

# Assessment of Fall Risk Using a Self-Structured Questionnaire Among Community-Dwelling Elderly: A Validation Study

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## Abstract

**Background:** Falls among the elderly remain a growing public health concern, affecting one-third of community-dwelling older adults annually<sup>[1]</sup>. While brief, practical screening tools are needed, rigorous validation approaches are essential before clinical implementation.

**Objectives:** (1) To evaluate the internal consistency and test-retest reliability of a self-structured Fall Risk Assessment Questionnaire (FRSQ) in community-dwelling elderly. (2) To examine its correlation with the Falls Efficacy Scale-International (FES-I) as a measure of concurrent validity. (3) To transparently report study design limitations and outline future validation directions.

**Methods:** A cross-sectional descriptive study enrolled 201 community-dwelling elderly (age  $\geq 60$  years) from Ahilyanagar, Maharashtra, India. Statistical analysis included Cronbach's alpha, Intraclass Correlation Coefficient (ICC), Pearson correlation, one-way ANOVA, and 95% confidence intervals.

**Results:** The FRSQ demonstrated excellent internal consistency (Cronbach's  $\alpha = 0.83$ ; 95% CI: 0.80--0.86) and test-retest reliability over 2 weeks (ICC = 0.92; 95% CI: 0.89--0.94). Strong positive correlation with FES-I ( $r = 0.78$ ;  $p < 0.001$ ; 95% CI: 0.71--0.84) supported concurrent validity. Risk categorization: Low risk (0--5) = 125 participants (62.2%), Moderate risk (6--10) = 56 participants (27.9%), High risk ( $\geq 11$ ) = 20 participants (10.0%). One-way ANOVA demonstrated significant group differences ( $F = 1247.8$ ,  $p < 0.001$ ).

**Conclusion:** The FRSQ demonstrates strong internal consistency, test-retest stability, and correlation with fall-related concern. However, the cross-sectional design limits conclusions regarding predictive validity. Prospective cohort studies examining prediction of actual falls are essential before clinical implementation.

**Keywords:** Fall risk assessment, questionnaire validation, psychometric properties, elderly, community-dwelling, reliability, validity

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## Introduction

Falls among community-dwelling older adults represent a substantial personal, social, and economic burden globally. The World Health Organization identifies falls as the second leading cause of unintentional injury death among adults aged 60+ years<sup>[1]</sup>. Approximately 30% of adults aged 65 years and older experience at least one fall annually, with prevalence rising to 40% in those aged 80 years and above<sup>[2,3]</sup>.

## Public Health Significance

Falls carry both immediate and long-term consequences. Acute complications include fractures, head injuries, and soft tissue trauma. Long-term sequelae include functional decline, loss of independence, psychological distress, reduced quality of life, and depression<sup>[4,5]</sup>. The burden is particularly acute in resource-limited healthcare settings, where access to specialized geriatric services remains limited<sup>[7]</sup>. In India, demographic transitions toward an aging population create urgent need for efficient, scalable, and culturally appropriate screening approaches.

## Current Assessment Approaches and Gaps

Standardized fall risk assessment instruments include the Berg Balance Scale (BBS), Timed Up and Go (TUG), and Falls Efficacy Scale-International (FES-I)<sup>[9,10,11]</sup>. While these tools demonstrate robust psychometric properties, they often require specialized equipment, trained administrators, or significant time investment<sup>[12,13]</sup>. These requirements limit practical applicability in community settings, particularly primary healthcare facilities typical in resource-limited regions.

There remains unmet need for brief, practical, self-administered screening questionnaires accessible to non-specialist healthcare providers. Community screening instruments enable population-level identification of high-risk individuals and facilitate targeted intervention allocation<sup>[6,8]</sup>.

## Questionnaire Development Framework

Rigorous instrument development requires systematic progression through evidence-based phases: (1) item generation and content validity, (2) preliminary psychometric validation, (3) reliability assessment, (4) concurrent/construct validity, (5) predictive validity testing, (6) multi-sample validation, (7) diagnostic accuracy evaluation, and (8) clinical responsiveness<sup>[12,13]</sup>. The present manuscript reports findings addressing phases 3 and 4 (reliability and concurrent validity) in a single geographic sample.

## Study Rationale and Objectives

Our research team developed a self-structured Fall Risk Assessment Questionnaire (FRSQ) incorporating both intrinsic (individual physiological) and extrinsic (environmental) fall risk factors<sup>[14,15]</sup>. A preliminary feasibility study demonstrated acceptable internal consistency. The current investigation expands upon preliminary findings through substantially increased sample size (n = 201), rigorous statistical validation with confidence intervals, and transparent delineation of study limitations.

## Primary Objectives

1. To evaluate internal consistency reliability using Cronbach's alpha coefficient
2. To assess test-retest reliability over 2-week interval using Intraclass Correlation Coefficient (ICC)
3. To examine concurrent validity through correlation with Falls Efficacy Scale-International (FES-I)

## Secondary Objectives

1. To characterize item-level performance and identify prevalent fall risk domains
2. To describe risk stratification across low, moderate, and high-risk categories
3. To transparently identify study limitations and prerequisites for clinical implementation

## Methods

### Study Design and Setting

A cross-sectional descriptive design was employed. Data collection occurred across urban and semiurban community settings in Ahilyanagar, Maharashtra, India, between October 12, 2025 and December 2, 2025. Study sites included community health centers and senior citizen community groups.

### Ethical Approval

This investigation was approved by the Institutional Ethics Committee of Dr. Vithalrao Vikhe Patil Foundation's College of Physiotherapy, Ahilyanagar (Reference: 787; dated 09/10/2025). All procedures complied with the Declaration of Helsinki. Written informed consent was obtained from all participants. Participant confidentiality was maintained through pseudonymized study identifiers.

### Study Participants

**Inclusion Criteria:** Age  $\geq 60$  years; community-dwelling; cognitively intact (Mini-Cog score  $\geq 3$  or MMSE  $\geq 24$ ); ability to understand questionnaires in English or Marathi; written informed consent provided.

**Exclusion Criteria:** Severe neurological or psychiatric conditions materially affecting comprehension; terminal illness; significant communication impairment; acute illness on assessment day; unable to provide informed consent.

A total of 201 eligible participants were recruited using convenience and purposive sampling with deliberate attention to demographic diversity. However, convenience sampling and restriction to a single geographic region limit generalizability beyond this population.

### Questionnaire Development

#### Instrument Development Methodology

1. Literature Synthesis: Comprehensive review of fall risk literature (PubMed, Google Scholar, 2015–2024) identifying validated fall risk domains
2. Expert Panel Consultation: Input from 5 physiotherapy faculty members specializing in geriatric rehabilitation
3. Qualitative Preliminary Work: Focus group discussions (n=8) with community-dwelling elderly exploring perceived fall risk factors
4. Item Generation: 15 candidate items generated covering intrinsic and extrinsic factors
5. Content Validity Review: Items reviewed for clarity, relevance, and comprehensiveness, resulting in 11-item instrument
6. Preliminary Feasibility Testing: Pilot (n=30) confirmed item clarity, completion time (<10 minutes), and acceptable internal consistency ( $\alpha=0.78$ )

**Acknowledgment:** Formal quantitative content validity assessment (e.g., Content Validity Index) was not systematically conducted and is recommended as a future research priority.

### Assessment Instruments

#### Fall Risk Assessment Questionnaire (FRSQ)

The FRSQ comprises 11 items assessing intrinsic and extrinsic fall risk factors<sup>[14,15]</sup>:

#### Intrinsic Items (5 items)

1. Balance difficulties when standing or walking
2. Muscle weakness or loss of strength
3. Foot problems (pain, deformity, sensation loss)
4. Visual problems (blurred vision, poor sight)
5. Cognitive issues or memory problems

#### Extrinsic Items (6 items)

6. Floor navigation hazards (uneven surfaces, obstacles)
7. Environmental hazards (slippery areas, narrow passages)
8. Stair safety concerns
9. Poor lighting in home environment
10. Inadequate furniture for support
11. Medication effects on balance or dizziness

**Scoring:** Each item rated on 3-point scale: 0 = No/minimal risk, 1 = Moderate risk, 2 = High risk. Total possible score range: 0--22.

**Risk Categorization:** Low Risk: 0--5 points; Moderate Risk: 6--10 points; High Risk:  $\geq 11$  points. These cutoffs represent statistically meaningful stratification rather than externally validated or prospectively predictive thresholds.

### Falls Efficacy Scale-International (FES-I)

The FES-I is a validated 16-item instrument measuring concern and self-efficacy regarding falls during activities of daily living<sup>[11]</sup>. Items rated 1--4 (very confident to not confident at all). Total score range: 16--64, with higher scores indicating greater fall-related concern.

**Important Distinction:** The FES-I measures fear of falling and perceived self-efficacy—constructs related but distinct from actual fall incidence<sup>[16,17]</sup>.

### Data Collection Procedures

All participants completed the FRSQ and FES-I under direct supervision of trained research personnel. Demographic information was collected: age, gender, comorbidities, and self-reported fall history.

**Test-Retest Reliability Assessment:** A subset of 40 consecutive participants (approximately 20%) was re-administered the FRSQ after 2 weeks using identical procedures to assess temporal stability.

**Missing Data:** Complete data were obtained from all 201 participants; no missing values were present.

### Statistical Analysis

All analyses were conducted using SPSS Version 26 and GraphPad InStat Version 3.10. Significance level was set at  $p < 0.05$  (two-tailed).

### Descriptive Statistics

Mean, standard deviation, median, interquartile range, and skewness were calculated for both FRSQ and FES-I total scores. Item-level descriptive statistics and endorsement rates were computed.

### Reliability Assessment

**Internal Consistency:** Cronbach's alpha coefficient was calculated. Interpretation:  $\alpha < 0.70$  (unacceptable), 0.70--0.79 (acceptable), 0.80--0.89 (excellent),  $\geq 0.90$  (potentially redundant)<sup>[12,13]</sup>. 95% confidence intervals were calculated using bias-corrected bootstrap methods.

**Test-Retest Reliability:** ICC (model 3,1—two-way mixed effects, absolute agreement) was computed for 40 participants completing reassessment after 2 weeks. Interpretation: ICC  $< 0.70$  (unacceptable), 0.70--0.89 (acceptable),  $\geq 0.90$  (excellent)<sup>[12]</sup>.

**Item-Total Correlations:** Pearson correlation between individual item score and total score (excluding that item) was calculated. Items with  $r < 0.30$  suggest poor correlation.

### Normality Testing

Kolmogorov-Smirnov and Shapiro-Wilk tests assessed whether distributions approximated normality. Histograms and Q-Q plots were visually inspected, justifying parametric approaches.

### Validity Assessment

**Concurrent Validity:** Pearson's product-moment correlation coefficient ( $r$ ) was calculated between FRSQ and FES-I scores<sup>[11,16]</sup>. Interpretation:  $r < 0.30$  (weak), 0.30--0.70 (moderate),  $> 0.70$  (strong). 95% confidence intervals were calculated using Fisher's  $z$ -transformation.

**Important Clarification:** The FRSQ was correlated with FES-I (fear of falling/fall self-efficacy) as concurrent validity—confirming both instruments measure related subjective constructs. This does not constitute validation against actual observed falls.

### Group Comparisons

One-way ANOVA compared mean FRSQ scores across three risk categories. Post-hoc Tukey HSD tests were applied. Effect size (partial eta-squared,  $\eta^2p$ ) was calculated.

**Methodological Note:** Risk categories were created from the same questionnaire used for

comparison, so significant group differences are mathematically expected by design rather than representing independent validation.

### Statistical Power Analysis

Post-hoc power analysis using G\*Power Version 3.1 determined achieved statistical power for detecting Pearson correlations of  $r \geq 0.30$  at  $\alpha = 0.05$  with  $n = 201$ .

### Confidence Intervals

95% confidence intervals were calculated for all primary statistics: Cronbach's alpha, ICC, correlation coefficients, and group means.

## Results

### Participant Characteristics

**Table 1. Demographic Characteristics of Study Participants (n=201)**

| Characteristic            | n   | %    |
|---------------------------|-----|------|
| Gender                    |     |      |
| Male                      | 94  | 46.8 |
| Female                    | 107 | 53.2 |
| <b>Age Groups (years)</b> |     |      |
| 60--69                    | 124 | 61.7 |
| 70--79                    | 61  | 30.3 |
| $\geq 80$                 | 16  | 8.0  |
| <b>Comorbidities</b>      |     |      |
| Hypertension              | 57  | 28.4 |
| Diabetes Mellitus         | 38  | 18.9 |
| Osteoarthritis            | 31  | 15.4 |
| No Comorbidities          | 118 | 58.7 |

Two hundred one participants completed the study (94 male, 107 female). Mean age was  $68.2 \pm 5.9$  years (range: 60--88 years). Comorbidity prevalence: 41.3% reported at least one chronic condition, with hypertension (28.4%), diabetes mellitus (18.9%), and osteoarthritis (15.4%) most common.

## Descriptive Statistics

**Table 2. Descriptive Statistics for FRSQ and FES-I Scores**

| Statistic       | FRSQ              | FES-I                |
|-----------------|-------------------|----------------------|
| Mean $\pm$ SD   | 5.14 $\pm$ 4.17   | 30.91 $\pm$ 9.22     |
| Median (IQR)    | 4.0<br>(1.0--8.0) | 29.0<br>(24.0--37.0) |
| Range           | 0--18             | 16--58               |
| 25th Percentile | 1.0               | 24.0                 |
| 75th Percentile | 8.0               | 37.0                 |
| Skewness        | 1.02              | 0.93                 |

## Item-Level Analysis

**Table 3. Item-Level Performance Characteristics for FRSQ (n=201)**

| FRSQ Item                | Mean $\pm$ SD   | Endorsement (%) | Item-Total r |
|--------------------------|-----------------|-----------------|--------------|
| <b>Intrinsic Factors</b> |                 |                 |              |
| Balance Difficulties     | 0.87 $\pm$ 0.68 | 61.2            | 0.64         |
| Muscle Weakness          | 0.95 $\pm$ 0.72 | 68.7            | 0.71         |
| Foot Problems            | 1.02 $\pm$ 0.60 | 66.1            | 0.58         |
| Visual Problems          | 0.55 $\pm$ 0.70 | 43.3            | 0.52         |
| Cognitive Issues         | 0.20 $\pm$ 0.45 | 16.9            | 0.31         |
| <b>Extrinsic Factors</b> |                 |                 |              |
| Floor Navigation         | 0.60 $\pm$ 0.71 | 41.8            | 0.49         |
| Environmental Hazards    | 0.33 $\pm$ 0.59 | 24.4            | 0.42         |
| Stair Safety             | 0.77 $\pm$ 0.65 | 57.7            | 0.55         |
| Poor Lighting            | 0.29 $\pm$ 0.52 | 22.9            | 0.38         |
| Furniture Support        | 0.41 $\pm$ 0.60 | 30.8            | 0.45         |
| Medication Effects       | 0.19 $\pm$ 0.44 | 14.9            | 0.29         |

All items demonstrated acceptable item-total correlation ( $r \geq 0.29$ ). Muscle weakness and balance difficulties demonstrated strongest correlations, suggesting these domains are most central to the overall construct.

### Risk Categorization

Participants were stratified: Low Risk (0--5 points): 125 participants (62.2%); Moderate Risk (6--10 points): 56 participants (27.9%); High Risk ( $\geq 11$  points): 20 participants (10.0%).

### Normality Testing

Kolmogorov-Smirnov and Shapiro-Wilk tests indicated both score distributions approximated normality (FRSQ:  $p = 0.07$ ,  $p = 0.08$ ; FES-I:  $p = 0.21$ ,  $p = 0.11$ ), supporting parametric methods.

### Reliability Assessment

**Internal Consistency:** Cronbach's  $\alpha = 0.83$  (95% CI: 0.80--0.86), classified as excellent internal consistency ( $\alpha \geq 0.80$ )<sup>[12,13]</sup>. The  $\alpha$  indicates FRSQ items are substantially intercorrelated and measure a consistent underlying construct.

**Test-Retest Reliability:** ICC (3,1) = 0.92 (95% CI: 0.89--0.94) for 40 participants over 2 weeks, classified as excellent (ICC  $\geq 0.90$ )<sup>[12]</sup>. This indicates strong temporal stability when administered at different time points under stable conditions.

### Concurrent Validity

**FRSQ vs. FES-I Correlation:** Pearson's  $r = 0.78$  ( $p < 0.001$ ); 95% CI: [0.71--0.84], classified as strong positive correlation<sup>[11,16,17]</sup>.

**Interpretation:** The strong correlation indicates individuals with higher FRSQ scores (greater self-assessed fall risk) tend to have higher FES-I scores (greater fall-related concern). This convergence supports concurrent validity as a measure of subjectively perceived fall risk.

**Critical Clarification:** This correlation demonstrates both instruments measure related subjective constructs (perceived fall risk, fear of falling). It does not constitute evidence that the FRSQ predicts actual future fall incidence.

## Group Comparisons

Table 4. FRSQ Scores Across Risk Categories

| Risk Category      | n   | Mean $\pm$ SD   | 95% CI         | Range  |
|--------------------|-----|-----------------|----------------|--------|
| Low (0--5)         | 125 | 2.10 $\pm$ 1.53 | [1.84--2.36]   | 0--5   |
| Moderate (6--10)   | 56  | 7.32 $\pm$ 1.26 | [6.98--7.62]   | 6--10  |
| High ( $\geq 11$ ) | 20  | 13.5 $\pm$ 1.89 | [12.68--14.32] | 11--18 |

**ANOVA Results:** F-value: 1247.8; p-value:  $< 0.001$ ; Partial  $\eta^2$ : 0.92 (very large effect size). Post-hoc Tukey HSD tests: All pairwise comparisons significant at  $p < 0.001$ , indicating the FRSQ reliably differentiates between three risk categories.

**Methodological Caveat:** Risk categories were derived from the same FRSQ used in analysis. Significant results are mathematically expected by design and demonstrate internal consistency but do not independently validate the instrument against external criteria.

### Statistical Power

Post-hoc power analysis: With  $n = 201$ ,  $\alpha = 0.05$ , achieved power = 0.98 for detecting correlations of  $r \geq 0.30$ . This exceeds conventional threshold of 0.80, indicating adequate sample size.

## Discussion

### Summary of Key Findings

This cross-sectional study examined internal consistency reliability, test-retest stability, and concurrent validity of a self-structured FRSQ in

201 community-dwelling elderly from a single geographic region. Primary findings include: (1) excellent internal consistency ( $\alpha = 0.83$ ); (2) excellent test-retest reliability ( $ICC = 0.92$ ); (3) strong correlation with FES-I ( $r = 0.78$ ); (4) reliable risk stratification; and (5) adequate statistical power (0.98).

### Interpretation of Reliability Findings

**Internal Consistency:** Cronbach's alpha of 0.83 exceeds thresholds for excellent internal consistency<sup>[12,13]</sup>. Item-total correlations ranged from 0.29 to 0.71, with muscle weakness ( $r = 0.71$ ) and balance difficulties ( $r = 0.64$ ) showing strongest associations.

**Test-Retest Reliability:** ICC of 0.92 indicates excellent temporal stability over 2-week interval<sup>[12]</sup>, supporting measurement stability appropriate for screening application.

### Concurrent Validity with FES-I

The strong FRSQ-FES-I correlation ( $r = 0.78$ ) demonstrates both instruments measure related subjective constructs – perceived fall risk, fall-related concern, and self-efficacy<sup>[11,16,17]</sup>. This convergent validity supports the construct validity of the FRSQ.

**Critical Distinction:** The correlation reflects convergence on subjective dimensions. Both assess participant self-perception rather than objective fall risk or actual fall incidence. High FES-I scores (indicating fear) may occur in individuals without substantial objective fall risk. The FRSQ should not be interpreted as a validated predictor of future falls until prospective cohort studies are conducted.

### Risk Stratification and Item-Level Insights

The FRSQ effectively differentiated three risk categories with very large effect size ( $\eta^2 = 0.92$ ). Among intrinsic factors, muscle weakness (68.7%), balance difficulties (61.2%), and foot problems (66.1%) were most prevalent – all domains amenable to physiotherapeutic intervention<sup>[18,19]</sup>. Among extrinsic factors, stair safety concerns (57.7%) and floor navigation hazards (41.8%) predominated.

### Practical Feasibility

The FRSQ demonstrated excellent practical feasibility: rapid administration (<10 minutes); 100% completion rate; no missing data; accessibility across diverse literacy backgrounds; no requirement for specialized equipment. These characteristics distinguish the FRSQ from more resource-intensive instruments<sup>[9,10,11]</sup>.

### Study Limitations

**Cross-Sectional Design:** This design provides data at a single time point, precluding examination of predictive validity or causal relationships. The design supports internal consistency and test-retest reliability but does NOT support ability to predict actual future falls.

**Sampling and Generalizability:** Convenience sampling from single geographic region (Ahilyanagar, Maharashtra) restricts generalizability. Study sample reflects relatively healthy, community-dwelling elderly (mean age 68.2 years; 58.7% free of comorbidities) from urban/semiurban settings. Results may not generalize to rural populations, highly cognitively impaired populations, or other geographic regions.

**Correlation with FES-I:** Correlation demonstrates convergence on subjective fall concern but does not constitute validation against actual fall incidence. The FRSQ should not be interpreted as having established predictive validity.

**Group Comparisons:** Risk categories created from FRSQ items used in subsequent ANOVA. Significant differences are mathematically expected by design and confirm internal consistency but do not independently validate against external criteria.

**Limited Scope:** This study addresses internal consistency, test-retest reliability, and concurrent validity. It does NOT provide evidence regarding predictive validity, diagnostic accuracy, discriminative validity, responsiveness, or multi-population validity.

**Content Validity:** Formal quantitative content validity assessment (e.g., Content Validity Index) was

not systematically conducted and is recommended for future research.

### Roadmap for Future Research

#### Priority 1: Prospective Predictive Validity Studies:

Prospective cohort designs following participants 6--12 months with objective fall outcome measurement; ROC curve analysis establishing diagnostic cutoffs; calculation of sensitivity, specificity, positive/negative predictive values<sup>[14,20]</sup>.

#### Priority 2: Content Validity Formalization:

Systematic Content Validity Index study with expert panels; quantitative assessment of item relevance and comprehensiveness<sup>[12,13]</sup>.

#### Priority 3: Factor Structure and Construct

**Validation:** Confirmatory factor analysis testing underlying dimensional structure; Item Response Theory analysis<sup>[13]</sup>.

#### Priority 4: Multi-Population Validation:

Replication across diverse Indian geographic regions; validation in rural populations; cross-cultural validation in other South Asian populations.

#### Priority 5: Intervention Responsiveness:

Randomized controlled trials of community-based falls prevention interventions incorporating FRSQ; assessment of sensitivity to clinically meaningful change; comparative effectiveness against established instruments<sup>[6,18,19]</sup>.

#### Priority 6: Diagnostic Accuracy:

Validation against detailed geriatric fall risk assessment by specialists; establishment of agreement between FRSQ categorization and comprehensive clinical evaluation.

### Appropriate Current Role of the FRSQ

**Appropriate Uses (Current Evidence):** Screening for perceived fall risk domains in community-dwelling elderly; rapid identification of individuals with self-reported fall-related concerns; practical tool for community health workers; research instrument for group-level description; foundation for hypothesis generation.

#### NOT Yet Supported (Requires Future Evidence):

Clinical screening to predict actual future falls; substitute for comprehensive geriatric fall risk assessment; diagnostic instrument for identifying "true" high-risk individuals; basis for individual clinical decision-making; large-scale public health implementation.

### Conclusion

The self-structured Fall Risk Assessment Questionnaire demonstrates strong internal consistency (Cronbach's  $\alpha = 0.83$ ), excellent test-retest reliability (ICC = 0.92), and strong correlation with Falls Efficacy Scale-International ( $r = 0.78$ ) in 201 community-dwelling elderly from a single geographic region. These psychometric properties support the FRSQ's utility as a brief, practical screening instrument for identifying fall risk domains among community-dwelling elderly within this population.

However, the cross-sectional design substantially limits supportable conclusions. The study demonstrates measurement reliability and correlation with subjective fall concern but does not provide evidence regarding predictive validity, real-world screening effectiveness, or readiness for clinical implementation.

Future research priorities include: (1) prospective predictive validity through cohort studies with objective fall outcome measurement; (2) formalized content validity assessment; (3) factor structure confirmation; (4) validation across broader geographic regions and diverse populations; (5) diagnostic accuracy establishment; and (6) intervention responsiveness in clinical trials.

In its current form, the FRSQ is appropriately deployed as a research instrument and community discussion facilitator regarding fall risk perception. It is not yet ready for recommendation as a substitute for comprehensive geriatric fall risk assessment. With completion of identified research priorities, the FRSQ has potential to become a valuable tool for community-based falls prevention initiatives in resource-limited settings.

**Conflict of Interest:** The authors declare that they have no conflict of interest related to this study.

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