SOF index can be easily used in subjects who might benefit from the healthy ageing promotion and prevention programs.

Comprehensive geriatric assessments are time-consuming and are not available in all parts of our and other high income country and in low-income countries. Given resource scarcity and the busy workload in clinical and primary care settings, the self-administered questionnaire seems suitable for old persons' self-evaluation of frailty and would benefit for countries with limited healthcare resources.

This simple and easy to apply tool may represent, as well, an opportunity for empowering elders to identify frailty themselves and raising frailty awareness.

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