

**THE FALLS EFFICACY SCALE INTERNATIONAL (FES-I). A COMPREHENSIVE LONGITUDINAL
VALIDATION STUDY**

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ABSTRACT

Objective: To perform a comprehensive validation of the 16-item and 7-item Falls Efficacy Scale International (FES-I) by investigating the overall structure and measurement properties, convergent and predictive validity, and responsiveness to change.

Method: Five hundred community-dwelling older people (70-90 years) were assessed on the FES-I in conjunction with demographic, physiological, and neuropsychological measures at baseline and at 12 months. Falls were monitored monthly and fear of falling three monthly.

Results: The overall structure and measurement properties of both FES-I scales, as evaluated with item response theory, were good. Discriminative ability on physiological, and neuropsychological measures indicated excellent validity, both at baseline (N=500, convergent validity) and at one-year follow-up (N=463, predictive validity). The longitudinal follow-up suggested that FES-I scores increased over time regardless of any fall event, with a trend for a stronger increase in FES-I scores when a person suffered multiple falls in a 3 month period. Additionally, using receiver-operating characteristic (ROC) curves, cut-points were defined to differentiate between lower and higher levels of concern.

Conclusions: The current study builds on the previously established psychometric properties of the FES-I. Both scales have acceptable structures, good validity and reliability, and can be recommended for research and clinical purposes. Future studies should explore the FES-I's responsiveness to change during intervention studies and confirm suggested cut-points in other settings, larger samples and across different cultures.

Keywords: fear of falling, Rasch analyses, accidental falls, ageing, sensitivity to change

INTRODUCTION

Fear of falling is an important psychological factor associated with falls in older people and has been reported in both risk factor [1, 2] and intervention studies [3, 4]. It has been inconsistently defined in studies [5] and these inconsistencies have resulted in a large variability in reported prevalence of fear of falling ranging from 12 to 92% [6]. In order to maximize interpretation of findings from epidemiological and intervention studies on fear of falling, a consistent measure is necessary.

The Falls Efficacy Scale International (FES-I), developed and validated by the Prevention of Falls Network Europe (ProFaNE), has become a widely-accepted tool for assessing concern about falling [7, 8]. Previous studies indicate that the FES-I has excellent reliability and validity [7, 8] across different cultures and languages [9]. The psychometric properties of the FES-I have been evaluated using classical test theory [7-9]. However, with the interest in fear of falling, it is important to further explore the psychometric properties of the FES-I with robust statistical methods and longitudinal data.

This study aimed to further evaluate the psychometric properties of the FES-I. The structure and measurement properties were evaluated with item response theory [10]. This approach is becoming the chosen approach amongst psychometricians and is arguably the best method for developing scales and questionnaires [11]. We explored convergent and predictive validity of the scale by investigating discriminative ability of the FES-I on a range of physiological and neuropsychological measures. A longitudinal follow-up allowed us to explore the stability over time and responsiveness to change of the FES-I.

METHODS

Participants

A total of 500 people aged 70 - 90 years were recruited from a cohort of 1037 community-dwelling people living in Sydney and participating in the Sydney Memory and Ageing Study (see acknowledgements). Exclusion criteria were neurological, cardiovascular or major musculoskeletal impairments that precluded participants from completing assessments. Approval for the study was obtained from the University of New South Wales Human Research Ethics Committee.

Measures

The Falls Efficacy Scale International

The FES-I is a self-report questionnaire, providing information on level of concern about falls for a range of activities of daily living (Figure 1). The original questionnaire contains 16 items scored on a four point scale (1 = not at all concerned to 4 = very concerned) [7]. The shortened questionnaire contains seven items [8]. The FES-I was assessed at baseline, and then three monthly for 12 months.

Other measures

Physical performance was assessed with (1) maximal isometric quadriceps strength (kg) [12], (2) postural sway by recording displacements of the body at the level of the waist (mm) while standing on a foam mat with eyes open [12], and (3) gait speed (in seconds) by walking 3 meters, turning and returning at normal pace. The Physiological Profile Assessment (PPA) was used to gain an estimate of physiological falls risk [12]. Levels of disability were assessed using the 12-item World Health Organization Disability Assessment Schedule

(WHODAS II, total score range 0-36) [13]. Quality of life was assessed using the 20-item AQOL II (total score range 0-100) [14]. Symptoms of depression were assessed using the self-report 15-item Geriatric Depression Scale (GDS, total score range 0-15, with scores ≥ 5 indicating possible depression) [15]. Symptoms of anxiety in the past month were assessed using the 9-item Goldberg Anxiety Scale (GAS, total score range 0-9, with scores ≥ 5 indicating possible anxiety) [16]. Cognitive processing performance was tested using the Trail Making Test (Trails B), which requires subjects to draw lines connecting a number of circles alternating between letters and numbers [17]. A fall was defined as ‘an unexpected event in which the participants come to rest on the ground, floor, or lower level’ [18]. The number of falls in the previous year was recorded at baseline. Falls frequency during the one-year follow-up was monitored with monthly falls diaries [19]. All participants were assessed on each measure at baseline. A total of 494 participants completed the 12-month follow-up for falls and 463 participants were reassessed after one year.

Analyses

The questionnaire structure was evaluated by using item response theory, i.e. Rasch modelling (Winsteps[®], John M. Linacre). Rasch modelling concentrates on the probability that an individual with a certain level of concern will answer each item in a given way to match that level of concern [11]. Fit statistics were used to examine how well the data from people and items met the model assumptions. The internal structure of the questionnaires was examined by factor analysis using an unrotated principal components analysis. Internal consistency (Cronbach’s alpha) was evaluated by calculating the reproducibility of the responses of each person on the questionnaires [10]. The item-respondent map shows how each participant responded on each item. This map was inspected to evaluate content representation of each item to ensure items and respondents were appropriately targeted [10].

Further analyses were performed using SPSS for Windows (Version 17, SPSS, Inc., Chicago, IL, USA). After a logarithmic transformation of the FES-I, assumptions for parametric analyses were met [20]. Pearson's correlations were calculated to compare the different questionnaires. Sensitivity-to-change was assessed by investigating main and interaction effects using a mixed 2-factor Repeated Measures (RM) ANOVA with one within factor (occasion at 2 levels) and one between factor (falls, injurious falls). Validity of the baseline FES-I was assessed by using independent t-tests to examine between-group differences in total scores according to age, gender, and a variety of falls risk factors that have previously been associated with falls and fear of falling [7, 21-25]. Convergent validity used criterion measures collected at baseline and predictive validity used criterion measures collected at the one-year follow-up reassessment. Cut-off scores were established for each FES-I based on examination of receiver-operating characteristic (ROC) curves.

RESULTS

Participants

The mean age of participants was 77.4 years (SD 6.08) and 279 (55.8%) were women. A small majority of participants (N=269, 53.8%) completed high school, and 208 (41.6%) previously worked in managerial or professional occupations. On self-rated health status using a five-point scale, 85% (N=425) of the sample rated their health as good, very good, or excellent. Thirty percent (N=149) of the participants reported one or more falls in the previous year, and 43.6% (N=214) reported one or more falls during the one-year follow-up. Means and standard deviations for the total FES-I scores are presented in Table 1.

Questionnaire structure of the FES-I

The principal component analysis revealed the greatest eigenvalue was less than 3 (1.9), supporting the uni-dimensionality of the scale [10]. Internal consistency of the FES-I as a whole was excellent with Cronbach's alpha of 0.79 [26].

A bubble chart was inspected to ascertain the overall fit of the 16-item FES-I (Figure 1, Panel A). Bubble charts display three-dimensional data in two dimensions, with the position of the centre of the bubble indicating two of the values (weighted t statistics [x-axis] and average measure [y-axis]) and the size of the bubble the standard error. The weighted t statistics report the significance of the chi-square statistics occurring by chance when the data fit the Rasch model. The values reported are unit-normal deviates, in which 5 percent significance corresponds to 1.96. Overfit (i.e. redundancy of individual items) is reported with negative values. The weighted t statistic was not acceptable for four items of which items 5 and 12 showed values smaller than -2.00 and items 11 and 13 values greater than 2.00 [10]. The average measure is the location of an item (expressed in logits) on the latent variable, and is the average 'difficulty' of that item in the tested population. Items rated as assessing higher levels of concern will have higher average measures. The item-responder map showed that all items were located between -4.1 and +1.6 logits. Most items (1, 2, 3, 4, 6, 8, 10, 16) assessed high levels of concern in a small distribution (positive logits, 0 to +1.6) suggesting some redundancy of items. The distribution of items (7, 9, 14 and 15) assessing lower levels of concern was wider (negative logits, 0 to -4.1). In order to reduce the floor effect, these items are crucial for the diversity of the scale.

The analyses of the 16-item FES-I supports the item selection for the shortened FES-I [8] (Figure 1, Panel B). The weighted t statistic of the 7-item FES-I was excellent, with item 15 slightly outside the acceptable range (-2.31) [10]. The shorter version was found to be unidimensional, but as expected the Cronbach's alpha decreased to 0.63, which is still

acceptable. The item-respondent map showed a smaller distribution of items on the continuum than the longer version towards the assessment of lower levels of (-1.5 to +1.6 logits). One item assessed very low levels of concern, two moderately low, two moderately high and two very high. This distribution of items indicates that the scale has a good content representation of the construct, and will allow scoring of older people with different levels of concern.

Convergent and predictive validity

Significant between-group differences in total scores demonstrated that both questionnaires were sensitive to group differences relating to demographic characteristics and fall risk factors (Table 2). Scores for both versions of the FES-I were significantly higher in women and older participants; participants with a falls history, increased physiological falls risk, poor balance, low muscle strength and slower gait speed; and participants with depressive symptoms, lower quality of life, and poor cognitive processing performance. These group differences remained after the one-year follow-up (N=463) for future falls, physiological falls risk, muscle weakness, overall disability and depressive symptoms.

Stability over time and responsiveness to change

A Spearman Rho correlation of the serial FES-I measurements suggests it was only moderately stable over time with correlation coefficients between 0.66 and 0.83 across all versions (Table 1). To assess responsiveness to change, participants were selected who had at least one period of 3 months without suffering a fall (N=404, Figure 1). The FES-I at the start of the next 3-month period was then compared to the FES-I at the end of that same 3-month period. Participants were classified with respect to two different falls outcome measures: falls (3 groups: no falls, N=294; one fall, N=93; two or more falls, N=17) and injurious falls (2

groups: no injury, N=330; injury, N=74). An RM ANOVA revealed a main effect of time indicating that the level of concern increased over time in all participants (Wilks=0.96, $F_{1,402}=17.36$, $p<0.001$). The group x time interaction was not significant for number of falls (Wilks=0.99, $F_{2,401}=1.95$, $p=0.143$) or injurious falls (Wilks=0.99, $F_{1,402}=0.69$, $p=0.406$). A trend for an interaction effect was found between no falls and multiple falls (Wilks=0.99, $F_{1,402}=3.51$, $p=0.062$).

Identification of cut-points

ROC plots were used to define cut-points for the FES-I scales. Each of the previously described differentiating factors was used separately as a state variable. We defined cut-points as the best trade-off between sensitivity and specificity and aimed to have identical areas under the curve before and after recoding of the FES-I scales. The area under the curve for the 16-item FES-I ranged between 0.58 for balance, 0.67 for previous falls, up to 0.74 for depressive symptoms, and was similar for the shortened version of the FES-I. We defined a cut-point to differentiate between low and high concern (16-item FES-I: 16-22 and 23-64; 7-item FES-I: 7-10 and 11-28) and between low, moderate and high concern (16-item FES-I: 16-19, 20-27 and 28-64; 7-item FES-I: 7-8, 9-13 and 14-28).

DISCUSSION

The aim of this study was to address limitations of the initial validation study [7], and to provide evidence for the predictive validity of the FES-I. Overall, the current study was able to confirm the good validity and reliability of the FES-I found in the previous study.

The overall structure of both FES-I versions is acceptable but skewed towards assessing people with higher levels of concern about falling, resulting in a floor effect [27]. To increase the ability of the FES-I to track the full range of concern about falling in healthy older people, additional more demanding balance-related activities should be explored. In the 16-item version, two out of the six more demanding items had an unacceptable fit. The poor fit of the item ‘walking on a slippery surface’ is possibly a result of the current study being undertaken in a temperate climate in which it was difficult for participants to relate to negotiating icy surfaces. Another possibility is that these two contexts are not related to fear of falling, but to other psychological constructs such as quality of life (item 13) or risk-taking behaviour (item 11). Our analyses of the 16-item FES-I support the item choice for the shortened version [8].

Convergent and predictive validity of the FES-I were explored extensively by including both physical and psychological measures in a longitudinal design. Convergent validity was confirmed for previous falls [2, 7, 25, 28], depressive symptoms [25], overall disability [24], low quality of life [23], and physical impairment [21, 22]. Generalized anxiety has been suggested to be related to fear of falling [24, 28, 29], however in our study the evidence for this was not strong. Predictive validity analyses resulted in similar findings. After 12 month follow-up, the baseline FES-I was able to discriminate between multiple fallers and non multiple fallers [2, 22, 28], certain falls risk factors and overall disability [30]. This is in line with previous findings suggesting that fear of falling might lead to physical frailty [23, 28] and as a consequence increases the risk of suffering future falls [22].

Responsiveness to change of fear of falling scales is usually investigated as part of an intervention study [3, 4], but the short-term effect of a fall on fear of falling has never been investigated. Overall, the FES-I increased over time regardless of any fall event with a trend

for a stronger increase when a person suffered multiple falls in a 3-month period. Based on these results, we cannot provide strong evidence for a good responsiveness to change in healthy older people. However, the target population for fear of falling interventions will be either people with high levels of concern about falling or frailer people. Additional analyses indicated that the floor effect was less apparent in a frailer subsample of our population (PPA ≥ 1.70 ; N=87) with a skewness of 0.90 compared to 1.70 for the total sample. Therefore, we believe the FES-I will allow for detecting changes in fear of falling in these populations without any required modifications. Future studies should explore the FES-I's responsiveness to change during intervention studies.

This is the first study to calculate cut-points for increased levels of concern about falling. By using related measures of balance, previous falls and depressive symptoms as state variables, it proved feasible to derive FES-I cut-points for low, moderate and high levels of concern. In order to better understand the way in which older people use the FES-I to report their concern, data-driven cut-points are crucial. The suggested cut-points will help to establish norms for acceptable ranges of fear of falling in different populations. However, we acknowledge the validity of these cut-points is hard to establish in the absence of a gold standard. These cut points should therefore be regarded as preliminary and further work is warranted to confirm them in other settings, larger samples and across different cultures [7]. In the meantime, we advise caution if using these cut-points in clinical practice and clinical trials.

The current study builds on the previously established psychometric properties of the FES-I. The shortened 7-item FES-I proved to be a good alternative to the original 16-item FES-I. Both versions have acceptable structures and good reliability. The validity analyses indicate a

strong relationship between the FES-I and both previous and future falls. Based on these analyses, we suggest the FES-I can be recommended as a screening tool for concern about falling for research and clinical purposes. Future studies should explore the FES-I's responsiveness to change during intervention studies and confirm the suggested cut-points in external populations.

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CONFLICTS OF INTEREST

None to declare

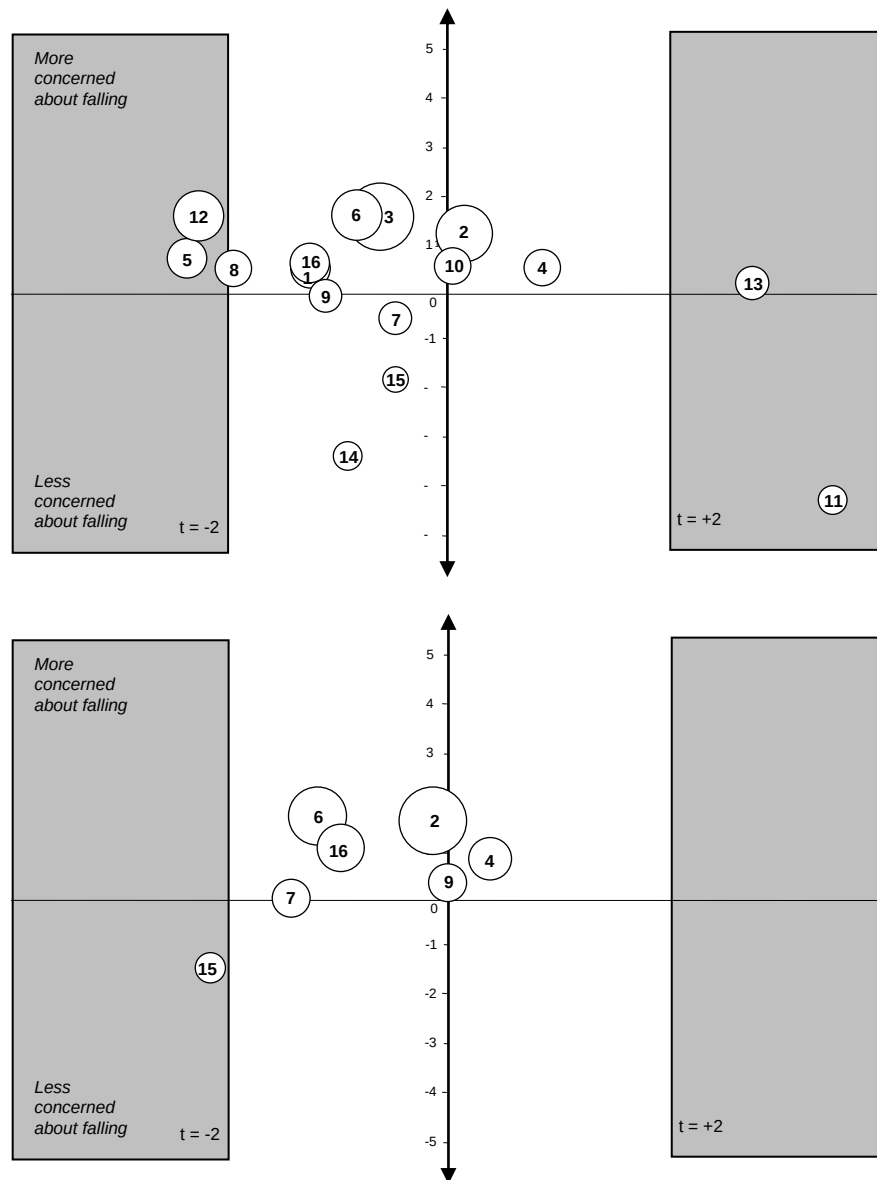
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FES-I items (Shortened FES-I *)

1. Cleaning the house (e.g. sweep, vacuum or dust)
2. Getting dressed or undressed (*)
3. Preparing simple meals
4. Taking a bath or shower (*)
5. Going to the shop
6. Getting in or out of a chair (*)
7. Going up or down stairs (*)
8. Walking around in the neighbourhood
9. Reaching for something above your head or on the ground (*)
10. Going to answer the telephone before it stops ringing
11. Walking on a slippery surface (e.g. wet or icy)
12. Visiting a friend or relative
13. Walking in a place with crowds
14. Walking on an uneven surface (e.g. rocky ground, poorly maintained pavement)
15. Walking up or down a slope (*)
16. Going out to a social event (e.g. religious service, family gathering or club meeting) (*)

Figure 1. Bubble charts for the 16-item FES-I (Panel A) and the 7-item FES-I (Panel B) as a graphical representation of measures and fit values. Bubbles are named after the item as presented in Table 1 and sized by their standard errors. Items assessing ‘high levels of concern’ are at the top of the fear of falling continuum (positive logits) and items assessing ‘lower levels of concern’ are at the bottom (negative logits).

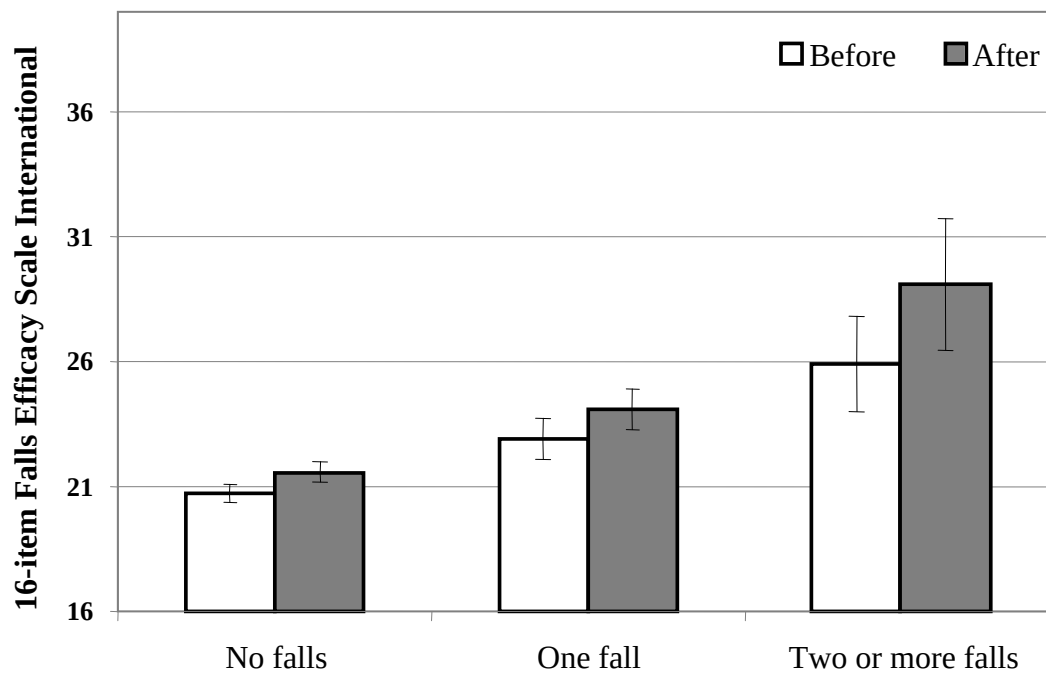


Figure 2. Responsiveness to change to falls of the 16-item FES-I (Mean $\pm$ SEM) over a period of 3 months (in participants who had no falls (N=294), one fall (N=93) or multiple falls (N=17) in the same 3 month period).

Table 1. Total score ranges, means, standard deviations and Persons correlations between all FES-I scores assessed in three monthly intervals

16-item FES-I	Range	Mean $\pm$ SD	2	3	4	5
1. FES-I at 0 months	16-57	22.6 $\pm$ 6.4	0.708	0.711	0.698	0.715
2. FES-I at 3 months	16-55	21.7 $\pm$ 6.6	---	0.780	0.736	0.701
3. FES-I at 6 months	16-64	22.8 $\pm$ 7.8	---	---	0.771	0.763
4. FES-I at 9 months	16-62	23.6 $\pm$ 8.2	---	---	---	0.830
5. FES-I at 12 months	16-64	23.6 $\pm$ 8.1	---	---	---	---
7-item FES-I	Range	Mean $\pm$ SD	2	3	4	5
1. FES-I at 0 months	7-25	9.4 $\pm$ 3.0	0.694	0.694	0.692	0.683
2. FES-I at 3 months	7-23	9.2 $\pm$ 3.0	---	0.747	0.693	0.658
3. FES-I at 6 months	7-28	9.7 $\pm$ 3.3	---	---	0.750	0.730
4. FES-I at 9 months	7-27	10.1 $\pm$ 3.7	---	---	---	0.803
5. FES-I at 12 months	7-28	10.0 $\pm$ 3.8	---	---	---	---

Table 2. Means and standard deviations on total 16-item (range 16 to 64) and 7-item (range 7 to 28) FES-I scores for sub-groups based on demographic characteristics and falls risk factors at baseline (convergent validity) and after one-year follow-up (predictive validity)

	Convergent validity		Predictive validity	
	16-item FES-I	7-item FES-I	16-item FES-I	7-item FES-I
1. Gender: Male	21.7 ± 5.8	9.1 ± 2.8	UC	UC
Gender: Female	23.4 ± 6.6 **	9.7 ± 3.1 *	UC	UC
2. Age ≤ 75	21.4 ± 5.7	8.9 ± 2.8	UC	UC
Age > 75	23.1 ± 6.5 **	9.6 ± 3.0 **	UC	UC
3. Multiple falls: No	22.1 ± 6.1	9.2 ± 2.8	22.3 ± 6.2	9.3 ± 2.9
Multiple falls: Yes	26.1 ± 7.4 ***	11.0 ± 3.5 ***	24.4 ± 6.8 ***	10.1 ± 3.1 **
4. PPA ≤ 0.75	21.4 ± 5.4	8.8 ± 2.4	21.4 ± 5.2	8.8 ± 2.3
PPA > 0.75 ¶	23.5 ± 6.8 ***	9.9 ± 3.2 ***	23.3 ± 6.9 ***	9.8 ± 3.2 ***
4. Sway path foam ≤ 155	22.1 ± 6.3	9.1 ± 2.8	22.4 ± 6.0	9.3 ± 2.8
Sway path foam > 155 ¶	22.9 ± 6.1 *	9.6 ± 2.9 *	22.7 ± 6.5 ^	9.4 ± 3.0 ^
5. Strength ♀ ≤ 20, ♂ ≤ 30	21.5 ± 5.2	8.8 ± 2.3	21.8 ± 5.4	9.0 ± 2.6
Strength ♀ > 20, ♂ > 30 ¶	24.1 ± 7.2 ***	10.2 ± 3.4 ***	23.3 ± 7.2 *	9.7 ± 3.3 *
6. Gait speed ≤ 8 s	21.1 ± 5.2	8.6 ± 2.3	NA	NA
Gait speed > 8 s ¶	24.2 ± 7.0 ***	10.2 ± 3.3 ***	NA	NA
7. AQOL ≤ 91.5	20.2 ± 4.1	8.3 ± 1.8	NA	NA
AQOL > 91.5 ¶	24.8 ± 7.1 ***	10.5 ± 3.4 ***	NA	NA
8. WHODAS ≤ 16	20.3 ± 4.5	8.3 ± 2.0	19.9 ± 4.5	8.1 ± 1.9
WHODAS > 16 ¶	24.8 ± 7.0 ***	10.5 ± 3.3 ***	23.8 ± 6.4 ***	9.9 ± 3.0 ***
9. GDS ≤ 4	22.2 ± 6.1	9.2 ± 2.8	22.1 ± 6.1	9.1 ± 2.8
GDS ≥ 5	26.8 ± 7.5 ***	11.6 ± 3.6 ***	25.8 ± 8.1 **	10.7 ± 3.6 **
10. GAS ≤ 4	22.24 ± 6.0	9.3 ± 2.8	22.2 ± 6.2	9.2 ± 2.9
GAS ≥ 5	25.6 ± 9.0 ^	10.5 ± 4.0 ^	23.4 ± 5.5 ^	9.8 ± 2.9 ^
11. Trails B ≤ 105	21.9 ± 5.4	9.1 ± 2.5	NA	NA
Trails B > 105 ¶	23.2 ± 7.0 *	9.7 ± 3.3 *	NA	NA

¶: median of total sample; * $p \leq 0.050$; ** $p \leq 0.010$, *** $p \leq 0.001$, ^ $p > 0.050$, UC=Unchanged, NA=Not Available