J Nutr Health Aging. 2019;23(9):856-861

PHYSICAL FRAILTY AND RISK OF NEEDING LONG-TERM CARE IN COMMUNITY-DWELLING OLDER ADULTS: A 6-YEAR PROSPECTIVE STUDY IN JAPAN

S. CHEN[1,2,3,*], T. HONDA[3,*], K. NARAZAKI[4], T. CHEN[5], H. KISHIMOTO[6,7], S. KUMAGAI[5]

1. Department of Epidemiology and Prevention, Center for Clinical Sciences, National Center for Global Health and Medicine, Tokyo, Japan; 2. Environments Research Laboratory, Fukuoka Institute of Technology, Fukuoka, Japan; 3. Department of Epidemiology and Public Health, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan; 4. Faculty of Socio-Environmental Studies, Fukuoka Institute of Technology, Fukuoka, Japan; 5. Center for Health Science and Counseling, Kyushu University, Fukuoka, Japan; 6. Department of Behavior and Health Sciences, Graduate School of Human-Environment Studies, Kyushu University, Fukuoka, Japan; 7. Faculty of Arts and Science, Kyushu University, Fukuoka, Japan; S. Chen and T. Honda contributed equally to this article. Corresponding author: Dr. Kenji Narazaki, Faculty of Socio-Environmental Studies, Fukuoka Institute of Technology 3-30-1 Wajiro-higashi, Higashi-ku, Fukuoka, Fukuoka Prefecture 811-0295, Japan, Telephone number: +81 92-606-6219, Fax number: +81 92-606-6497, E-mail: narazaki@fit.ac.jp. Dr. Shuzo Kumagai, Center for Health Science and Counseling, Kyushu University, 744 Motooka Nishi-ku, Fukuoka, Fukuoka Prefecture 819-0315, Japan, Telephone number: +81 92-802-5112, Fax number: +81 922-802-5112, E-mail: shuzo@ihs.kyushu-u.ac.jp

Abstract: *Objective:* To examine the association between physical frailty and risk of needing long-term care, and compare the predictive value and clinical usefulness of a simple frailty scale (FRAIL) with that of the original Cardiovascular Health Study (CHS) criteria. *Design and Setting:* A 6-year prospective cohort study of community-dwelling older adults in a west Japanese suburban town. *Participants:* 1,554 older adults aged 65 years and over who were initially free of long-term care needs at baseline. *Measurements:* Physical frailty was defined by the CHS criteria and the FRAIL scale. The onset of needing long-term care was ascertained using national records of certification of long-term care needs. Cox proportional hazard models were used to estimate the association between physical frailty and risk of needing long-term care. Decision curve analysis was performed to compare the clinical usefulness of the two physical frailty criteria. *Results:* During a median follow-up of 5.8 years, 244 were ascertained as needing long-term care. Baseline physical frailty was significantly associated with elevated risk of needing long-term care, with a multivariable-adjusted hazard ratio (HR) of 2.00 (95% confidence interval [CI], 1.32-3.02) for being frail and 1.50 (95% CI, 1.10-2.03) for being pre-frail as defined by the CHS criteria, compared with being robust (p for trend = 0.001). Similar results were found for physical frailty defined by the FRAIL scale, with a multivariable-adjusted HR (95% CIs) of 2.11 (1.25-3.56) for being frail and 1.73 (1.28-2.35) for being pre-frail vs. being robust (p for trend < 0.001). The two physical frailty criteria had similar net benefits in identifying individuals at high risk for needing long-term care. *Conclusions:* Physical frailty is significantly associated with an increased risk of needing long-term care in community-dwelling older adults in Japan. Compared with the original CHS criteria, the simple FRAIL scale has comparable predictive value and clinical usefulness for identifying individuals at risk for needing long-term care.

Key words: Physical frailty, long-term care needs, elderly, prospective study.

Introduction

Long-term care needs among older adults cause huge social, medical, and economic burdens worldwide (1). In Japan, 18.3% of older adults aged 65 years and over had long-term care needs in 2018 as ascertained by the universal long-term care insurance (LTCI) system, which cost more than 10 trillion yen per year (2–4). Given the possibility of delaying the onset of needing long-term care, early identification of individuals at high risk is particularly important. Physical frailty, a medical syndrome that affects about one tenth of community-dwelling older adults (5,6), has been reported to be predictive of falls, disability in activity of daily life, hospitalization, and mortality (7–9), but epidemiological data linking physical frailty to the risk of needing long-term care are sparse. In Japan, the LTCI system, initiated in 2000 with standardized criteria for ascertaining long-term care needs (4), presents a unique opportunity to assess the predictive ability of physical frailty in identifying individuals at risk of needing long-term care.

To the best of our knowledge, only three cohort studies have examined this association (10–12). These prior studies showed an association between physical frailty and an elevated risk of needing long-term care. Nevertheless, some limitations with these studies need to be addressed. First, results of these studies (10–12) were constrained by a short follow-up period (≤ 3 years) and were, therefore, more prone to the effects of reverse causality. Second, these studies have used unvalidated definitions of physical frailty, distinct from the original definition in the Cardiovascular Health Study (CHS) (7), resulting in low comparability of results. Third, no study has quantified the benefit of the screening of frailty to identify individuals at high risk of needing long-term care in a community.

Hence, with a 6-year follow-up in a cohort study of community-dwelling older adults in Japan, we aimed to investigate the association between physical frailty and risk of needing long-term care. We assessed physical frailty using the CHS criteria that we have previously confirmed satisfactory internal validity in a community-dwelling older population in Japan (6). We also defined physical frailty using a simple frailty

Received February 26, 2019
Accepted for publication May 9, 2019
Published online August 30, 2019, http://dx.doi.org/10.1007/s12603-019-1242-6

questionnaire (FRAIL) (13, 14), which has been validated for predicting adverse health consequences such as deficits in activities of daily living and mortality in African-American (15), Chinese (16), and European (17) populations, but not yet been studied in Japan. We tested whether the FRAIL scale has comparable predictive ability and clinical usefulness with the CHS criteria in predicting the onset of needing long-term care.

Methods

Study Population

This prospective study used data from the Sasaguri Genkimon Study (SGS), which was designed to explore risk and protective factors for the need for long-term care in late life. The participants of the SGS cohort were recruited from Sasaguri, a town in Fukuoka Prefecture, Japan. Details of the SGS design and recruitment methods have previously been reported (18, 19). Briefly, 4,979 inhabitants aged 65 years and over who had not been identified by the LTCI system as needing long-term care as of January 2011 were considered to meet our inclusion criteria. After excluding subjects who had died or moved out of the district (n = 66) by study initiation, 4,913 residents were invited to participate health examinations. A total 2,629 subjects consented to participate. We excluded 6 subjects who certified as requiring LTCI before the date of their baseline survey date (May to August 2011), 36 subjects with medical history of dementia, Parkinson's disease, or depression at baseline, and 1,030 subjects lacking complete data for baseline physical frailty phenotypes (n = 962) and other covariates (n = 68). The final sample was 1,554 older adults having no needs for long-term care at baseline. The study protocols were approved by the Institutional Review Board of the Institute for Health Sciences, Kyushu University. Written informed consent was obtained from all participants.

Follow-up

Participants were consecutively followed for newly onset of certification of needing long-term care. Follow-up time was counted from the date of baseline survey until the date of being ascertained as needing long-term care, death, loss-to-follow-up, or March 31, 2017, whichever came first.

Ascertainment of needing long-term care

We ascertained the onset of needing long-term care by using data from the national database of the universal LTCI system, which were provided by the municipal government office. The certification of needing long-term care by the LTCI system is based on standardized assessments of an individual's physical and mental functional capacity (4). Specically, a uniform computer-assisted standard needs-assessment system together with a physician's assessment determines whether an older adult has long-term care needs or not. For those who were identified as needing long-term care, their care needs were categorized into seven levels: support level 1 to 2; care level 1 to 5. The onset of long-term care needs was set at the first level (support level 1) or above.

Assessment of physical frailty

We identified physical frailty according to the CHS criteria and the FRAIL scale. The CHS criteria consists of the following 5 components: unintentional weight loss, low grip strength, exhaustion, slow gait speed, and low physical activity (7). Participants with 3 or more affected components were considered frail, 1 to 2 affected components pre-frail, and no affected components non-frail (or robust). Grip strength was measured using a handhold dynamometer (GRIP-D, TKK 5401; Takei Scientific Instruments Co., Ltd., Niigata, Japan). Gait speed was measured with a 5-meter walking test at the individual's maximum walking speed. We objectively assessed low physical activity using a tri-axial accelerometer (Active Style Pro, HJA350-IT, Omron Healthcare, Inc., Kyoto, Japan). We identified weight loss as self-reported unintentional loss of more than 2–3 kg in the previous 6 months. Exhaustion was indicated by a positive answer to either of two questions with reference to the previous month: "Did you feel that everything you did was an effort?" and "Did you feel exhausted without any reason?" The detailed procedure with these operational definitions in the SGS has been previously reported elsewhere (6).

The FRAIL scale comprises the following 5 domains: fatigue, resistance, ambulation, illness, and weight loss (15). The resistance and ambulance domains were assessed, respectively, using single questions that correspond to items in the FRAIL scale: "Do you usually climb stairs without holding the arm rail or wall for support?" and "Do you often walk continuously for 15 minutes?" Those items were obtained from a questionnaire survey — Needs in the Sphere of Daily Life — of Japan's Ministry of Health, Labour and Welfare (20). We assessed fatigue and weight loss with the corresponding items (exhaustion and weight loss domains) of the CHS criteria. Illness was defined as having 4 or more of the following conditions in the self-reported medical history: hypertension, chronic heart disease, diabetes, stroke, minor trauma fracture, chronic pulmonary disease, chronic kidney disease, osteoarthritis or rheumatism, and any cancer.

Covariates

We obtained information on age and sex from the municipality office. Data on baseline covariates were collected using questionnaires: number of years of education, living alone (yes or not), economic status (comfortable, relatively comfortable, relatively uncomfortable, or uncomfortable), smoking (current smoker or not), drinking (current drinker or not). We employed the Mini-Mental State Examination (MMSE) to assess global cognitive function. Cognitive impairment was defined as an MMSE score of 23 points or less (21). Polypharmacy was defined as taking 4 or more prescription medications.

Table 1
Baseline characteristics of study participants according to baseline physical frailty status

	Frailty phenotype			
	Robust	**Pre-frail**	**Frail**	**p value**
CHS Criteria	(n = 727)	(n = 680)	(n = 147)	
Age, mean (SD)	71.5 (5.1)	74.0 (5.9)	79.3 (6.2)	< 0.001
Men, n (%)	287 (39.5)	272 (40.0)	57 (38.8)	0.99
Years of education, mean (SD)	11.5 (2.5)	10.8 (2.4)	10.2 (2.2)	< 0.001
Low education (< 12 years), n (%)	290 (39.9)	356 (52.4)	105 (71.4)	< 0.001
Living alone, n (%)	78 (10.7)	105 (15.4)	21 (14.3)	0.03
Household finance, (relatively) comfortable, n (%)	431 (59.3)	418 (61.5)	90 (61.2)	0.45
Current smoker, n (%)	55 (7.6)	55 (8.1)	9 (6.1)	0.81
Current drinker, n (%)	311 (42.8)	265 (39.0)	39 (26.5)	0.001
Polypharmacy (≥ 4 medications), n (%)	149 (20.5)	214 (31.5)	87 (59.2)	< 0.001
Mini-Mental State Examination, score	27.9 (2.0)	27.5 (2.3)	26.5 (2.9)	< 0.001
Cognitive impairment, n (%)	20 (2.8)	42 (6.2)	21 (14.3)	< 0.001
FRAIL scale	(n = 735)	(n = 739)	(n = 80)	
Age, mean (SD)	71.8 (5.2)	74.6 (6.3)	76.3 (6.7)	< 0.001
Men, n (%)	322 (43.8)	269 (36.4)	25 (31.3)	0.001
Years of education, mean (SD)	11.5 (2.6)	10.8 (2.4)	10.3 (1.9)	< 0.001
Low education (< 12 years), n (%)	447 (60.8)	328 (44.4)	28 (35.0)	< 0.001
Living alone, n (%)	89 (12.1)	103 (13.9)	12 (15.0)	0.25
Household finance, (relatively) comfortable, n (%)	430 (58.5)	454 (61.4)	55 (68.8)	0.07
Current smoker, n (%)	62 (8.4)	55 (7.4)	2 (2.5)	0.11
Current drinker, n (%)	318 (43.3)	271 (36.7)	26 (32.5)	0.004
Polypharmacy (≥ 4 medications), n (%)	150 (20.4)	250 (33.8)	50 (62.5)	< 0.001
Mini-Mental State Examination, score	27.8 (2.3)	27.4 (2.3)	27.1 (2.2)	< 0.001
Cognitive impairment, n (%)	32 (4.4)	47 (6.4)	4 (5.0)	0.18

CHS, Cardiovascular Health Study; SD, standard deviation; Cognitive impairment was defined as a Mini-Mental State Examination score of ≤ 24.

Statistical analyses

We summarized descriptive characteristics as means and standard deviations or medians and interquartile range for continuous variables, as appropriate; we employed percentages for categorical variables. We tested trends in baseline characteristics across physical frailty status using a linear regression model for continuous variables and a logistic regression model for categorical variables.

The cumulative incidence of being ascertained as needing long-term care according to baseline frailty status and each component was plotted using Kaplan-Meier estimates. We evaluated the associations of physical frailty with the onset of needing long-term care using Cox proportional hazard models with adjustment for age (years), sex, education (years), living alone (year or no), household finance (comfortable, relatively comfortable, relatively uncomfortable, or uncomfortable), smoking (current smoker or not), drinking (current drinker or not), cognitive impairment (year or no), and polypharmacy (year or no). We compared these models by means of Harrell's C index (22) and Akaike's information criterion.

To further assess and compare the clinical usefulness of the criteria of two physical frailty in predicting the risk of needing long-term care, we utilized decision curve analysis (23). The decision curve analysis is a statistical technique to estimate the clinical value of risk prediction for stratification, which compares the net benefits of correctly detecting individuals who will develop diseases with the harms due to false-positive classification (i.e., incorrect detection of a disease-free individual as positive) (23). For this analysis, we fitted univariate Cox regression models separately for CHS criteria and the FRAIL scale and compared the net benefits of making a decision about initiating interventions based on the absolute

Table 2
Hazard ratios (95% confidence intervals) for newly onset of needing long-term care according to baseline physical frailty status

	No. of events /subjects	Incidence rate (per 10^3 person-years)	Age- and sex-adjusted HR (95% CI)	Multivariable-adjusted HR (95% CI)
CHS criteria				
Robust	66/727	16.6	1.00	1.00
Pre-frail	126/680	35.8	1.54 (1.14-2.09)	1.50 (1.10-2.03)
Frail	52/147	88.4	2.17 (1.45-3.23)	2.00 (1.32-3.02)
p for trend			< 0.001	0.001
FRAIL scale				
Robust	65/735	16.2	1.00	1.00
Pre-frail	158/739	42.7	1.73 (1.28-2.34)	1.73 (1.28-2.35)
Frail	21/80	57.8	2.11 (1.28-3.50)	2.11 (1.25-3.56)
p for trend			< 0.001	< 0.001

HR, hazard ratios; CI, confidence intervals; CHS, Cardiovascular Health Study. Multivariable-adjusted models were adjusted for age (years), sex, education (years), living alone (year or no), household finance (comfortable, relatively comfortable, relatively uncomfortable, or uncomfortable), smoking (current smoker or not), drinking (current drinker or not), cognitive impairment (year or no), and polypharmacy (year or no).

risks estimated from the Cox models. We also compared the net benefit with alternative strategies assuming that no or all individuals would undergo interventions.

We conducted the following sensitivity analyses: exclusion of participants who were certified as requiring long-term care in the first year of follow-up (n = 18); exclusion of participants with a MMSE score of < 18 (n = 8). We also did a sensitivity analysis by defining the onset of needing long-term care as having the third-level care needs (care level 1) and above. All the analyses were conducted using SAS, version 9.4 (SAS Institute Inc., Cary, NC, USA). We set the significance level at $\alpha = 0.05$.

Results

The baseline characteristics of the participants regarding baseline physical frailty status defined by CHS criteria and the FRAIL scale were presented in Table 1. According to both CHS criteria and the FRAIL scale, age and rate of cognitive impairment and polypharmacy increased across the severity of physical frailty; educational levels and percentage of current drinkers decreased across the severity of physical frailty. The proportion of men increased according to the severity of physical frailty defined by the FRAIL scale. Approximately 70% of participants were categorized in the same categories by CHS criteria and by the FRAIL scale (Supplementary Table S1). Supplementary Table S2 shows that older participants were more likely to be classified as frail when defined by CHS criteria, and the prevalence of low grip strength, low gait speed, and low physical activity were markedly higher among older than younger participants.

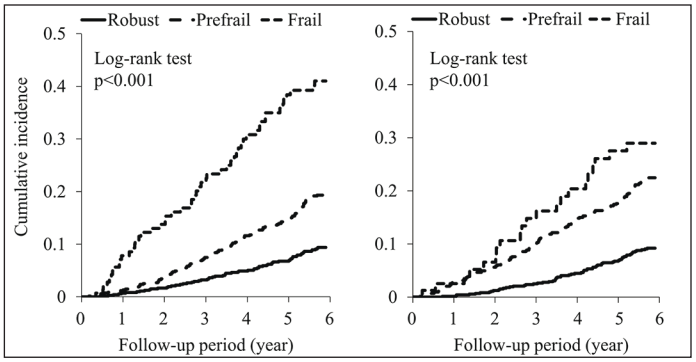
During a median follow-up of 5.8 years (interquartile range, 5.7-5.8), 137 of the 1,554 participants died and 39 moved out of town; 244 participants were identified as needing long-term care. Cumulative incidence curves for the risk of needing long-term care by the two criteria of physical frailty were shown in Figure 1. With both definitions, the cumulative incidence of needing long-term care increased with the severity of physical frailty (both log-rank $p < 0.01$).

As shown in Table 2, baseline physical frailty as defined by both the CHS criteria and the FRAIL scale was significantly associated with an increased risk of needing long-term care in a basic model adjusted for age and sex. This association was virtually unchanged after further adjustment for education, living alone, household finance, smoking, drinking, presence of cognitive impairment, and presence of polypharmacy. The multivariable-adjusted hazard ratio (HR) were 2.00 (95% confidence interval [CI], 1.32-3.02) for being frail and 1.50 (95% CI, 1.10–2.03) for being pre-frail as defined by the CHS criteria, compared with being robust at baseline (p for trend = 0.001). Similar results were found for physical frailty defined by the FRAIL scale, with a multivariable-adjusted HR (95% CI) of 2.11 (1.25-3.56) for being frail and 1.73 (1.28-2.35) for being pre-frail vs. being robust (p for trend < 0.001). The models that included physical frailty phenotype defined by CHS criteria or the FRAIL scale showed a similarly better goodness-of-fit statistics than the model that only included covariates (Supplementary Table S3). Figure 2 showed the results of the decision curve analysis. Both CHS criteria and the FRAIL scale had generally higher net benefits than the treat-all or treat-none strategy. The net benefits were similar with the two definitions.

In sensitivity analyses, the associations remained unchanged after excluding participants who were certified as needing long-term care in the first year of follow-up or participants with a MMSE score of < 18. Further, we found similar significant associations of frailty defined by CHS criteria and the FRAIL

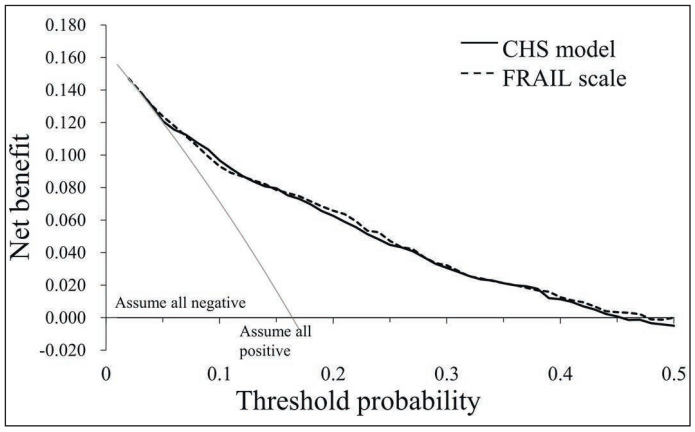
scale with the certification for LTCI need when such need was defined as the third level (care level 1) and above.

Figure 1
Cumulative incidence for long-term care needs by physical frailty phenotype based on the CHS criteria and the FRAIL scale



CHS, Cardiovascular Health Study

Figure 2
Decision curve analysis for 6-year risk of the onset of needing long-term care



Gray thin line: assuming treatment of all subjects; horizontal line (on Y=0): assuming treatment of no subjects; black thick line: prediction based on CHS model; dotted line: prediction based on the FRAIL scale. Threshold probability refers to the cut-offs of predicted 6-year risk of needing long-term care for use in the decision to initiate intervention/treatment. CHS, Cardiovascular Health Study

Discussion

In this 6-year prospective study of a community-dwelling older population in Japan, we demonstrated that physical frailty defined by both the CHS criteria and the FRAIL scale was significantly associated with an increased risk of needing long-term care as ascertained by the national LTCI system using a standardized procedure. We found that the FRAIL scale had had similar clinical usefulness with the CHS criteria in identifying individuals at high risk of needing long-term care. the present study confirmed the association between physical frailty and risk of needing long-term care using a longer follow-up period with a validated CHS-based assessment for frailty. To our knowledge, this is the first to evaluate the potential utility of the frailty phenotype to stratify future risk of LTCI needs in community settings.

In our study, being physical frail and pre-frail (vs. being robust) at baseline were associated with 1.5- and 2-fold increase, respectively, in the risk of needing long-term care, compared with being robust. The strength of this association in our study cannot be directly compared with findings from prior prospective studies that used different definitions of frailty from the original CHS criteria (10, 12). Probably owing to different definitions, these two studies yielded incomparable results, with one showing 2- and 5- fold increased risk in pre-frail and frail individuals (10), while another one reported 8- and 23-fold increased risk in pre-frail and frail individuals (12). In one prior study that used the CHS criteria, being pre-frail and frail [vs. being robust] were associated with 2.5- and 4.6-fold increased risk for needing long-term care (11). These estimates were higher than our estimates. This discrepancy may relate to the longer follow-up in our study (6 years) compared with 2 years in the other study. A short follow-up period (2 years) for the incidence of long-term care needs could have led to overestimation of the association or reverse causality — that is, the presence of physical frailty at baseline may be due to existing sever functional limits that are immediately prior to the onset of long-term care. In a sensitivity analysis, we excluded certified events of needing long-term care in the initial year of follow-up. This did not materially alter the observed association. Accordingly, the possibility of reverse causality may be minor in our study. Taken together, with a 6-year follow-up, we confirmed a significant association between baseline physical frailty and an increased risk of needing long-term care.

Generally, the CHS-criteria- and FRAIL-scale-based frailty phenotypes consistently classified individuals into the same phenotype category; on the other hand, one-third of our participants were classified differently according to each definition. Specifically, the FRAIL scale tended to classify individuals in better categories than did the CHS criteria. The cumulative incidence in the frailty category was higher when defined with CHS criteria than with the FRAIL scale: CHS criteria appeared able to more accurately detect individuals at high risk of needing long-term care. However, after adjusting for potential covariates, we found that HRs in the frailty category were similar between the CHS-criteria and FRAIL-scale models; the model fitness was also comparable. This finding is probably due to the difference in age distribution among the frailty categories. The mean age in the frailty category was higher when using CHS criteria than with the FRAIL scale. Components in the CHS criteria were more sensitive to age-related decline in physical function; thus, older individuals were more likely to be positive for each component and be categorized as frail when using the CHS criteria.

In the decision curve analysis, the estimated net benefit was

about 0.08 with the threshold probability of 15%, indicating that both definitions can correctly identify eight in 100 people who will have long-term care needs through physical frailty in a population with an expected incidence of 15% over 6 years without increasing the number of false-negative cases. In other words, when screening physical frailty in a community, the benefit of identifying high-risk individuals for future LTCI needs outweigh the harm of misclassification in this situation. Also, the net benefit of the assessment by each of the CHS criteria and the FRAIL scale was higher than the treat-all strategy, suggesting that the screening of frail individual in a community could be cost-effective compared with the strategy to perform intervention on all community residents. Taken together, these results suggested that screening for physical frail community residents using the CHS criteria and the FRAIL scale can be beneficial in determining individuals who will be at risk of developing long-term care needs.

The strengths of the present study included its prospective design and in-depth evaluation, nationally standardized assessment of long-term care needs. In addition, the comparisons of the clinical usefulness of physical frailty assessments based on the decision curve analysis provided an additional information for societal decision makers to explore effective strategies for the prevention of LTCI needs. Several limitations of this study deserve mention. First, transitions in physical frailty status during the follow-up period were not taken into consideration. Other studies provide evidence to suggest that transition from less frail to more frail are association with higher risk of impaired mobility (24) and death (25–27). Work is now warranted to establish the added value of assessing transition compared with assessment at just one time point for predicting the onset of needing long-term care. Second, although we accounted for a wide range of confounders, we cannot rule out the chance of bias due to residual confounding effects and unmeasured confounders. Third, the participants were recruited from one town, and a number of participants were excluded from analysis owing to lack of information on physical frailty phenotype; thus, the generalizability of our findings may be limited.

In conclusion, in the present 6-year prospective cohort study of community-dwelling older Japanese adults, we demonstrated that physical frailty is associated with an increased risk of needing long-term care. Our data also suggested that the simple FRAIL scale has comparable predictive value and clinical usefulness in predicting the newly onset of needing long-term care to the standard assessment of physical frailty phenotype.

Funding and Acknowledgements: This work was partly supported by a Health and Labour Sciences Research Grant of the Ministry of Health, Labour and Welfare of Japan (2013-Ninchisho-Ippan-004) to SK, a research grant from the Mitsui Sumitomo Insurance Welfare Foundation to SC, a grant from Sasaguri Town to SK (2011-2016), and JSPS KAKENHI Grant Number JP17K09146 to KN, JP18K17925 to TH, and JP19K19474 to SC. None of the funding sources had any role in the study design, data analysis, data interpretation, writing of the manuscript, or decision about submission. We would like to thank Ms.Yuka Haeuchi, Dr. Yu Nofuji, Ms. Eri Shiokawa, and the municipal staff in the primary care-giving division in Sasaguri who helped us coordinate the survey in the community.

Conflict of interest: We have no conflicts of interest to declare.

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