Accepted Article

Journal of Frailty, Sarcopenia and Falls

Original Article

Physical Frailty, Balance Function, and Falls in Community-Dwelling Older Adults: A Cross-Sectional Study

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Abstract

Objectives: To examine the association between physical frailty and a history of falls among community-dwelling older adults. **Methods**: This cross-sectional study included 886 community-dwelling Japanese adults aged 65–75 years who were not certified as requiring long-term care. Physical frailty was assessed using the modified Fried phenotype, and a history of falls was defined as at least one self-reported fall during the preceding 12 months. Multivariable logistic regression analysis was performed to estimate odds ratios (ORs) and 95% confidence intervals (CIs) for a history of falls according to physical frailty status. **Results**: The age- and sex-adjusted prevalence of previous falls was 13.9% in the Robust group, 16.1% in the Pre-frailty group, and 31.6% in the Frailty group. Compared with the Robust group, the multivariable-adjusted ORs for a history of falls were 1.18 (95% CI: 0.80–1.76) in the Pre-frailty group and 2.63 (95% CI: 1.22–5.66) in the Frailty group. **Conclusions**: Physical frailty was associated with a history of falls among community-dwelling older adults. However, the cross-sectional design precludes conclusions regarding temporal or causal relationships.

Keywords: Community-dwelling older adult, Physical frailty, Fall, Balance function

Introduction

Falls among older adults are a major public health concern, as they can lead to fractures and long-term care dependency, thereby reducing healthy life expectancy. Approximately 28% of individuals aged ≥65 years' experience at least one fall within a 1-year period[1]. According to the Ministry of Health, Labour and Welfare of Japan, 'fractures and falls' as a leading cause of long-term care need increased from 12.2% in 2012 to 13.9% in 2022; in addition, the number of older adults is projected to continue increasing due to the country's ongoing population aging[2]. Given the growing older population and the risk of transitions to fractures and long-term care following falls, fall prevention in older adults is an urgent public health priority in many countries and regions.

Falls by older adults are influenced by a wide range of risk factors. Intrinsic factors include declines in

The authors have no conflict of interest.

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Edited by: *Dawn Skelton*

Accepted *30 October 2026*

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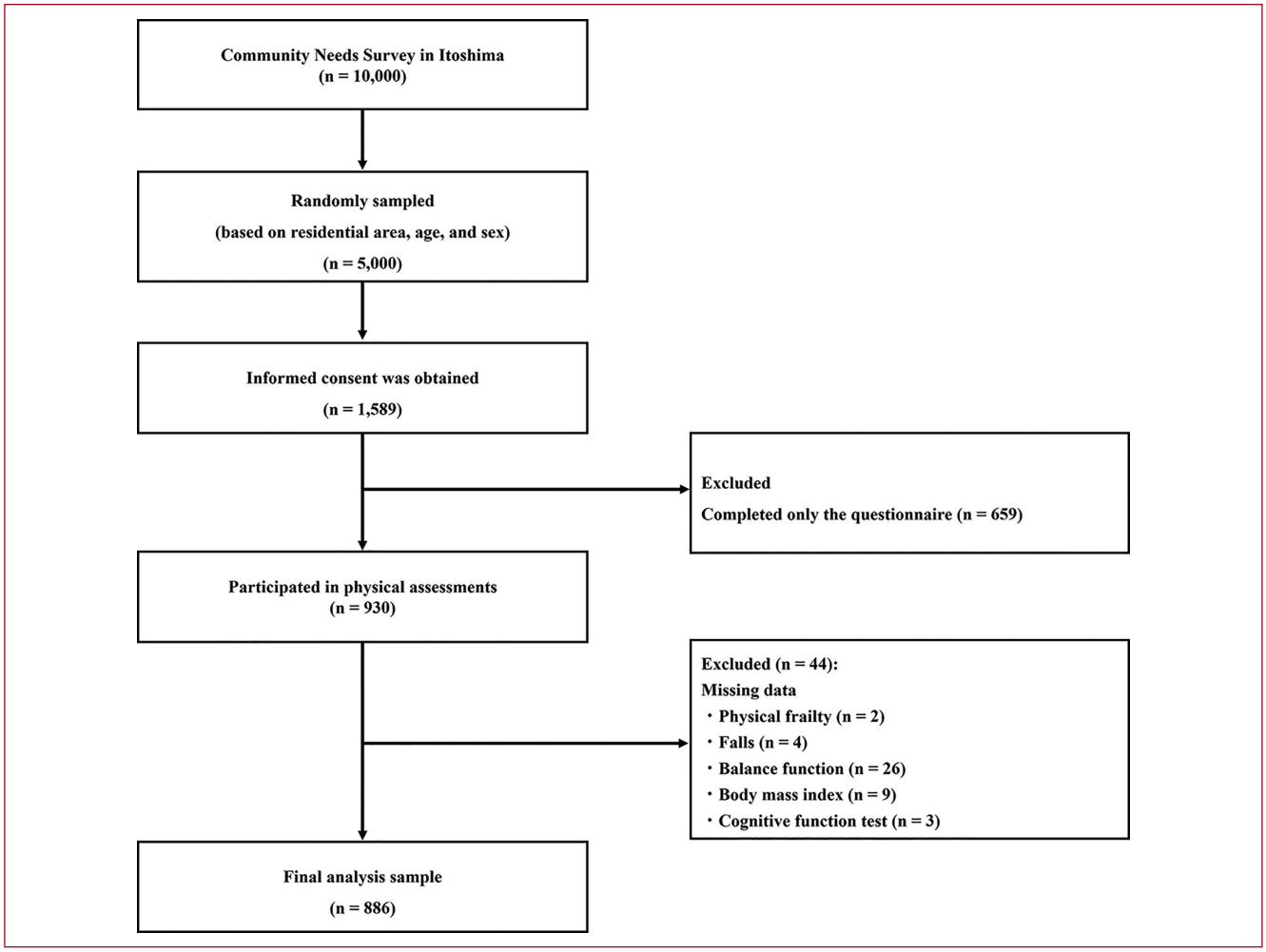

Figure 1. Flowchart of the process for selecting the study participants.

muscle strength, vision, hearing, cognitive function, and balance; extrinsic factors include environmental hazards and polypharmacy[3,4]. In recent years, frailty, a condition specific to older age, has gained increasing attention as an important intrinsic factor. Frailty is a condition characterized by increased vulnerability to external stressors due to age-related declines in multiple physiological functions and reduced physiological reserve, leading to a higher risk of adverse outcomes such as functional impairment, long-term care dependency, and mortality[5]. In particular, physical frailty, defined by the frailty phenotype comprising five components (weight loss, low handgrip strength, self-reported exhaustion, slow gait speed, and low physical activity), has been reported to be associated with an increased risk of falls, hospitalization, long-term care dependency, and mortality[5–8]. It is therefore important to better understand the factors involved in the association between physical frailty and falls among older adults.

With aging, older adults experience declines not only in muscle strength and mass but also in vestibular, visual, and proprioceptive functions, resulting in impaired balance[9,10]. Balance impairment has been shown to be more pronounced among older adults with physical frailty[11,12], which suggests that balance may be indirectly associated with the relationship between physical frailty and falls. A study of potential mediators of the association between frailty and falling that used the Falls Efficacy Scale-International (FES-I) highlighted psychological factors, demonstrating that frailty is associated with falls[13].

Balance impairment has also been associated with lower self-efficacy[14], suggesting that balance function may be related to both physical and psychological factors associated with falls. Older individuals' balance can be

readily assessed by the one-leg standing test with eyes open[15], and this test has been identified as an important predictor of future falls among community-dwelling older adults[16]. However, the relationship between physical frailty, balance function, and previous falls has not been fully characterized among community-dwelling older adults. Therefore, the primary aim of this cross-sectional study was to examine the association between physical frailty status and a history of falls. As a secondary, exploratory aim, we examined the potential indirect statistical association between physical frailty and falls through balance function, while recognizing the limitations of the cross-sectional design and the measurement ceiling of the one-leg standing test.

Participants and Methods

Study population

This cross-sectional study used baseline data from the Itoshima Felix Study[17–19], a prospective cohort study that has been conducted since 2017 in Itoshima City, Fukuoka Prefecture, Japan. The cohort included community-dwelling adults aged 65–75 years who were living in Itoshima City and had not been certified as requiring support or long-term care under Japan's public long-term care insurance system. Figure 1 illustrates our study's participant selection process. Potential participants were randomly selected from approximately 10,000 community-dwelling residents aged 65–75 years who had responded to a Community Needs Survey conducted by Itoshima City in 2016. Using information obtained from this survey, 5,000 individuals were selected by stratified random sampling according to residential area, gender, and 5-year age group and were invited to participate in the measurement survey. For residential area, participants were sampled from the Shima, Nijo, and Maebaru areas in a ratio of 1:1:2, with equal numbers of men and women selected within the sampling strata. Of the 5,000, 1,589 individuals submitted their informed consent and questionnaires, and 930 participated in the measurement sessions for objective assessments of physical function. In the present study, we excluded two of these participants due to missing physical frailty data, four with missing data regarding falls, and 26 with missing data concerning the balance assessment. Another 12 participants were excluded due to missing data on covariates, including body mass index (BMI) (n = 9) and cognitive function (n = 3). These exclusions resulted in an analytic sample of 886 participants. For each subsequent multivariable model, participants with missing data for variables included in that specific model were excluded using complete-case analysis; therefore, the number of participants included varied slightly across models. To assess potential selection bias related to participation in the measurement session, we compared the available basic demographic characteristics, including age and sex, between individuals who participated in the measurement session (n = 930) and those who did not (n = 659). The results are presented in Supplementary Table S1.

Assessment of falls

A fall was defined as an event in which "a person unintentionally comes to rest on the ground or a lower level"[20]. In the present study, a history of falls was ascertained by a participant's self-report of at least one such event in the past 12 months, based on a "yes" response to the question, "Have you experienced a fall in the past year?"

Assessment of physical frailty

Physical frailty was assessed using a modified version of the Fried frailty phenotype described by Fried et al.[8]. The operational definition used in the present study was based on a previously described approach that incorporated objectively measured physical activity and study-specific thresholds and has been evaluated in community-dwelling older adults in Japan[21]. The phenotype comprises five components: weight loss, self-reported exhaustion, low handgrip strength, slow gait speed, and low physical activity. We classified participants with three or more affected components as having frailty (Frailty group); those with one or two affected components were classified as having pre-frailty (Pre-frailty group), and those with no affected components were classified as robust (Robust group). Each component was assessed as follows[17–19]: (i) Unintentional weight loss: Assessed by asking whether the participant had experienced an unintentional weight loss of >2–3 kg in the previous 6 months. (ii) Exhaustion: Self-reported exhaustion was assessed using two questions reflecting fatigue and vitality from the Kessler 6-Item Psychological Distress Scale, based on the method reported by Liu et al.[17]: "Did you feel so depressed that nothing could cheer you up?" and "Did you feel that everything you did was an effort?"[22]. (iii) Low handgrip strength: Grip strength was measured using a dynamometer (GRIP-D TKK 5401, Takei Scientific Instruments, Niigata, Japan). For the assessment, the participant maintained a standing position, and two measurements were taken on each hand, with the maximum value used. Low handgrip strength was defined as a value in the lowest quintile (20%) of the present study population, stratified by gender and BMI categories. (iv) Slow gait speed: Gait speed was assessed using a 5-m walk test at the participant's maximum comfortable pace along an 11-m walkway, with speed (m/sec) measured between the 3-m and 8-m marks. Slow gait speed was defined as a value in the slowest quintile (20%) of the study population, stratified by gender and height. (v) Low physical activity: The participant's physical activity was objectively measured for ≥7 consecutive days by a triaxial accelerometer (Active Style Pro HJA350-IT, Omron Healthcare, Kyoto, Japan). The participants were instructed to wear the device on the right side of the waist and to remove it only during sleep

	Robust n = 382 (43.1%)	Pre-frailty n = 462 (52.1%)	Frailty n = 42 (4.8%)
Age, yrs	70.2 (2.8)	71.1 (3.1)*	72.3 (3.2)*
Women	191 (50.0)	229 (49.6)	22 (52.4)
Education, ≥12 yrs	333 (87.2)	390 (84.4)	32 (76.2)
Employed (i.e., with income)	145 (38.0)	153 (33.1)	7 (16.7)*
BMI, kg/m^2	22.6 (3.0)	23.1 (3.3)*	24.4 (3.5)*
Current alcohol consumption	202 (53.0)	240 (52.0)	17 (40.5)
Current tobacco consumption	30 (7.9)	43 (9.3)	2 (4.8)
MoCA-J score	24.9 (2.7)	23.9 (2.9)*	22.8 (3.5)*
Sleep disturbance	51 (13.4)	81 (17.5)	15 (35.7)*
One-leg standing time, sec	120.0 [70.4–120.0]	89.5 [35.0–120.0]*	20.0 [8.7–74.0]*

*Data are mean (SD), median [interquartile range], or n (%). *p<0.05 vs. Robust. For one-leg standing time, post-hoc pairwise comparisons were performed using the Dwass–Steel–Critchlow–Fligner (DSCF) method following the Kruskal–Wallis test. The significance indicators denote comparisons with the Robust group based on DSCF-adjusted p-values. BMI: body mass index, MoCA-J: Japanese version of the Montreal Cognitive Assessment, PSQI: Pittsburgh Sleep Quality Index.*

Table 1. Characteristics of the 886 community-dwelling older Japanese participants according to their physical frailty status.

or water-based activities. Low physical activity was defined as daily energy expenditure from physical activity in the lowest quintile (20%) of the study population, stratified by gender. Energy expenditure was quantified as kilocalories per kilogram of the participant's body weight per day (kcal/kg/day).

Assessment of balance

The participants' balance ability was assessed using the one-leg standing test with eyes open[15], a widely used and validated measure for predicting future falls[16,23]. For the assessment, the participant was instructed to stand with his or her feet together on a line drawn 1 m from a wall and to fix their gaze on a target positioned at eye level. Upon the examiner's signal, the test was initiated and recorded for up to 120 sec. The test was performed once on each leg, and the longer duration (seconds) was used for the analysis. The test was terminated at 120 sec; therefore, values of 120 sec represented the maximum observable test duration.

Potential confounders

Based on previous studies, the following variables were assessed as potential confounders: age[9,10], gender[9,10], educational attainment[24,25], employment status[24,25], BMI[26], current tobacco smoking status[25], alcohol consumption[26], cognitive function[10], and sleep disturbance[3]. Body weight (kg) and height (m) were measured using standard procedures with the participant wearing light clothing and no shoes. The BMI was calculated as the participant's weight (kg) divided by his/her height squared (m^2). Educational attainment was categorized into two groups based on years of education (<12 vs. ≥12 years). Employment status was defined as a 'yes' response to the question, "Do you currently have a job with income?" Current tobacco smoking status was defined as responding 'almost every day' or 'sometimes' to the question, "Do you smoke tobacco cigarettes?" Alcohol consumption was defined as responding 'almost every day' or 'sometimes' to the question, "Do you drink alcohol?" The participants' cognitive function was assessed using the Japanese version of the Montreal Cognitive Assessment (MoCA-J)[27], which evaluates domains including orientation and executive function. Sleep disturbance was assessed using the Pittsburgh Sleep Quality Index (PSQI), a self-administered questionnaire, and the presence of sleep disturbance was defined as a total PSQI score ≥6 points[28,29].

Statistical Analysis

Continuous variables are presented as the mean (standard deviation [SD]) or the median (interquartile range), and categorical variables are presented as numbers and percentages. Differences in baseline characteristics across the three groups defined by physical frailty status (robust, pre-frailty, and frailty) were examined by a one-way analysis of variance (ANOVA) with Dunnett's test for continuous variables, and the chi-squared test for categorical variables, with the Robust group as the reference. One-leg standing time was analyzed as a continuous variable rather than dichotomized using the study-specific median. Because its distribution was non-normal and showed a marked ceiling

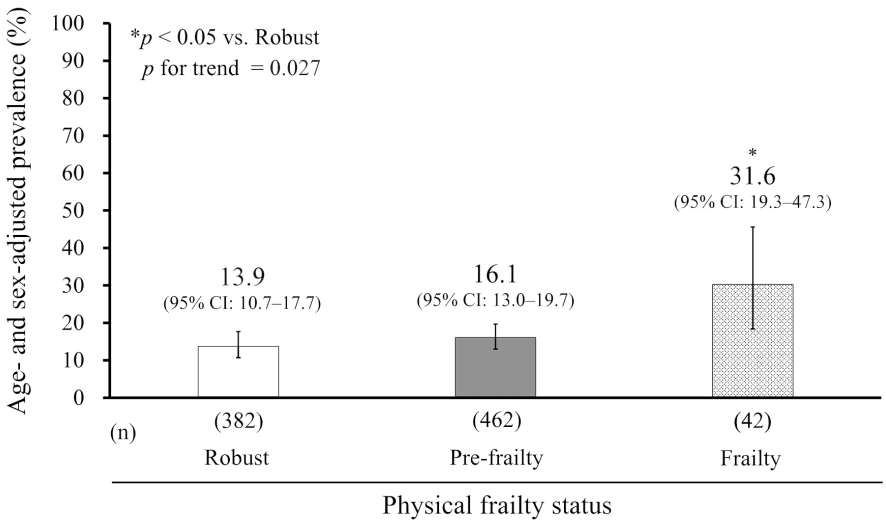

Figure 2. The age- and gender-adjusted prevalence of a history of falls according to the participants' frailty status. Bars represent adjusted prevalence estimates, and error bars indicate 95% confidence intervals. Numbers below the bars indicate the number of participants in each frailty group.

effect due to the 120-second test limit, differences in one-leg standing time across frailty groups were examined using the Kruskal–Wallis test. Post-hoc pairwise comparisons were performed using the Dwass–Steel–Critchlow–Fligner (DSCF) method, which accounts for multiple comparisons. Comparisons with the Robust group were reported in Table 1. Age- and gender-adjusted proportions of falls were estimated using logistic regression models according to physical frailty status. Group differences and linear trends were also assessed with the Robust group as the reference.

We performed a binary logistic regression analysis to examine the association between the participants' physical frailty status and their history of falls. Odds ratios (ORs) and 95% confidence intervals (CIs) for falls were estimated for the Pre-frailty and Frailty groups, with the Robust group as the reference. To address potential confounding, we constructed two models. Model 1 was an unadjusted model (crude), and Model 2 was adjusted for age, gender, educational attainment, employment status, BMI, current tobacco smoking status, alcohol consumption, MoCA-J score, and sleep disturbance presence/absence. These covariates were selected based on previous studies[3,9,10,17–19,24–26] and included all of the potential confounders assessed in this study.

An exploratory counterfactual-based analysis was performed to estimate the indirect statistical association involving one-leg standing time in the relationship between physical frailty and falls. A logistic regression model was used for the binary outcome (falls), and a linear regression model was used for the continuous mediator (one-leg standing time). Separate models were constructed comparing the Pre-frailty and Frailty groups with the Robust group as the reference. The total effect (TE), natural direct effect (NDE), and natural indirect effect (NIE) were estimated on the OR scale using the SAS PROC CAUSALMED procedure. No exposure–mediator interaction term was specified in the outcome model. All models were adjusted for the potential confounders. Uncertainty in the TE, NDE, and NIE estimates was evaluated using nonparametric bootstrap resampling with 5,000 replications[30], and percentile bootstrap 95% CIs are reported. Analyses were performed separately for the Pre-frailty and Frailty groups, with the Robust group as the reference. Because one-leg standing time was right-censored at the maximum test duration of 120 seconds, the linear mediator model did not explicitly account for this censoring.

As a sensitivity analysis, we repeated the indirect-association analysis using ≤75 sec as an alternative reference threshold, based on previously reported one-leg standing performance in Japanese adults aged 65–75 years[31]. This value was used to examine the consistency of the findings under an alternative operationalization of balance function and should not be interpreted as an established clinical cutoff. This sensitivity analysis was also considered exploratory, given that the primary continuous mediator model did not explicitly account for right-censoring at 120 seconds.

All of the statistical analyses were performed using SAS

	Participants, n	Falls	Crude		p-value	Multivariable-adjusted		p-value
			OR	95%CI		OR	95%CI	
Robust	382	54	1.00	Reference	–	1.00	Reference	–
Pre-frailty	462	74	1.16	0.79–1.70	0.449	1.18	0.80–1.76	0.401
Frailty	42	13	2.72	1.33–5.57	0.006	2.63	1.22–5.66	0.013
p for trend					0.037			0.052

The multivariable model was adjusted for age, gender, education, employment status, BMI, current tobacco consumption, current alcohol consumption, MoCA-J, and sleep disturbance. BMI: body mass index, MoCA-J: Japanese version of the Montreal Cognitive Assessment.

Table 2. The ORs and 95%CIs for the history of falls according to physical frailty status.

software ver. 9.4 (SAS Institute, Cary, NC, USA) on the computing system of the Research Institute for Information Technology, Kyushu University. For conventional regression analyses, a two-sided p-value <0.05 was considered statistically significant. For the exploratory indirect-association analyses, effect estimates are presented with percentile bootstrap 95% CIs.

Results

The participants' characteristics

Table 1 summarizes the characteristics of the study participants (n = 886). The mean (SD) age was 70.8 (3.0) years, and 442 participants (49.9%) were women. We classified the participants according to their physical frailty status as the Frailty (n = 42, 4.8%), Pre-frailty (n = 462, 52.1%), and Robust (n = 382, 43.1%) groups. Compared to the Robust group, the participants' age, BMI, and prevalence of sleep disturbance were significantly higher and the proportion of employed participants and the one-leg standing time were significantly lower in the Pre-frailty and/or Frailty groups ($p < 0.05$). The MoCA-J scores were also significantly lower in the Pre-frailty and Frailty groups compared to the Robust group (both $p < 0.01$). Of the 886 participants, 421 (47.5%) reached the maximum test duration of 120 seconds, indicating a substantial ceiling effect. The proportion reaching the 120-second maximum was 231 (60.5%) in the Robust group, 182 (39.4%) in the Pre-frailty group, and 8 (19.0%) in the Frailty group. However, there were no significant differences among the three groups in gender, educational attainment, alcohol consumption, or tobacco smoking status. The basic characteristics of participants and non-participants in the measurement session are presented in Supplementary Table S1. The mean age and proportion of women were broadly similar between participants and non-participants (70.8 ± 3.0 vs. 70.7 ± 3.1 years and 470 (50.5%) vs. 314 (47.6%), respectively).

Age- and gender-adjusted prevalence of falls by physical frailty status

The overall prevalence of falls in this study was 15.9% (n = 141). As shown in Figure 2, the age- and gender-adjusted proportions of falls were 13.9% (95% CI: 10.7–17.7%) in the Robust group, 16.1% (95% CI: 13.0–19.7%) in the Pre-frailty group, and 31.6% (95% CI: 19.3–47.3%) in the Frailty group. The adjusted proportion of falls increased with the increasing severity of physical frailty (p for trend = 0.027). However, compared to the Robust group, only the Frailty group had a significantly higher prevalence of falls ($p < 0.05$).

Multivariable-adjusted association between physical frailty and falls

Table 2 presents the OR (95% CI) data for physical frailty status according to the participants' falls. There was a trend toward a higher multivariable-adjusted OR with increasing severity of physical frailty (p for trend = 0.052). Compared with the Robust group, the multivariable-adjusted OR was 1.18 (95% CI: 0.80–1.76, p = 0.401) in the Pre-frailty group and 2.63 (95% CI: 1.22–5.66, p = 0.013) in the Frailty group. A significantly higher odds of falls was observed in the Frailty group, whereas the Pre-frailty group did not.

Exploratory indirect-association analysis

Supplementary Table S2 presents the results of the exploratory indirect-association analysis involving one-leg standing time. For the comparison of pre-frailty versus robust, 842 of the 844 eligible participants were included in the fully adjusted analysis; two participants were excluded because of missing data on alcohol consumption (n = 1) or smoking (n = 1). The TE was OR 1.20 (95% bootstrap CI: 0.81–1.83), the NDE was OR 1.12 (95% bootstrap CI: 0.75–1.72), and the NIE through one-leg standing time was OR 1.07 (95% bootstrap CI: 1.01–1.16).

For the comparison of Frailty with Robust, 423 of the

424 participants in the analysis dataset were included in the fully adjusted analysis. One participant was excluded because of missing data on alcohol consumption (n = 1). The TE was OR 3.18 (95% bootstrap CI: 1.27–9.06), the NDE was OR 2.17 (95% bootstrap CI: 0.81–6.15), and the NIE through one-leg standing time was OR 1.47 (95% bootstrap CI: 1.10–2.17).

Sensitivity analysis

The results of the sensitivity analysis using 75 sec as an alternative reference threshold are presented in Supplementary Table S3. For the comparison of pre-frailty with Robust, 842 of the 844 participants in the analysis dataset were included in the analysis; two participants were excluded because of missing data on alcohol consumption (n = 1) or smoking (n = 1).

In the analysis comparing Pre-frailty with Robust, the TE was OR 1.21 (95% bootstrap CI: 0.82–1.84), the NDE was OR 1.15 (95% bootstrap CI: 0.78–1.75), and the NIE was OR 1.05 (95% bootstrap CI: 0.99–1.14). In the analysis comparing Frailty with Robust, 423 of the 424 participants in the analysis dataset were included. One participant was excluded because of missing alcohol-consumption data. The TE was OR 3.22 (95% bootstrap CI: 1.30–9.22), the NDE was OR 2.37 (95% bootstrap CI: 0.94–6.51), and the NIE was OR 1.36 (95% bootstrap CI: 1.06–2.00).

Discussion

In this cross-sectional study of community-dwelling Japanese adults aged 65–75 years, physical frailty was associated with a higher prevalence of previous falls. Compared with the Robust group, the Frailty group had higher odds of previous falls after adjustment for potential confounders, whereas no statistically significant association was observed in the Pre-frailty group. One-leg standing performance also differed across frailty groups. These findings should be interpreted in light of the cross-sectional design, which precludes conclusions about temporal or causal relationships.

According to a 2022 meta-analysis of 104 studies, the prevalence of falls among older adults was 26.5%[32]. The prevalence of falls among older adults with physical frailty has been reported to range from 39% to 41%[33,34]. In the present study, the overall prevalence of falls was 15.9%, and the prevalence among the participants with physical frailty was 31.6%; both of these values are somewhat lower than the reported data. According to a national physical fitness and motor ability survey conducted by the Japan Sports Agency involving ~1,800 older adults, the mean one-leg standing times with eyes open for individuals aged 65–69 years were 83.8 sec for men and 86.2 sec for women, and those for individuals aged 70–74 years were 72.2 sec for men and 78.2 sec for women[31]. In contrast, the one-leg standing time in the present study was relatively long, and 421 participants (47.5%) reached the maximum test duration of 120 sec, indicating a marked ceiling effect. Accordingly, the observed one-leg standing times may not fully distinguish balance ability among participants with relatively high performance. Although one-leg standing time was analyzed as a continuous variable in the supplementary exploratory analysis, the ceiling imposed by the 120-second test limit should be considered when interpreting the indirect-association estimates. In particular, the mediator model did not explicitly account for right-censoring at 120 sec, which may have affected the indirect-association estimates. It is also possible that these differences may have been influenced by variations in study design, participation rates, age ranges, and/or the definition of falls.

The association between physical frailty and falls observed in the present study is consistent with previous studies[24,25,33–35]. A cross-sectional study of 28,285 community-dwelling adults aged ≥60 years by Thakkar et al. revealed that the individuals with physical frailty had significantly higher odds of falls compared to those without frailty[24]. Similarly, a cross-sectional study of 408 community-dwelling older adults aged ≥60 years by Kendhapedi et al. showed that the individuals with physical frailty had significantly higher odds of both falls and fear of falling compared to the robust individuals[25]. Longitudinal studies have also shown that physical frailty is associated with recurrent falls (defined as two or more falls), although these findings concern subsequent fall events and therefore differ in temporal design from the present cross-sectional study[33–35]. In the present study, physical frailty remained significantly associated with falls even after adjustment for potential confounders. Nevertheless, some conceptual overlap between physical frailty and balance function should be considered. Although balance performance is not a component of the Fried phenotype, several frailty components, particularly slow gait speed, low handgrip strength, and low physical activity, reflect aspects of physical function that may be related to balance performance. Therefore, the observed indirect statistical association may partly reflect the related nature of these constructs rather than a distinct mediating process.

Our exploratory analysis suggests an indirect statistical association involving balance function in the relationship between physical frailty and previous falls. However, the one-leg standing time measure had a pronounced ceiling effect because the test was capped at 120 seconds, with nearly half of the participants reaching this maximum. This right-censoring may have affected the validity of the mediator model and, consequently, the interpretation of the estimated indirect association. Furthermore, the temporal ordering of these variables cannot be established in the present study. In a cross-sectional study of 1,080 community-dwelling older adults in Rotterdam, Netherlands and Valencia, Spain, a mediation analysis using a bootstrap approach showed that greater frailty, as assessed by

the Tilburg Frailty Index, was associated with a higher prevalence of falls, and that the participants' scores on the FES-I partially mediated this association (95% CI for the NIE: 0.131–0.247)[13]. A key strength of the present study is that, unlike prior work focusing on psychological factors such as FES-I, we examined an objective physical measure (i.e., one-leg standing time with eyes open) as a potential factor indirectly associated with the relationship between physical frailty and falls.

The total effect estimated using PROC CAUSALMED differed from the adjusted association estimated using conventional multivariable logistic regression. The two estimates were derived from different statistical models and represent different estimands: the total effect from PROC CAUSALMED was estimated within a counterfactual framework, whereas the conventional logistic regression model estimated the adjusted association between frailty status and falls. In addition, the analyses were based on different analytic samples because the pairwise PROC CAUSALMED analyses excluded the frailty category not involved in each comparison and required complete data for the mediator and model covariates. Therefore, the two estimates should not be expected to be numerically identical. Our findings suggest an indirect statistical association involving balance function rather than a causal pathway linking physical frailty to falls. This association should be interpreted cautiously because the analysis depends on the variables included and underlying assumptions, and unmeasured confounding may have influenced the results. In addition, the Frailty group was relatively small (n = 42), including only 13 participants with a history of falls, which limited the precision and stability of the estimates. Although percentile bootstrap 95% CIs based on 5,000 replications were used and a parsimonious model-stability analysis produced a similar NIE estimate, the limited number of participants and fall events and the absence of an a priori sample-size calculation specifically for the indirect-association analysis warrant cautious interpretation. These findings should therefore be confirmed in larger longitudinal studies.

The relationship between physical frailty, balance function, and falls may involve individual components of the physical frailty phenotype. A study assessing postural sway in older adults reported positive correlations between physical frailty scores and sway in both the anteroposterior and mediolateral directions[11]. Similarly, a study measuring the center of pressure (COP) during standing in older adults found that physical frailty was independently associated with increased COP displacement[12]. Declines in muscle strength (e.g., grip strength) and gait speed, which are components of physical frailty[36,37], may contribute to reduced balance ability. These declines are thought to reflect, at least in part, age-related degenerative changes in the central and peripheral nervous systems involved in postural control and neuromuscular coordination, which contribute to decreased force production in the lower-extremity muscles[38,39]. Consequently, such impairments may result in reduced balance and an increased risk of falls.

Study strengths

Our study has several strengths. It examined the association between physical frailty and previous falls among community-dwelling Japanese adults aged 65–75 years. In addition, balance function was assessed objectively using one-leg standing time with eyes open, providing an objective measure of physical performance in this population.

Study limitations

Several study limitations should be acknowledged. (1) Because of the study's cross-sectional design, our findings cannot establish the temporal or causal relationships among physical frailty, balance function, and falls. Physical frailty and balance function were assessed at the study visit, whereas falls were retrospectively reported for the preceding 12 months. Therefore, some falls may have occurred before the assessment of frailty and balance function, and previous falls may themselves have influenced subsequently measured physical function or balance. Longitudinal studies with appropriate temporal ordering are required to evaluate whether balance function lies on a causal pathway between physical frailty and subsequent falls. (2) Although the available basic demographic characteristics of participants and non-participants in the measurement session were broadly similar in terms of age and sex, information on non-participants was limited. Differences in physical function, frailty status, overall health status, and other characteristics could therefore not be fully assessed. Individuals who attended the measurement session may have been healthier, more physically capable, or more willing to participate in health assessments than those who did not attend. Healthy-volunteer selection therefore cannot be excluded, and the direction and magnitude of this potential selection bias cannot be determined from the available data. In addition, the study was restricted to adults aged 65–75 years without long-term care needs. Thus, the findings may not be generalizable to older adults with greater functional limitations, those requiring long-term care, or the broader older adult population. (3) Falls were assessed by a self-reported questionnaire, which may have led to underestimation due to recall bias. In addition, the number of falls was not precisely assessed, precluding an analysis of recurrent falls. (4) Data concerning the participants' comorbidities were not collected, and their potential confounding effects could not be fully accounted for. Moreover, our results may have been affected by unmeasured confounding factors, including intrinsic and extrinsic factors such as visual function, medication use, and living environment. (5) The one-leg standing time with eyes open was capped at 120 seconds, and 47.5%

of participants reached this maximum duration, resulting in a substantial ceiling effect. Although one-leg standing time was analyzed continuously, the linear mediator model used in PROC CAUSALMED does not explicitly account for right-censoring at 120 seconds. This model limitation may have affected the estimated indirect associations, and the findings should therefore be interpreted as exploratory.

Conclusions

Among community-dwelling Japanese adults aged 65–75 years, physical frailty was associated with a higher prevalence of previous falls. One-leg standing performance with eyes open differed according to physical frailty status. These findings suggest that physical frailty and balance function are related characteristics in this population; however, the cross-sectional design does not allow temporal or causal relationships to be established.

Ethical Approval

This study was approved by the Institutional Review Board of Kyushu University (approval no. 201708). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Consent to Participate

Written informed consent was obtained from all participants regarding the use and publication of their data.

Authors' contributions

Eisei Harayama: Writing–original draft, Conceptualization, Methodology, Formal analysis, Data curation, Project administration. Takafumi Saito: Writing–review & editing, Conceptualization, Methodology, Formal analysis, Data curation. Lefei Wang: Writing–review & editing. Ziming Gong: Writing–review & editing. Hiro Kishimoto: Writing–review & editing, Conceptualization, Methodology, Data curation, Project administration. All authors read and approved the final version of the manuscript.

Funding

This study was supported in part by Grants-in-Aid for Scientific Research (B) (JP23K20353 [previous no. JP20H04016], JP24K02766, and JP 25K00719) and (C) (JP23K10763 and JP 20K11446) from the Ministry of Education, Culture, Sports, Science and Technology of Japan, and by Itoshima City (2025-0036 and 2026-0048). None of the funding sources had any role in the study design, data analysis, data interpretation, writing of the manuscript, or decision on the submission of this manuscript.

Acknowledgements

We thank all of the individuals who supported and contributed to this study. We also sincerely thank all the participants from Itoshima City, Fukuoka, for their involvement in the study.

Participants neither incurred any costs related to participation nor received any financial compensation.

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	Participants n = 930	Non-participants n = 659
Age, yrs	70.8 ± 3.0	70.7 ± 3.1
Women, n (%)	470 (50.5)	314 (47.6)

Data are presented as mean (SD) or n (%).

Supplementary Table S1. Comparison of characteristics between participants and non-participants in the measurement session.

Model	n	Effect	OR	95% bootstrap CI
Pre-frailty vs. Robust	842	TE	1.20	0.81–1.83
		NDE	1.12	0.75–1.72
		NIE	1.07	1.01–1.16
Frailty vs. Robust	423	TE	3.18	1.27–9.06
		NDE	2.17	0.81–6.15
		NIE	1.47	1.10–2.17

Values are OR (95% bootstrap CI). All models were adjusted for age, gender, education, employment status, BMI, current tobacco smoking status, current alcohol consumption, MoCA-J score, and sleep disturbance. NDE: natural direct effect, NIE: natural indirect effect, TE: total effect.

Supplementary Table S2. Exploratory indirect-association analysis of the relationship between physical frailty and history of falls involving one-leg standing time.

Model	n	Effect	OR	95% bootstrap CI
Pre-frailty vs. Robust	842	TE	1.21	0.82–1.84
		NDE	1.15	0.78–1.75
		NIE	1.05	0.99–1.14
Frailty vs. Robust	423	TE	3.22	1.30–9.22
		NDE	2.37	0.94–6.51
		NIE	1.36	1.06–2.00

Values are OR (95% bootstrap CI). All models were adjusted for age, gender, education, employment status, BMI, current tobacco smoking status, current alcohol consumption, MoCA-J score, and sleep disturbance. NDE: natural direct effect, NIE: natural indirect effect, TE: total effect.

Supplementary Table S3. Sensitivity analysis of the exploratory indirect association between physical frailty and history of falls using ≤75 seconds as an alternative reference threshold for one-leg standing time.

Model	n	Effect	OR	95% bootstrap CI
Pre-frailty vs. Robust	844	TE	1.16	0.79–1.72
		NDE	1.09	0.73–1.63
		NIE	1.07	1.00–1.15
Frailty vs. Robust	424	TE	2.64	1.12–6.15
		NDE	1.78	0.73–4.31
		NIE	1.48	1.10–2.16

Values are OR (95% bootstrap CI). All models were adjusted for age, gender and BMI. NDE: natural direct effect, NIE: natural indirect effect, TE: total effect.

Supplementary Table S4. Model stability of the exploratory indirect association between physical frailty and falls using a parsimonious model adjusted for age, sex, and BMI.