Development of a Static Balance Assessment Tool for High-Functioning Older Adults

NCT ID not yet assigned

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Study Protocol

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1. Official Study Title

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2. Background and Rationale

Taiwan has entered an aged society since 2018 and is expected to become a super-aged society by 2025. Although average life expectancy has increased, the gap between life expectancy and healthy life expectancy (HALE) continues to widen. Older adults commonly face sarcopenia, osteoarthritis, osteoporosis, and impaired postural control, all of which increase the risk of frailty and falls. Falls in the elderly result in fractures, injuries, fear of falling, reduced activity, accelerated functional decline, and substantial healthcare burden.

Long-term care policy (LTC 2.0) in Taiwan emphasizes preventive strategies for healthy aging, with community-based C-level long-term care stations widely incorporating exercise and functional training. However, commonly used balance measures, such as the Short Physical Performance Battery (SPPB) and open-eye single-leg stance, demonstrate **ceiling effects** among high-functioning older adults. These tools therefore fail to detect meaningful changes after training.

The **Balance Error Scoring System (BESS)**, originally designed for concussion and athletic balance assessment, includes more challenging postural tasks that require proprioceptive control and sensory integration. It incorporates both firm and foam surfaces and requires participants to maintain balance with closed eyes, thereby increasing task difficulty. BESS may overcome the ceiling effect observed in community-dwelling high-functioning older adults, yet its applicability and reliability in this population remain insufficiently studied.

This study aims to establish an advanced static balance measurement protocol suitable for high-functioning older adults using BESS, and to examine its

test–retest reliability, accuracy, and clinical feasibility.

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3. Study Objectives

Primary Objectives

1. To establish an advanced static balance assessment protocol for high-functioning older adults using the Balance Error Scoring System (BESS).
2. To evaluate the **test–retest reliability** of BESS in community-dwelling high-functioning older adults.

Secondary Objectives

3. To determine the **clinical feasibility and accessibility** of BESS in community settings.
4. To compare BESS performance with traditional balance tests (SPPB and open/closed-eye single-leg stance) to assess construct validity.

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4. Study Design

- **Type:** Cross-sectional reliability and validity study
- **Setting:**
    - Kaohsiung Municipal United Hospital – Department of Rehabilitation
    - Kaohsiung community C-level long-term care stations
- **Population:** High-functioning older adults aged ≥65 years
- **Sample Size:** 50 participants
- **Study Duration:** Approximately 12 months

The study includes two testing sessions separated by 1 week to assess test–retest reliability.

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5. Participant Eligibility

Inclusion Criteria

1. Age ≥ 65 years
2. SPPB score = 12 (full score)
3. Open-eye single-leg stance ≥ 10 seconds
4. Able to follow instructions and provide consent

Exclusion Criteria

1. Lower-limb osteoarthritis (Kellgren–Lawrence ≥ grade 3)
2. History of lower-limb surgery
3. Lower-limb pain affecting standing balance within the past 3 months
4. Neurological disease (e.g., stroke, TBI, cerebellar atrophy, Parkinson's disease)
5. Vertigo within the past 3 months (e.g., Ménière's disease, BPPV)

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6. Study Procedures

6.1 Baseline Assessment

- Demographics: age, sex, education level, living status
- Anthropometrics & body composition (BIA): body weight, segmental muscle mass, visceral fat
- Physical activity habits
- Dominant leg determined via ball-kick test
- Medical history & fall history within past year

6.2 Outcome Measures

A. Open-eye and Closed-eye Single-Leg Stance

- Barefoot, hands on hips, non-dominant leg lifted with toes resting against stance leg
- Time up to maximum 30 seconds
- Termination criteria include arm movement, stepping, excessive sway, or eyes opening (for closed-eye condition)

B. Balance Error Scoring System (BESS)

Six conditions (20 seconds each):

Surface	Stance
Firm	Double-leg stance
Foam	Double-leg stance
Firm	Tandem stance (dominant foot behind)
Foam	Tandem stance
Firm	Single-leg stance (dominant leg)
Foam	Single-leg stance

Scoring:
One point for each error (max 10 per condition):

- Hands lifted off iliac crest
- Eyes open
- Hip abduction > 30°
- Stepping or lifting heel/toe
- Moving out of position > 5 seconds

BESS total score = sum of errors across all six conditions.

6.3 Dual Observational Method

To enhance scoring reliability:

1. **Real-time scoring** by trained physical therapist
2. **Video-based scoring** from sagittal & frontal camera views
   A second licensed physical therapist, blinded to real-time results, will perform video scoring.

6.4 Test–Retest

All participants repeat:

- Open/closed-eye single-leg stance
- BESS

One week later.

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7. Risk Assessment and Safety

BESS and single-leg standing are low-risk clinical balance tests.
Participants may experience mild fatigue or sway; a therapist will stand nearby for safety to prevent falls.

No adverse events are expected.

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8. Ethical Considerations

- Written informed consent obtained from all participants
- Study approved by the Institutional Review Board (IRB) of Kaohsiung Municipal United Hospital
- Data anonymized and stored securely
- No identifiable personal information will appear in publications or submitted documents

Statistical Analysis Plan (SAP)

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1. Overview

All statistical analyses will be conducted using **SPSS v21.0**.
Significance level: **$p < 0.05$**.

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2. Descriptive Statistics

- Mean ± SD for continuous variables
- Frequencies & percentages for categorical variables

Variables include age, sex, body composition, SPPB score, fall history, and stance time.

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3. Reliability Analysis

3.1 Test–Retest Reliability

Evaluate reliability of:

- Open-eye single-leg stance
- Closed-eye single-leg stance
- BESS (real-time & video scores)

Using **Intraclass Correlation Coefficient (ICC3,2)**

Interpretation:

- ICC ≥ 0.75 → High reliability
- 0.50–0.75 → Moderate
- 0.25–0.50 → Fair
- < 0.25 → Low

3.2 Minimal Detectable Change (MDC)

MDC95 will be calculated using:

$$MDC95 = 1.96 \times SD_{\text{difference}} \times \sqrt{2}$$

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4. Validity Analysis

4.1 Construct Validity

Examine correlation between:

- BESS scores
- Single-leg stance times (open/closed-eye)

Using **Spearman Rank Correlation**.

Expected relationships:

- Higher BESS score → poorer balance
- Shorter stance time → poorer balance

Interpretation:

- $r > 0.75$ → High
- 0.50–0.75 → Moderate
- 0.25–0.50 → Fair
- < 0.25 → Low

4.2 Predictive Validity

Explore whether BESS predicts:

- Fall history

- Balance performance decline

Binary logistic regression may be applied if fall history data is sufficient.

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5. Responsiveness Analysis

Compare baseline vs. 1-week follow-up scores using:

- **Wilcoxon matched-pairs signed rank test**
  (for non-normally distributed balance measures)

Outcome:
Identify whether BESS or single-leg stance can detect subtle changes over time.

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6. Handling Missing Data

- Missing items will be reported
- Participants with incomplete BESS recordings will be excluded from reliability analysis
- No imputation will be used

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7. Subgroup Analysis (Exploratory)

Based on body composition or age groups (e.g., 65–74 vs ≥75 years):

- Compare BESS total score
- Compare single-leg stance duration

Using Mann–Whitney U or Kruskal–Wallis tests.