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**THE CONCURRENT VALIDITY OF THE 7-ITEM BBS 3P WITH OTHER
CLINICAL MEASURES OF BALANCE IN A SAMPLE OF ELDERLY
COMMUNITY-DWELLING ADULTS**

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*A dissertation submitted in partial fulfillment of the requirements for the degree of MSc
in Neurology & Gerontology.*

School of Physiotherapy,
Faculty of Medicine and Health Sciences,
Royal College of Surgeons in Ireland.

September 2014

Supervisor: Dr. Helen French

CANDIDATE THESIS DECLARATION

I declare that this thesis, which I submit to RCSI for examination in consideration of the award of a higher degree *MSc in Neurology & Gerontology* is my own personal effort. Where any of the content presented is the result of input or data from a related collaborative research programme this is duly acknowledged in the text such that it is possible to ascertain how much of the work is my own. I have not already obtained a degree in RCSI or elsewhere on the basis of this work. Furthermore, I took reasonable care to ensure that the work is original, and, to the best of my knowledge, does not breach copyright law, and has not been taken from other sources except where such work has been cited and acknowledged within the text.

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SUMMARY

Introduction

Effective balance screening and treatment is vital to minimise the potential detrimental effects that may result from unidentified and untreated balance impairment in the vulnerable community-dwelling elderly population. Therefore, an appropriate screening measure for balance with established psychometric properties, is required for use in the community-dwelling elderly population. This research study aims to address the gap in the current evidence base, by identifying the psychometric properties of the 7-item BBS-3P and determining its suitability as a clinical measure in community-dwelling adults over the age of 65.

Aims and objectives

The aim of this study was to investigate the concurrent validity of the 3-level 7-item Berg Balance Scale (7-item BBS-3P) with other clinical measures of balance in a sample of elderly community-dwelling adults. The objectives of the study were to:

- Identify the strength of a positive correlation between the 7-item BBS-3P and the Berg Balance Scale (BBS);
- Identify if the 7-item BBS-3P positively correlates with the Mini Balance Evaluation Systems Test (Mini-BESTest);
- Identify if the BBS positively correlates with the Mini-BESTest;
- Determine if the 7-item BBS-3P can be used interchangeably with the BBS.

Methods

This cross sectional study examined the correlations between the 7-Item BBS 3P, BBS and Mini BESTest, in 30 elderly community-dwelling adults, aged 69 to 90 years. Outcome measures included the 7-Item BBS 3P, BBS and the Mini-BESTest.

Results

Significant correlations were demonstrated between the 7-Item BBS 3P, BBS and Mini BESTest. The strongest correlation was found between the 7-item BBS-3P and the BBS, which was highly correlated ($\rho=0.84$, $p<0.01$). The weakest correlation was found between the 7-item BBS-3P and the Mini BESTest, which was moderately correlated ($\rho=0.57$, $p<0.01$). A high correlation was also observed between the BBS and Mini BESTest ($\rho=0.74$, $p<0.01$). A difference of up to seven points on the BBS, for a score obtained by the participant in the 7-Item BBS 3P, exceeds the minimum detectable change (MDC) of 3.3-6.3 points in the BBS for elderly people.

Conclusion

These results confirm that the 7-Item BBS 3P correlates highly with the BBS and moderately with the Mini BESTest in a sample of community-dwelling elderly adults. This demonstrates that the 7-Item BBS 3P measures the same functional construct of balance as the BBS and that the 7-Item BBS 3P can be used as a screening tool for balance impairment in the elderly. However, the 7-Item BBS 3P and BBS cannot be used interchangeably as demonstrated by the correlation values. Further research is needed to establish normative, MDC and cut-off data for the 7-Item BBS 3P.

Implications of findings

The 7-Item BBS 3P, BBS and Mini-BESTest, may be used as screening tools for balance ability in the community-dwelling elderly. The 7-Item BBS 3P cannot be used interchangeably with the BBS.

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LIST OF ABBREVIATIONS

AUC	Area Under the Curve
ABC	Activities and Balance Confidence Scale
ADL	Activities of Daily Living
BESTest	Balance Evaluation Systems Test
BI	Barthel Index
BBS	Berg Balance Scale
BBS-3P	3-level 14-item Berg Balance Scale

7-Item BBS 3P	3-level 7-item Berg Balance Scale
BOOMER	Balance Outcome Measure for Elder Rehabilitation
CoG	Centre of Gravity
COM	Centre of Mass
CoP	Centre of Pressure
CVA	Cerebrovascular Accident
r^2	Co-efficient of determination
CB&M	Community Balance and Mobility Scale
CNU	Community Nursing Unit
95% CI	95% Confidence Interval
α	Cronbach α co-efficient
DGI	Dynamic Gait Index
FOF	Fear of falling
FSST	Four Square Step Test
FGA	Functional Gait Assessment
GP	General Practitioner
GRRAS	Guidelines for Reporting Reliability and Agreement Studies
HTN	Hypertension
I	Independent
IQR	Interquartile range
ICC	Intra class correlation
KGH	Kerry General Hospital
LOS	Length of Stay
Max	Maximum
Mini-BESTest	Mini Balance Evaluation Systems Test
MMSE	Mini Mental State Examination
Min	Minimum

MDC	Minimum Detectable Change
MS	Multiple Sclerosis
n	Number
OA	Osteoarthritis
r	Pearson product-moment correlation
p	Predictive Value (p-value)
SFBBS	Short form Berg Balance Scale
SLS	Single leg stand
STS	Sit-to-stand transfer
SD	Standard Deviation
ρ	Spearman's rank order correlational coefficient
TUG	Timed Up and Go test
THR	Total Hip Replacement
VOR	Vestibulo-ocular reflex
WS	Walking stick
WHO	World Health Organisation

INTRODUCTION

Balance can be defined as the ability to maintain an upright posture under a variety of conditions (Berg et al, 1995). It involves maintaining the centre of mass (COM) within the limits of stability during static and dynamic situations. Static balance is often used to describe situations where the body maintains stability without changing the base of support (BOS) (Shumway-Cook and Woollacott, 2012). Dynamic balance may be defined as the ability to maintain stability as the COM moves from one BOS to another (Shumway-Cook and Woollacott, 2012). This can be voluntary or in response to an external perturbation via proactive and reactive mechanisms (Stelmach et al. 1989; Lord. 2006; Sturnieks et al. 2008).

Balance is an important factor that underpins the ability to perform activities of daily living (ADL) (Lajoie and Gallagher. 2004; Salavati et al. 2012). The multifactorial nature of the balance system is complex due to a myriad of contributions from vision, vestibular sense, proprioception, muscle strength and reaction time (Sturnieks et al. 2008). However, these systems are subject to progressive deterioration due to the ageing process, use of medications or disease (Berg et al. 1992b; Wang et al. 2006; Conradsson et al. 2007; Sturnieks et al. 2008). Delayed reaction time, slow movement velocity, constricted limits of stability boundary or uncontrolled centre of gravity (CoG), may result in an increased falls risk (Cheung et al. 2007). Although some elderly individuals with a history of falls may limit their activity, many will lead sedentary lives because they fear falling. This will accelerate their decline in muscle force production and function (Shumway-Cook et al. 1997; Boulgarides et al. 2003; Kornetti et al. 2004; Jacobson et al. 2011).

According to the World Health Organisation (WHO) (2012), falls are considered the second leading cause of accidental death in the world. Approximately one third of the community-dwelling elderly population in Ireland will fall, with two thirds of people falling again within six months. One in two people over 85 years of age fall every year in Ireland (Prudham and Evans. 1981; Campbell et al. 1981; National Steering Group, 2008). It is estimated that the current annual economic cost of falls in older people is approximately €400 million. This could increase to €2 billion in the next 25 years unless effective falls prevention strategies are implemented (National Steering Group, 2008). Not included in this figure are the profound psychological effects that result in a loss of independence, such as fear of falling (FOF), social isolation or carer burden (Lajoie and Gallagher. 2004). This presents a significant challenge to the nation considering that by 2041, the elderly population aged 65 years and above, is expected to reach approximately 1.4 million (22% of the population) (Lajoie and Gallagher, 2004; McGill, 2010). Older adults that present with poor balance are at risk of falling, which creates a serious vital medical concern. Identification of this risk would subsequently reduce rates of morbidity, mortality and associated health care costs.

Although there is a wide availability of balance tests, there is no one measure that addresses all aspects of balance for all populations in any given setting (Scott et al. 2007). However, designing a single balance measure that minimises ceiling and floor effects and can predict falls risk across a range of individuals, may be impractical due to the multifactorial nature of the balance system (Pardasaney et al. 2012).

The BBS was originally developed as a measure of balance in elderly individuals. However, it is also used in other patient populations and serves to address a quantitative description of ability and effective evaluation of interventions in clinical practice and

research (Berg et al, 1995). It consists of 14 items with each item assessed on a five level scale. It works on the principle that a person's balance is challenged by reducing their BOS (Berg et al. 1992b). It is recognised as one of the most reliable and valid balance outcome measures used in the elderly population and is accepted as the clinical criterion or gold standard in the clinical measurement of balance and postural control (Berg et al. 1989; Berg et al. 1992b; Berg et al. 1995; Bogle Thorbahn and Newton, 1996; Kornetti et al. 2004; Wang et al. 2006; Conradsson et al. 2007; Neuls et al. 2011). However, the BBS can take 20-30 minutes to complete, depending on the sensory, motor and cognitive function of the elderly individual (Frykberg et al. 2007). This may place unreasonable demands on the individual particularly in situations where they may be unwell or fatigued (Berg et al. 1992a; Chou et al. 2006). Time consuming outcome measures may also limit their utilisation by practitioners in daily clinics and on researchers who use these measures in their studies (Jogi et al, 2010; Liaw et al. 2012). In comparison, the 7-Item BBS 3P, a reduced version of the BBS, takes approximately 10 minutes to complete, as it contains only half the items of the BBS.

Use of a relatively simple, convenient fall predictive model, would help identify individuals with a substantial risk of falling, thus allowing them to be enrolled into a preventative programme (Lajoie and Gallagher, 2004). As the 7-Item BBS 3P requires less equipment, is faster and more convenient to use than the BBS, it shows promise as a screening tool for balance impairment. To date, the concurrent validity of the 7-Item BBS 3P has not been well researched. No study has been identified, that has investigated the concurrent validity of the 7-Item BBS 3P in the community-dwelling elderly.

CHAPTER 1 LITERATURE REVIEW

The Berg Balance Scale (BBS) is a 14-item functional performance measure that quantitatively assesses balance and risk of falls in older community-dwelling adults through direct observation of their performance (Berg et al, 1989). Performance is rated on a five-level scale per item from zero (cannot perform) to four (normal performance). The total maximum score is 56, indicating excellent balance (Shumway-Cook et al. 1997). The psychometric properties of the BBS have been well researched with a variety of other outcomes including the timed up and go (TUG), usual gait speed, prediction of falls in the elderly and length of stay (LOS) (Bogle Thorbahn and Newton. 1996; Shumway-Cook et al. 1997; Wee et al. 2003; Wang et al. 2006; Conradsson et al. 2007). However, the validity and reliability of shortened versions of the BBS in the clinical assessment of balance have not been well researched to date in any population. This void in the literature demonstrates a need to establish the psychometric properties of shortened versions of the BBS prior to their implementation in the clinical setting.

Wang et al. (2004) were one of the first authors to examine the psychometric properties of a shortened version of the BBS in people following stroke. It was demonstrated that the 3-level 14-item BBS (BBS-3P) was comparable to the full non-truncated scale. A subsequent study by Chou et al. (2006), further simplified this outcome measure, by reducing the number of items, while maintaining the three level grading criteria for each item. This involved the examination of the psychometric properties of four shortened BBS-3P versions in people following stroke (four-item, five-item, six-item and seven-item BBS-3P). Of the four shortened BBS-3P scales, the 7-item BBS 3P was found to be the most psychometrically similar to the original BBS in people following stroke.

Test-retest reproducibility of the 7-Item BBS 3P in a stroke population has also been established (Liaw et al, 2012).

Therefore, research examining the validity and reliability of the BBS will be discussed in greater detail initially, including another balance outcome measure, the Mini-BESTest, followed by a detailed analysis of the shortened versions of the BBS.

1.1 Psychometric properties of the BBS with the elderly

Berg et al. established the BBS after a three phase development process in 1989. Thirty two health care professionals based in a geriatric setting, including physical therapists, occupational therapists, nurses and physicians along with a sample of 38 participants, aged 60-93 years were included. Participants were required to have a balance impairment for inclusion and conditions included stroke and Parkinson's disease. Three of the participants lived in a senior's residence, 14 lived independently in the community and 21 were hospital in-patients. The professionals were asked to (i) define balance, (ii) indicate how they evaluated balance in their patients and (iii) detail examples of movements that they felt may challenge an individual's balance. Open-ended questions were utilised to determine what participants felt about movements that made them unsteady and the circumstances of their falls. A physical therapist administered the test, which originally consisted of three phases, where 38 items were reduced to 16. A further two items were excluded due to the researchers' belief that reaching forward while sitting and changing position from lying to sitting were more closely related to flexibility or strength than balance. High levels of inter-rater and intra-rater reliability were demonstrated (Intra Class Correlation (ICC): 0.98 and 0.99

respectively for total scores and ICC: 0.71-0.99 for individual items). It was demonstrated that the BBS measured the domain of balance and that the total score provided more information about balance than any single item (Cronbach α coefficient=0.96).

A systematic review examined the psychometric qualities and clinical utility of 19 measurement tools (Tyson and Connell 2009). They found the BBS was psychometrically robust and feasible to use in clinical practice. Strong correlations with the BBS in the elderly were demonstrated with the Activities-specific and Balance Confidence Scale (ABC) ($r=0.81$, $p=0.01$) and the Functional Gait Assessment (FGA) ($\rho=0.84$, $p<0.01$) (Lajoie and Gallagher, 2004; Wrisley and Kumar, 2010). Other outcome measures that correlated highly or very highly with the BBS in the elderly population included the Tinetti Balance subscale ($r=0.91$, $p<0.01$); TUG ($r=-0.76$, $p<0.01$); Falls Efficacy Scale International ($r=-0.84$, $p<0.01$) and the Balance Outcome Measure for Elder Rehabilitation (BOOMER) ($\rho=0.89-0.91$, $p<0.01$) (Berg et al. 1992b; Kuys et al. 2011; Ulus et al. 2012). Moderate correlations of the BBS in the elderly were found with the Dynamic Gait Index (DGI) ($\rho=0.67$, $p\leq 0.01$); Barthel Mobility subscale ($r=0.67$, $p<0.01$) and self-selected gait speed ($r=0.55$, $p<0.01$) (Berg et al. 1992b; Shumway-Cook et al. 1997; Stevenson et al. 2010).

Studies of elderly people have shown that a baseline BBS score can assist in discriminating between fallers and non-fallers (Berg et al. 1992b; Bogle Thorbahn and Newton, 1996; Shumway-Cook et al. 1997; Jacobsen et al. 2011; Hohtari-Kivimaki et al. 2012). However, a systematic review by Neuls et al. (2011), which included nine studies, determined that the BBS alone is not useful as a predictor of falls in older

adults. The review included case-control and cohort studies consisting of 771 community-dwelling elderly, stroke and people with Parkinson's disease. They concluded that clinicians should use the BBS in conjunction with other measures as part of a comprehensive falls assessment (Steffen et al. 2002; Neuls et al. 2011).

The BBS has also assisted in determining the estimated LOS and eventual discharge destination of 313 people (aged 50-95 years) admitted to a stroke rehabilitation unit (Wee et al. 2003). This was particularly evident when the BBS score was combined with the assessment of family support and the availability of caregivers at home. Admission BBS score inclusion resulted in 6.5% fewer misclassifications in discharge destination. Furthermore, the correlation between admission BBS score and LOS ($r = -0.53$, $p < 0.01$) was considered to be moderate (Plichta Kellar and Kelvin, 2013).

Berg et al. (1992b) established that provision of a walking aid could be determined by a BBS cut-off score of 45/56 and that higher BBS scores were associated with reduced dependence on aids for mobility ($r = -0.75$; $p < 0.01$). It was also found that the threshold score for identifying those who walked independently without an aid was associated with 76% sensitivity, 59% specificity and 59% agreement (Berg et al. 1992b). Conversely, Stevenson et al. (2010), established threshold BBS scores in 246 elderly adults and demonstrated that the ability to walk without an aid was identified by a BBS score greater than or equal to 49/56, (sensitivity: 63%; specificity: 86%; agreement: 75%). Ability to walk without a four-wheeled walker was identified by a BBS score greater than or equal to 43/56, (sensitivity: 84%; specificity: 48%; agreement: 64%).

Lower mean BBS scores were also identified in those requiring a walking aid in a study by Berg et al. (1992a). Sensitivity and specificity of the BBS to predict use of an assistive device in the older adult was also demonstrated by Bogle Thorbahn and Newton (1996). Furthermore, provision of a four wheeled walker was found to reduce falls risk in individuals with a low BBS score (less than or equal to 45) (Harris et al. 2005). Despite the determination of some threshold BBS scores, the variation between these scores limits their use in prescribing walking aids to elderly adults.

Riddle and Stratford (1999) combined the data of Bogle Thorbahn and Newton (1996) and Shumway-Cook et al. (1997) and found that the previously recommended BBS cut-off score of 45/56 was a poor predictor for identifying those at risk of falling (sensitivity=64%), but was relatively good for identifying those who are not at risk of falling (specificity=90%). This was further supported by Muir et al. (2008), where a BBS score of less than or equal to 45/56 in 210 community-dwelling adults (mean age: 79.47, Standard Deviation (SD): 5.83) identified 58% of people that fell. Conversely, 39% of people fell with scores obtained above 45 points on the BBS. Shumway-Cook et al. (1997), demonstrated that each point drop from 56-54, in the BBS score, was associated with a 3-4% increase in falls risk. This progressed to a 6-8% increase in falls risk with a one point change in BBS score in the 54-46 range. Below the score of 36 falls risk was close to 100%. Balance improvement has also been identified by changes in BBS scores. However, this can vary from 3.3-6.3 points depending on the initial BBS score (Donoghue et al. 2009).

1.2 Psychometric properties of BBS in other populations

Despite the BBS originally being developed for the assessment of balance in the elderly, validation of the BBS with other measures of balance has been established in other populations. In Multiple Sclerosis (MS), the BBS has demonstrated moderate to high correlations with the DGI, TUG and Four Square Step Test (FSST) ($\rho=0.78$; -0.62 ; -0.84 respectively, $p<0.01$) (Cattaneo et al, 2006; Wagner et al. 2013).

In people with Parkinson's disease, the BBS has demonstrated moderate to high correlations with the Functional Gait Assessment (FGA) and Balance Evaluation Systems Test (BESTest) ($\rho=0.78$ and 0.87 respectively, $p<0.01$) (Leddy et al. 2011). Similar findings were observed in 97 people with Parkinson's disease where the BBS significantly correlated with the Mini-BESTest, which supported concurrent validity between the two measures ($r=0.79$ and $\rho=0.94$, $p<0.001$) (Bergstrom et al. 2012; King et al. 2012).

In the stroke population, a systematic review of 21 studies identified the BBS as a psychometrically sound measure of balance impairment (Blum and Korner-Bitensky 2008). However, given the floor and ceiling effects of the BBS, the authors suggested that other balance measures may be needed to add support to its psychometric value. These may include the Community Balance and Mobility Scale (CB&M) ($\rho=0.83$, $p<0.01$); Barthel Index (BI) ($\rho=0.89-0.94$, $p<0.01$) and the Mini-BESTest ($\rho=0.83-0.86$, $p\leq 0.01$), as strong correlations were demonstrated with the BBS in the stroke population (Mao et al. 2002; Knorr et al. 2010; Bergstrom et al. 2012; Tsang et al. 2013).

1.3 The BBS and short form BBS

The utility of the five level scale in each item of the BBS has not been extensively investigated. Evidence has shown that increasing the number of levels may not improve the psychometric properties of a measure (Hocking et al. 1999; Hobart et al. 2001). However, the high internal consistency of the BBS ($\alpha=0.92-0.98$), has indicated some item redundancy, for example, unsupported sitting (Mao et al. 2002). This suggests that the BBS may need to be simplified in order to improve its utility. Therefore a modified 3-level (0-2-4) 14-item BBS (BBS 3P) was developed and compared to the original BBS in 77 people (mean age: 59.8 years, range 22-80) at 14, 30 and 90 days post stroke onset (Wang et al. 2004). Total score in the BBS 3P remained out of 56. The authors found that the BBS 3P was as effective as the original BBS with excellent agreement ($ICC \geq 0.99$) and that it correlated well with the BBS and Barthel Index (BI) ($\rho=0.96$ and 0.87 respectively, $p < 0.01$).

The BBS 3P was further amended by reducing item number while maintaining the three level scale per item. Eight versions of the short form BBS (SFBBS) were created by Chou et al. (2006) (four, five, six and seven item tests containing three and five level scales). The eight versions of SFBBS were administered in 226 subjects (mean age: 68.1; SD: 11.3) 14 days post stroke and in 167 of the same subjects 90 days post stroke. The 7-item BBS (five level: 0-1-2-3-4) and 7-item BBS 3P (three level: 0-1-2) were developed by including the seven items that best displayed the highest internal consistency and the greatest responsiveness from the original 14-item BBS. The simplified 7-Item BBS with a three level scale per item, was developed through the combination of the second, third and fourth scales of the original 5-level BBS. This resulted in the middle level of one point on the 7-Item BBS 3P (Figure 1.1). The 6-item,

5-item and 4-item BBS and BBS 3P were subsequently developed by removing the worst items from the 7-item BBS and BBS 3P.

7-Item BBS 3P	
14.	STANDING ON ONE LEG
2	able to lift leg independently and hold >10 seconds
1	able to lift leg independently and hold ≥ 3 seconds
0	unable to try or needs assist to prevent fall
BBS	
14.	Standing on one leg
INSTRUCTIONS: Stand on one leg as long as you can without holding.	
4	able to lift leg independently and hold >10 seconds
3	able to lift leg independently and hold 5 – 10 seconds
2	able to lift leg independently and hold ≥ 3 seconds
1	tries to lift leg, unable to hold 3 seconds but remains standing independently
0	unable to try or needs assist to prevent fall

7-Item BBS 3P = 7-Item 3-Level Berg Balance Scale (0-14); BBS = Berg Balance Scale (0-56)

Figure 1.1 Formation of the three level scale in item 14 of the 7-Item BBS 3P

The 7-item BBS 3P was the only scale that demonstrated the most satisfactory psychometric properties to the original BBS. The 7-item BBS-3P demonstrated very high concurrent validity with the BBS ($r=0.99$), high convergent validity with the BI ($r=0.86$) and the Fugl-Meyer Motor Test ($r=0.68$) and internal consistency ($\alpha=0.97$). Furthermore, the 7-item BBS 3P version did not demonstrate any systematic bias toward the BBS in Bland and Altman plots ($r^2 \leq 0.04$) or high ICC's (≥ 0.96), indicating excellent agreement. However, statistical significance of the correlations could not be stated due to the absence of probability values (p-values). Chou et al, (2006), found that the 7-item BBS 3P was faster to complete and could be used interchangeably with the BBS.

Liaw et al. (2012) determined the test-retest reliability of the 7-Item BBS 3P in 52 chronic stroke patients (mean age 60.4 years; SD: 13.4) (Liaw et al, 2012). The authors concluded that the ICC for the 7-item BBS-3P was excellent (0.99). Results also demonstrated an MDC of 2.83 indicating that the 7-Item BBS 3P had a small and acceptable measurement error. The MDC, is an estimate of the smallest change in an individual's score that can be objectively detected (Donoghue et al. 2009).

Original and reduced versions of the BBS have also been examined in 26 patients following hip arthroplasty and 28 patients following knee arthroplasty (Jogi et al. 2010). The 7-item 5-level BBS was compared to the original BBS on follow up: one week after hospital discharge and five to seven weeks post completion of a home exercise program (HEP). Correlation between the original BBS and the 7-item BBS at one week post discharge ($r=0.92$, 95% CI=0.86, 0.95) and five to seven weeks post HEP, were excellent ($r=0.97$, 95% CI=0.95, 0.98).

More recently, Hohtari-Kivimaki et al. (2012) examined the correlations between the 9-item 5-level BBS (BBS-9) (score range 0-36) with other static and dynamic aspects of balance in 519 elderly community-dwelling adults, over 65 years of age. Acceptable to good internal consistencies for the BBS-9 and BBS were demonstrated ($\alpha = 0.69$ and 0.74 respectively). Furthermore, force plate measurement showed significant negative correlations of the BBS-9 with lateral and antero-posterior sway, velocity and distance ($\rho = -0.25$ - -0.45 , $p<0.01$). Higher BBS-9 scores were associated with lower sway, velocity and distance scores. Conversely, this negative correlation is very low to low as it falls within the range of $\rho = 0.26$ - 0.49 (Plichta Kellar and Kelvin, 2013). The BBS-9 however, was not conducted separately in its entirety, as the scores for the BBS-9 were

extracted from the performance of the original BBS. Therefore any potential participant fatigue was not accounted for.

It is important to note that the time required to conduct the BBS is 20-30 minutes. Therefore, a more efficient, convenient, user friendly and affordable balance measure needs to be developed and validated with other measures of balance (Berg et al. 1992b; Bogle Thorbahn and Newton. 1996). It has been demonstrated in the stroke population that reduced versions of the BBS can provide similar information about balance and physical function as the BBS, in particular the 7-Item BBS 3P (Chou et al. 2006). Use of the 7-Item BBS 3P has yet to be validated in the elderly community population.

1.4 Psychometric properties of the Mini BESTest

The BESTest is a comprehensive balance assessment designed to identify the postural control systems underlying poor functional balance. It consists of 36 items that examine six balance domains and takes approximately 35 minutes to complete. A shorter version of the BESTest, the Mini-BESTest, developed by Franchignoni et al. (2010), includes 14 items addressing four of the six balance domains and it takes 10 to 15 minutes to complete. Each item is scored from 0-2 and total score ranges from 0 to 28 with higher scores indicating better balance.

The mini-BESTest correlated highly with the BBS in a population of 93 participants (mean age=66.2 years, SD =13.2) with balance disorders at baseline and following a two week exercise program ($r=0.85$, 95% Confidence Interval (CI) = 0.78-0.90) (Godi et al. 2013). However, in comparison to the BBS, the Mini-BESTest appeared to have a

lower ceiling effect, higher test-retest reliability and greater accuracy in classifying individual patients that demonstrated significant improvements in balance function.

A strong association between the Mini-BESTest and recurrent falls rate was identified by Duncan et al. (2013) in 80 patients with Parkinson's disease (Area under the curve (AUC): 0.86). However, use of a Mini-BESTest score range of 0-32 instead of 0-28, renders the results of this study difficult to incorporate into clinical practice. The Mini-BESTest has 14 items scored from 0-2 so maximum score is 28. However, two items were inappropriately counted into the total score because only the worst score between the left and right side should be counted in the total.

To date the Mini-BESTest has not been validated against the BBS or the 7-Item BBS 3P in the community-dwelling elderly nor has normative or cut-off data for the Mini-BESTest been ascertained in this population.

The 7-item BBS 3P requires minimal equipment and is less time consuming for the administrator, making it useful in a clinical and research setting. The reduced test duration may also decrease the response burden on patients and therefore, improve their willingness to partake in this outcome measure. Balance is a paramount issue for elderly community-dwelling adults over 65 years of age. To date, the validity of the 7-item BBS 3P has only been established in the stroke population. This presents a strong need to address the void in evidence based literature. Therefore, this study aims to determine the concurrent validity of the 7-item BBS 3P with the BBS and the mini-BESTest, in the community-dwelling elderly, for use in clinical practice and research settings. The

Mini BESTest will be included in this analysis due to its strong correlations with the BBS, high test-retest reliability and lower ceiling effect in comparison to the BBS. This study will also clarify if the 7-item BBS 3P can be used interchangeably with the BBS

CHAPTER 2 METHODOLOGY

2.1 Aims and objectives

The aim of this study was to investigate the concurrent validity of the 7-item BBS-3P with other clinical measures of balance in a sample of elderly community-dwelling adults.

The objectives of the study were to:

- Identify the strength of a positive correlation between the 7-item BBS-3P and the BBS;
- Identify if the 7-item BBS-3P positively correlates with the Mini-BESTest;
- Identify if the BBS positively correlates with the Mini-BESTest;
- Determine if the 7-item BBS-3P can be used interchangeably with the BBS.

2.2 Study design

This study was cross-sectional and was designed using the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) to ensure methodological validity (Kottner et al. 2011).

2.3 Participants

Two day care centres and five physiotherapy departments were approached and permission was granted to recruit 30 volunteers. The recruitment and testing sites included five physiotherapy departments; Kerry General Hospital (KGH), Tralee, Co. Kerry; Community Nursing Unit (CNU), Tralee, Co. Kerry; Blackrock Hall Primary Care Centre, Mahon, Co. Cork; Kinsale Community Hospital, Kinsale, Co. Cork and Turners Cross Day Care Centre, Turners Cross, Co. Cork. Participant recruitment was also from two day care centres; Turners Cross Day Care Centre, Turners Cross, Co. Cork and Kinsale Day Care Centre, Kinsale, Co. Cork. Volunteer recruitment involved the display of advertisement posters in the reception areas of the physiotherapy departments and the day care centres (Appendix 1). Volunteers were also suitably identified by physiotherapists or day care centre managers working at the recruitment sites. Participant recruitment duration was between November 2013 and March 2014.

Inclusion criteria were:

- Aged 65 years or older;
- Living at home;
- Independently mobile \pm walking stick > six metres;
- Greater than or equal to 24 on the Mini Mental State Examination (MMSE).

Exclusion criteria were:

- Unstable cardiac conditions or unstable hypertension (HTN) or orthostatic hypotension, that may have affected the participant's health status during testing;
- Cerebrovascular Accident (CVA) or Peripheral Neuropathy, as residual weakness or decreased sensation may have affected balance;
- All Total Hip Replacements (THR), as hip flexion is required for the BBS;

- Lower limb fractures within the previous 12 months;
- Less than 90° shoulder flexion, as 90° is required to complete the functional reach task in the BBS.

2.4 Sample Size

A minimum of 26 participants was required for concurrent validity based on an alpha level of 0.5 and a power of 0.8 (Tsang et al. 2013). However, Conroy (2009) recommended a sample size of 30, based on a correlation of 0.55 for a study powered at 90%. This was because less than 0.45 was unlikely to have clinical significance when investigating relationships between variables of clinical interest. According to Hsieh (2013) (co-author of the 7-item BBS 3P), 30 participants were required as a minimum standard for psychometric investigation. Based on these sample size calculations, 30 participants were required for this sample of convenience.

2.5 Ethical considerations

Written permission was obtained from the managers of the day care centres and physiotherapy departments to recruit participants (Appendix 2a-2d). Ethical approval was sought from and granted by the Clinical Research Ethics Committee of Cork Teaching Hospitals (Appendix 3a and 4a). An amendment to this application was subsequently granted by the aforementioned ethical committee (Appendix 3b and 4b). An information leaflet was provided, which advised that participation was entirely voluntary and withdrawal from the study was permitted at any time, without having to give a reason and without any personal consequence (Appendix 5). Informed written consent was obtained prior to participation following screening for inclusion criteria

(Appendix 6). Volunteers were assigned an identification number on data recording sheets known only to the co-investigator (SC) (Appendix 7). Each participant's General Practitioner (GP) was informed regarding his/her patient's involvement in the study (Appendix 8). All data remained confidential and was stored securely in a locked drawer in the physiotherapy department in Kinsale Community Hospital and was only accessible to the co-investigator (SC). Data will be stored securely for five years upon and thereafter will be destroyed.

2.6 Procedure

2.6.1 Procedure

The study took place in two physiotherapy departments (Kinsale Community Hospital and Turners Cross Day Care Centre) between December 2013 and March 2014. Recruitment and testing did not occur from the physiotherapy departments in KGH, CNU or Blackrock Hall as the sufficient number of participants was recruited from the remaining sites. Information leaflets were provided to the volunteers and they were given a week to assimilate the information leaflet and discuss it further with his/her GP or family if required. Volunteers were subsequently contacted by the co-investigator (SC) to arrange an appointment for testing at one of the physiotherapy departments.

Volunteers were screened for cognitive impairment, inclusion and exclusion criteria. The presence of cognitive impairment was determined on completion of the MMSE. Inclusion/exclusion criteria were ascertained by yes/no answers to required criteria. Written informed consent was obtained from volunteers who fulfilled the inclusion/exclusion criteria and MMSE. Data collection included anthropometric information such as height, weight, age and gender. Medical and medication history,

use of walking aid and a single performance of each measure of balance were also collected. All balance tests were performed in a randomised order, via random numbers generator (Randomness and Integrity Services Limited, 2010), to eliminate possible learning or fatigue effects and were conducted according to standardised test instructions (Appendix 9b – 9d). If subjects used a walking stick to mobilise, balance testing was performed without the use of the assistive device (Wong et al. 2013). Rest periods were also provided to the participant as often as required. Data collection took approximately one hour in total and all assessments were conducted in one visit. Participants were closely supervised during testing and wore a manual handling belt as a safety precaution, which is routine care during balance assessments. The first assessor (SC), a physiotherapist with six years professional experience and competent in the use of the BBS and mini-BEST outcome measures, collected the data. The second assessor (MOM), a physiotherapist blinded to the participant's identity and performance of the balance outcome measure) totalled up the score results to eliminate any recall bias from the first assessor.

2.6.2 Cognitive assessment

Mini Mental State Examination (MMSE)

The MMSE (Appendix 9a) is a short cognitive screening tool comprising of 30 questions that examines orientation, registration, attention and calculation, recall and language (Folstein et al. 1975). It has been validated in an elderly population (Espino et al. 2001; McDowell et al. 1997). Volunteers were screened with the MMSE to ensure that they could give an accurate medical history, understand test instructions and give informed consent. Volunteers who scored 24-30, indicated no cognitive impairment and

were included in the study (Tombaugh and McIntyre. 1992). Competency in administration of the MMSE by SC involved training from an Occupational Therapist.

2.6.3 Balance measurements

Three balance outcome measures were used to gain a comprehensive assessment of functional balance ability:

- Berg Balance Score (BBS)
- 7-item BBS-3P
- Mini BESTest

Berg Balance Scale (BBS)

The BBS (Appendix 9b) is a 14-item functional performance measure. It was originally designed to quantitatively assess balance and risk of falls in older community-dwelling adults through direct observation of their performance (Berg et al. 1989; Berg et al. 1995). It requires participants to maintain positions of varying difficulty and perform specific tasks such as sit-to-stand (STS) transfer and single leg stance (SLS). Scoring of these 14 items is based on the participant's ability to perform the tasks independently or complete them within a certain distance or time (Blum and Korner-Bitensky. 2008). Performance is rated on a 5-level scale from "0" (cannot perform) to "4" (normal performance) and the possible maximal score is 56 indicating excellent balance (Shumway-Cook et al. 1997). It is convenient and the equipment required includes two chairs (one with armrests and one without), a 15 centimetre high step, a shoe/slipper, ruler and a stopwatch. Reliability and validity of the BBS has been extensively demonstrated with ICC's of 0.98 and 0.99 for inter and intra-rater reliability respectively and correlated with the Barthel Mobility Subscale, TUG and Tinetti

Balance Subscale ($r= 0.67, -0.76$ and 0.91 respectively, $p<0.01$) (Berg et al. 1989; Berg et al. 1992b).

The 7-Item 3-level BBS (7-item BBS 3P)

The 7-item BBS 3P (Appendix 9c) is a functional performance based measure consisting of seven of the original 14 items from the BBS (Chou et al. 2006). The seven items included: reaching forward with outstretched arm, standing with eyes closed, standing with one foot in front, turning to look behind, retrieving object from floor, standing on one foot and sitting to standing. Each of the seven items was combined from 5-levels (0-1-2-3-4) to 3-levels (0-1-2), where the second, third and fourth levels of the original BBS scale were merged into a single level. The revised one point level is obtained when participants meet the criteria for the 2nd– 4th level but not the 5th level. Performance is rated from “0” (cannot perform) to “2” (normal performance) and the maximum score is 14. The 7-item BBS-3P takes less than 10 minutes to complete and requires a stopwatch and chair with no armrests. The reliability of the 7-item BBS-3P was high with an ICC of 0.99 (95% CI 0.98-0.99) and it was moderately to very highly correlated with the original BBS, Barthel Index and Fugl-Meyer Motor Test ($r\geq 0.97$, $r=0.84-0.86$ and $r=0.66-0.68$ respectively).

The Mini Balance Evaluation Systems Test (Mini-BESTest)

The Mini-BESTest (Appendix 9d) was chosen as the third outcome measure as it has been designed to analyse several postural control systems that may contribute to poor functional balance in adults (Franchignoni et al. 2010). The Mini-BESTest contains 14 items that focus on four of the six sections from the original 36-item BESTest. These include anticipatory postural adjustments, postural responses, balance during gait and sensory orientation (Franchignoni et al. 2010). The Mini-BESTest takes approximately

15 minutes to complete, performance is rated from “0” (cannot perform) to “2” (normal performance) and the total possible maximal score is 28 (King et al. 2012). Equipment required includes: a 4-inch foam mat, chair with no arm rests, incline ramp, stopwatch, 9-inch high box and 3-metre distance measured out on floor from chair. The Mini-BESTest has demonstrated excellent internal consistency ($\alpha=0.89-0.94$), inter-rater (ICC=0.96) and intra-rater reliability (ICC=0.97) (Tsang et al. 2013). The Mini BESTest has been validated with the BBS in people with balance disorders (mean age: 66.2 years; SD:13.2), chronic stroke (aged 57.1 years; SD:11) and Parkinson’s disease (mean age: 65.5 years; SD:7.1) (King et al. 2012; Godi et al. 2013; Tsang et al. 2013).

2.7 Statistical methods

Data were collected on separate identification sheets (Appendices 7 and 9a-9d). The data were quantitative and ordinal in nature. Windows Excel (Microsoft Office Professional Plus 2010, Version 14, Microsoft Corporation, Washington, United States of America (USA)) was used for data input. Data were subsequently transferred into the Statistical Package for Social Sciences (SPSS) (Windows Version 21, International Business Machines (IBM) Corporation, New York, USA) for analysis.

Analysis of data consisted of calculating means and SD for participant characteristics and median and interquartile range (IQR) for balance data. Data were examined for normality using skewness and kurtosis values, normal probability plots (normal Q-Q plots), Shapiro-Wilk statistic (as sample size less than 50) and histograms. For parametric data: means, SD and 95% CI were calculated. For non-parametric data: median, minimum, maximum, IQR and ranges were calculated. Correlations between balance outcome measures were examined using Spearman’s Rank Order Correlational

Coefficient for ordinal level and non-parametric data. Significance for correlations was set at $p < 0.05$. To aid comparison of the psychometric properties of the 7-Item BBS 3P with the BBS in the current study, total score range (0-14) for the 7-Item BBS 3P was linearly transformed into the BBS score range (0-56) via SPSS. This involved multiplying the mean of the variables by four. The strength of the correlations was ascertained using the following guidelines (Plichta Kellar and Kelvin, 2013) (Table 2.1).

Table 2.1 Strength of correlational value

ρ	0.00-0.25	Very low correlation
ρ	0.26-0.49	Low correlation
ρ	0.5-0.69	Moderate correlation
ρ	0.70-0.89	High correlation
ρ	0.9-1.00	Very high correlation

ρ = Spearman's Rank Order Correlational Coefficient value

The percentage of explained variance between the 7-Item BBS 3P with the remaining balance measures and use of walking stick for baseline mobility was assessed by the coefficient of determination (r^2). Thus the r^2 indicates the amount of variance in the 7-Item BBS 3P that may be attributed to a variation in other types of balance measures or use of a walking stick in this study. For this calculation, Pearson's r value was used. Therefore, Pearson's r value was squared and converted to a percentage by multiplying by 100.

CHAPTER 3 RESULTS

3.1 Participant Characteristics

Participants were recruited from two day care centres: Kinsale and District Day Care Centre and Turners Cross Day Care Centre and two physiotherapy departments: Kinsale Community Hospital and Turners Cross Day Care Centre. The process of participant recruitment is outlined in Figure 3.1.

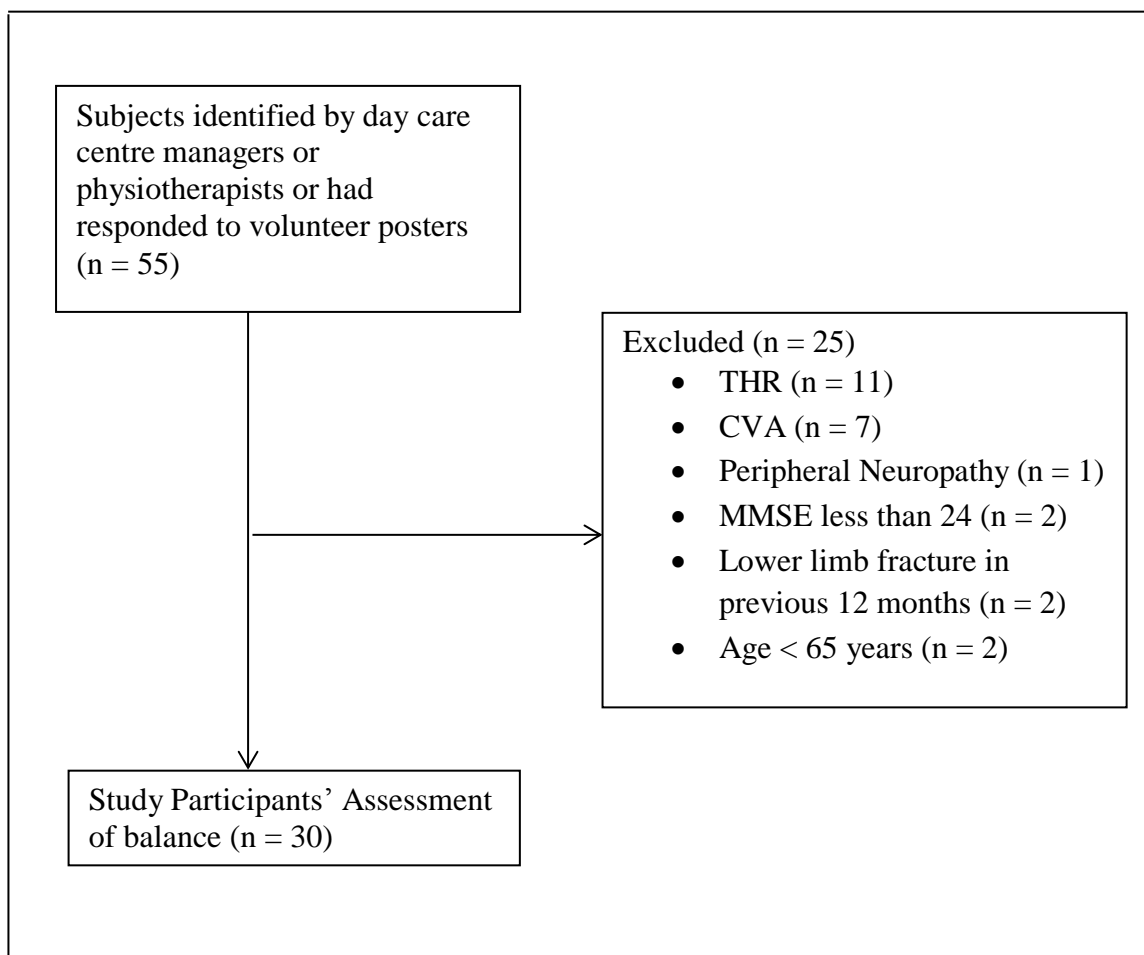


Figure 3.1 Participant recruitment

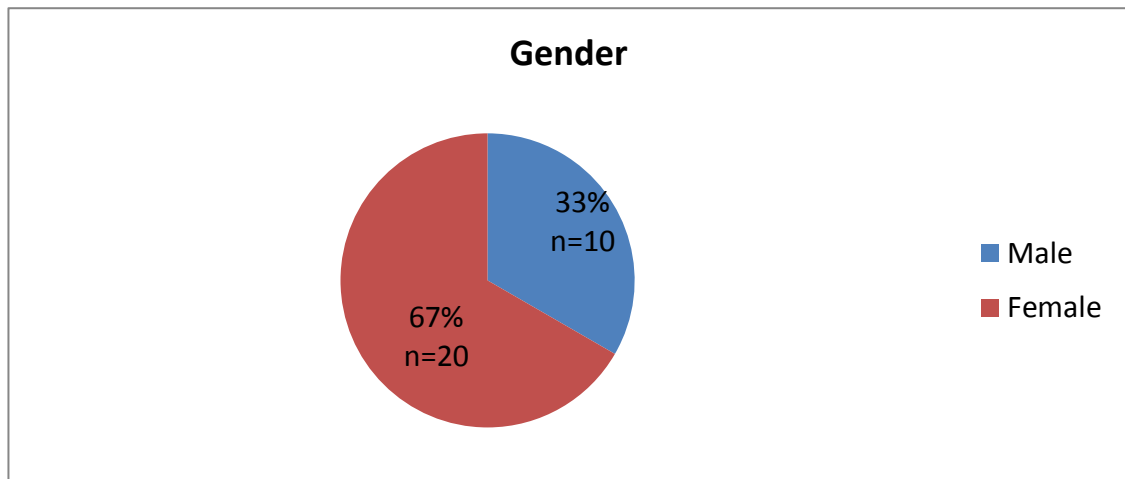
Descriptive statistics of the study sample included age, height, weight, number of co-morbidities and medications (Table 3.1). Gender is outlined in Figure 3.2. Age, weight

and height were all normally distributed ($p = 0.31, 0.6$ and 0.68 respectively). These variables were not analysed further, as the distribution of the 7-Item BBS 3P, BBS and Mini-BESTest were the same across the categories of age, weight and height. This was according to the Kruskal-Wallis test at $p > 0.05$ level ($p = 0.07-0.48$). However, the distribution of the 7-Item BBS 3P was different across the categories of weight ($p = 0.03$).

The most common medical conditions were Hypertension (HTN) (57%, $n = 17$), Osteoarthritis (OA) (40%, $n = 12$), Cardiovascular disease (30%, $n = 9$) and Diabetes (20%, $n = 6$), of which some participants had more than one co-morbidity. Twenty nine participants (97%) were on medications that may cause dizziness, which can affect balance (Diuretics, anti-depressants, benzodiazepines, anti-histamines, anti-hypertensives and other cardiac medications). Polypharmacy (greater than four medications per participant) affected 70% ($n = 21$) of participants (Patterson et al. 2012).

Table 3.1 Participant descriptive statistics

Variable	Mean	Standard Deviation (SD)	95% Confidence Interval (CI)
Age (years)	79.57	5.86	67.84 – 91.30
Height (centimetres)	162.32	8.86	144.61 - 180.04
Weight (kilograms)	75.77	14.01	47.75 – 103.80
Number of co-morbidities	4.3	1.97	3.57 - 5.03
Number of medications	6.03	3.22	4.83 – 7.24

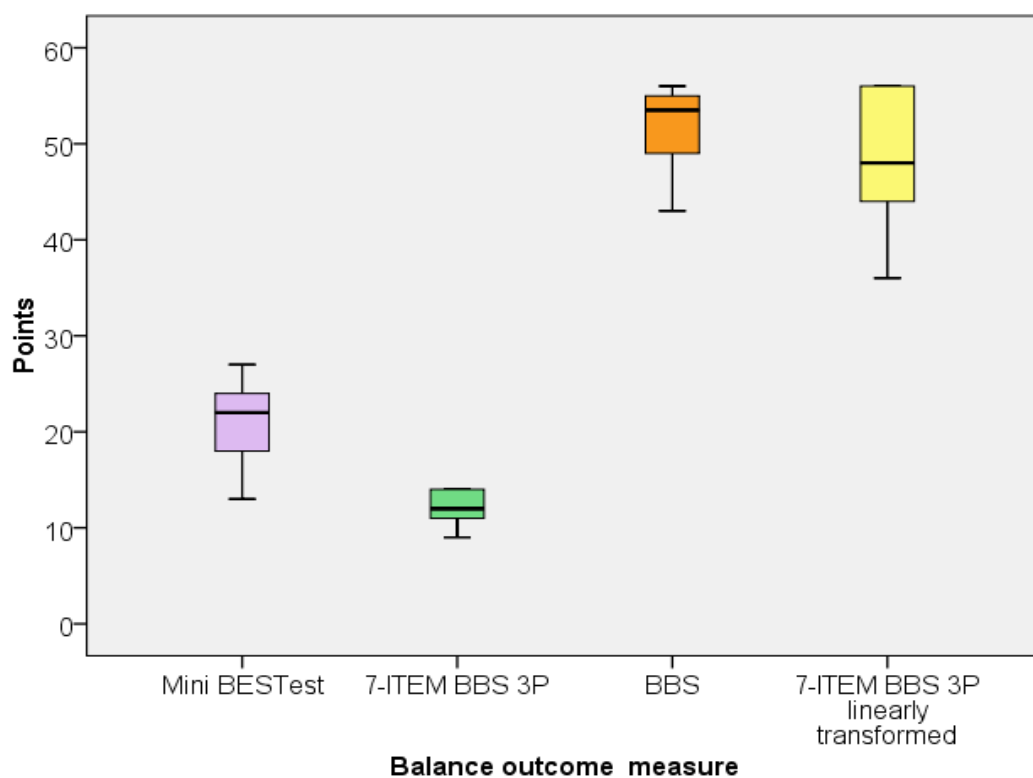


n=number; %=percentage

Figure 3.2 Participant distribution

3.2 Balance

Total scores for each outcome when assessed for normality, revealed that data for the BBS, 7-Item BBS 3P and linearly transformed 7-Item BBS 3P were not normally distributed ($p < 0.01$). Total score for the Mini-BESTest, despite being normally distributed ($p = 0.08$), was considered non-parametric data for correlational analysis as it was close to the significance level of 0.05. Therefore medians, minimum, maximum and IQR were reported due to the ordinal and non-parametric nature of the balance outcome measure data (Figure 3.3). However, mean and SD were also reported for the balance outcome measures of the study sample to allow direct comparison with published established cut off and normative data in the discussion (where applicable) (Table 3.2).



Mini-BESTest = Mini Balance Evaluation Systems Test (0-28); 7-Item BBS 3P = 7-Item 3-Level Berg Balance Scale (0-14); BBS = Berg Balance Scale (0-56); 7-Item BBS 3P linearly transformed = 7-Item 3-Level Berg Balance Scale linearly transformed (0-56)

Figure 3.3 Distribution of balance outcome measure scores

Table 3.2 Balance scores for study sample (n = 30)

Balance Measure	Mean	SD	Median	IQR	Min-max
BBS (0-56)	51.73	3.81	53.5	6	43-56
Mini-BESTest (0-28)	21.17	3.49	22	6	13-27
7-item BBS 3P (0-14)	12.07	1.68	12	3	9-14
7-Item BBS 3P linearly transformed (0-56)	48.27	6.72	48	12	36-56

BBS = Berg Balance Scale; 7-Item BBS 3P = 7-Item 3-Level Berg Balance Scale; Mini-BESTest = Mini Balance Evaluation Systems Test; 7-Item BBS 3P linearly transformed = 7-Item 3-Level Berg Balance Scale linearly transformed; SD = Standard deviation; IQR= Inner-quartile range; Min = minimum value; Max = Maximum value

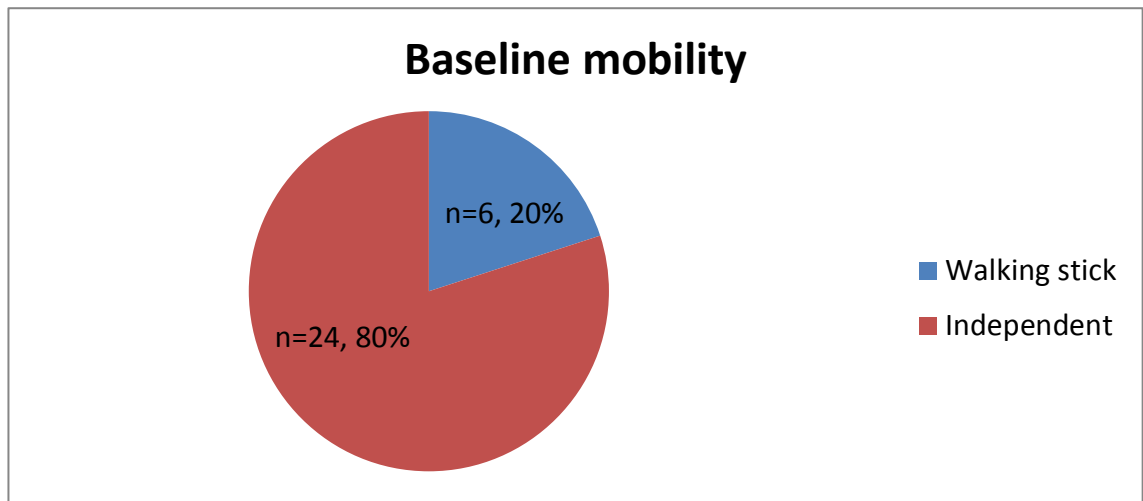
In the BBS, 97% (n = 29) had scores of 45 or above and 10% (n = 3) achieved the maximum score of 56/56. One participant who was the oldest participant in the study and used a walking stick for mobility, attained the lowest score of 43 points. According

to the Shumway-Cook et al (1997) criteria for falls risk, 50% of the study's participants' (n = 15) obtained BBS scores in the range of 54-56, 43% of participants' (n = 13) had BBS scores that were in the range of 54-46, 7% of participants (n = 2) had BBS scores below 46. No participant scored below 36 points.

In the Mini-BESTest, one participant achieved the lowest score of 13 points. They did not use a walking stick for baseline mobility. No participant achieved the maximum score of 28 points. In the 7-item BBS 3P, 10% of participants (n = 3) achieved the lowest score of nine points, all of whom used a walking stick for mobility. Thirty percent (n = 9) achieved the maximum score of 14/14. It can be observed that the linearly transformed 7-Item BBS 3P displays lower median values than the BBS (Figure 3.3). Sixty percent (n = 18) achieved a linearly transformed 7-Item BBS 3P mean cut-off score of 45 or more and 30% (n = 9) of study participants achieved the maximum score of 56/56.

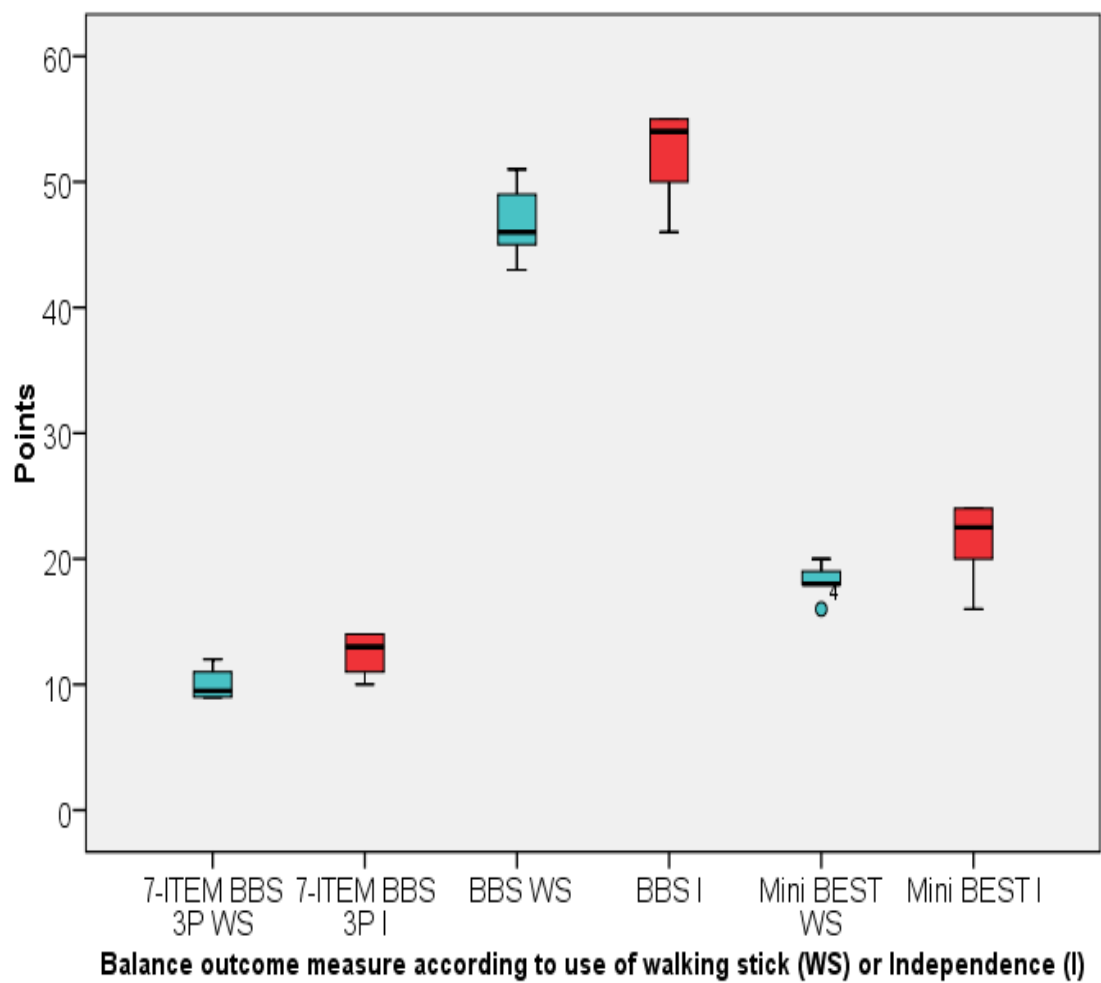
3.3 Effect of use of walking stick for baseline mobility on balance outcome measures

Twenty percent of participants (n = 24) used a walking stick at baseline (Figure 3.4). Median balance scores were lower in participants that used a walking stick for baseline mobility (Figure 3.5). Mean and standard deviations (SD) are also reported separately to allow direct comparison with published established cut off and normative data in the discussion (where applicable) (Table 3.3). The distribution of the 7-Item BBS 3P, BBS and Mini-BESTest, were different across the category of use of walking stick ($p < 0.01$). This was according to the Mann-Whitney U test at $p < 0.05$.



n=number; %=percentage

Figure 3.4 Baseline mobility



7-Item BBS 3P = 7-Item 3-Level Berg Balance Scale (0-14); BBS= Berg Balance Scale (0-56); Mini-BESTest = Mini Balance Evaluation Systems Test (0-28) WS = Walking stick; I = Independent

Figure 3.5 Median balance scores with use of a walking stick for baseline mobility

Table 3.3 Mean scores in balance outcome measures according to use of walking stick (n = 6) or independent mobility (n = 24)

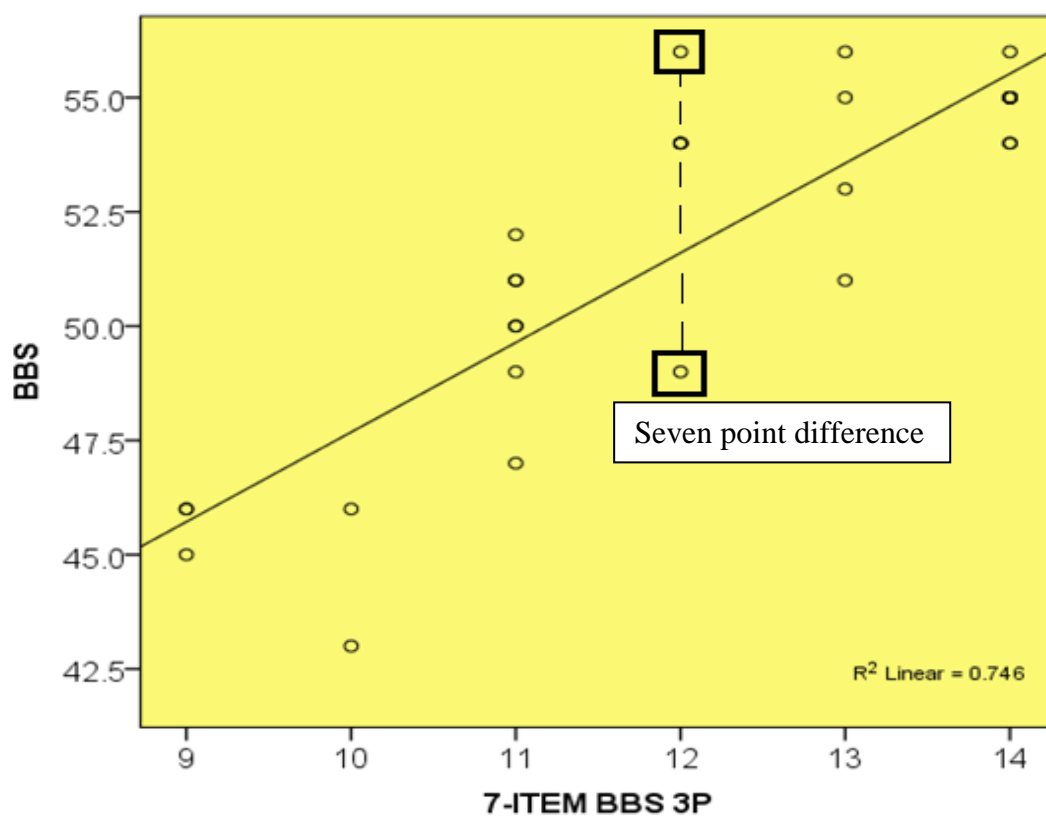
	Walking stick (n = 6)		Independent (n = 24)	
	Mean	SD	Mean	SD
7-Item BBS 3P (0-14)	10	1.27	12.58	1.35
BBS (0-56)	46.67	2.88	53	2.86
Mini-BESTest (0-28)	18.17	1.33	21.92	3.46
Linearly transformed 7-Item BBS 3P (0-56)	40	4.62	50.33	5.4

7-Item BBS 3P = 7-Item 3-Level Berg Balance Scale; BBS = Berg Balance Scale; Mini-BESTest = Mini Balance Evaluation Systems Test; 7-Item BBS 3P linearly transformed = 7-Item 3-Level Berg Balance Scale linearly transformed; SD = Standard deviation

3.4 Correlations between total scores of balance outcome measures and use of walking stick

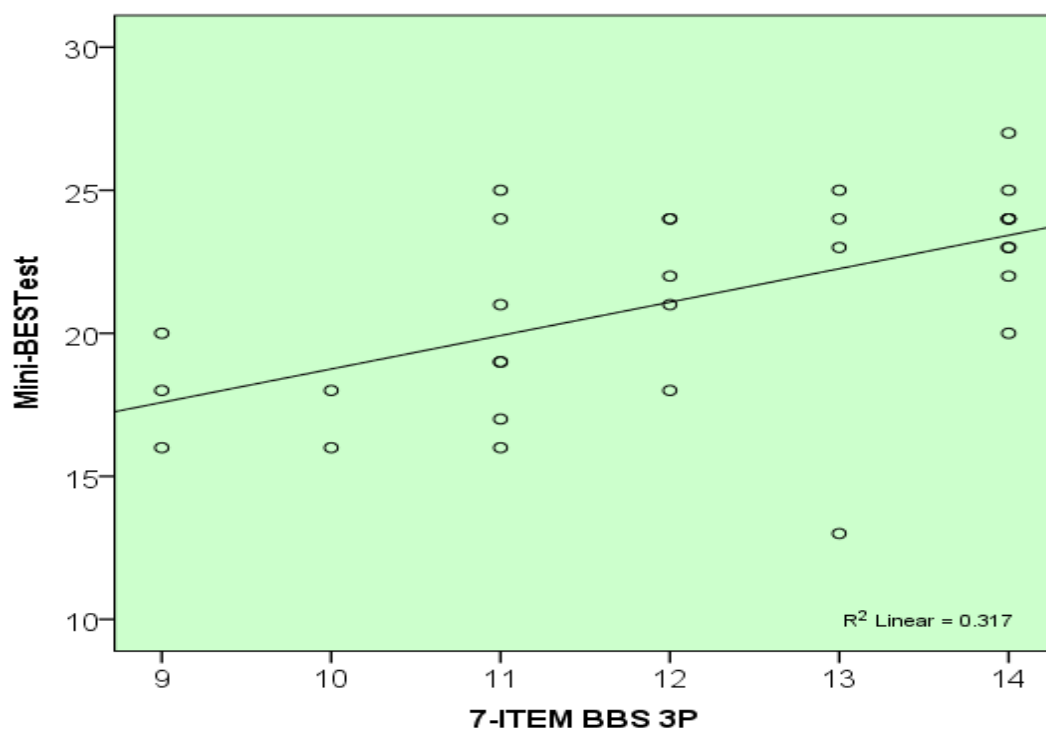
The strongest correlation was found between the 7-item BBS-3P and the BBS, which was highly correlated ($\rho=0.84$, $p<0.01$) (Figure 3.6). The weakest correlation was between the 7-item BBS-3P and the Mini-BESTest, which was moderately correlated ($\rho=0.57$, $p<0.01$) (Figure 3.7). A significantly high correlation was observed between the BBS and Mini-BESTest ($\rho= 0.74$, $p<0.01$) (Figure 3.8). A strong correlation was demonstrated between the linearly transformed 7-Item BBS 3P and the BBS, which was identical to that observed between the 7-Item BBS 3P and the BBS ($\rho=0.84$, $p<0.01$) (Figure 3.9). On examination of the correlation graph between the 7-Item BBS 3P and BBS, it was observed that a participant's score obtained on the 7-Item BBS 3P, may result in a corresponding score difference of up to seven points on the BBS (Figure 3.6).

There was a moderate correlation between use of a walking stick with the BBS and 7-Item BBS 3P ($\rho= 0.61$, $p<0.01$ and $\rho = 0.58$, $p<0.01$ respectively). A low correlation was found between use of a walking stick and the Mini-BESTest ($\rho = 0.47$, $p<0.01$).



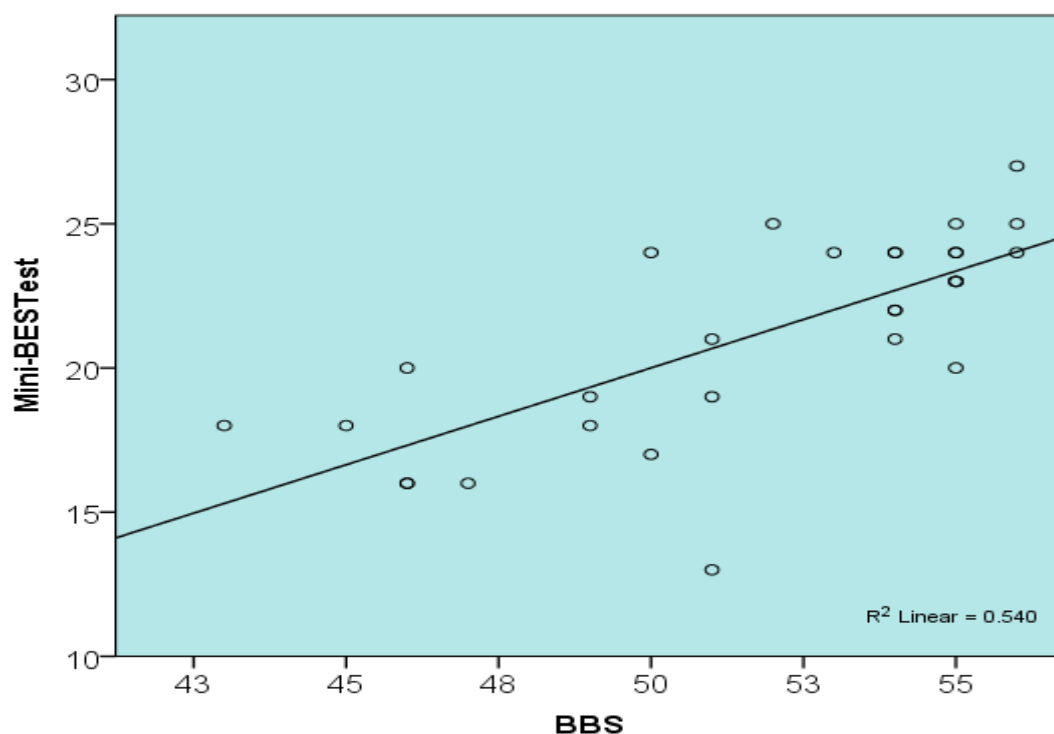
BBS = Berg Balance Scale; 7-Item BBS 3P = 7-Item 3-Level Berg Balance Scale

Figure 3.6 Correlation between 7-Item BBS 3P and BBS



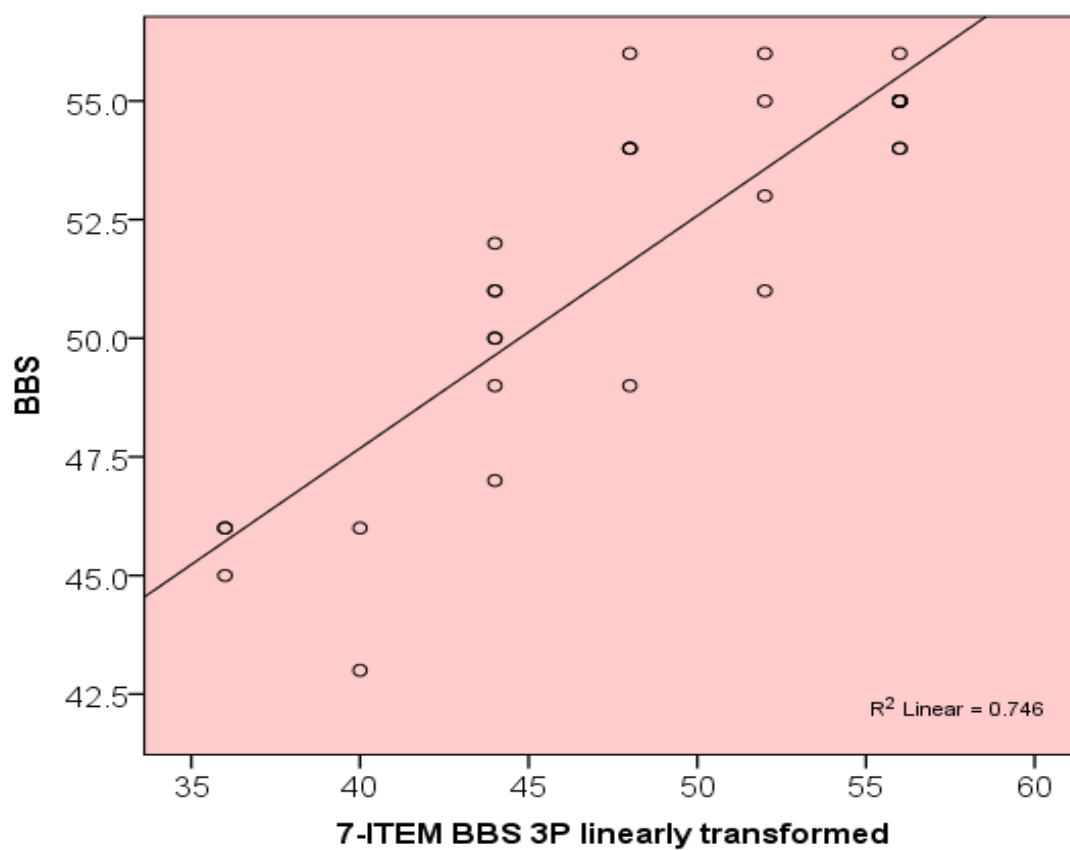
Mini-BESTest = Mini Balance Evaluation Systems Test; 7-Item BBS 3P = 7-Item 3-Level Berg Balance Scale

Figure 3.7 Correlation between 7-Item BBS 3P and Mini-BESTest



BBS = Berg Balance Scale; Mini-BESTest = Mini Balance Evaluation Systems Test

Figure 3.8 Correlation between BBS and Mini-BESTest



BBS = Berg Balance Scale; 7-Item BBS 3P linearly transformed = 7-Item 3-Level Berg Balance Scale linearly transformed

Figure 3.9 Correlation between linearly transformed 7-Item BBS 3P and BB

3.5 Linear regression analysis between balance measures

The Mini-BESTest assists in explaining 32% of the variance in participants' balance scores in the 7-Item BBS 3P, as indicated by the lowest r^2 value (Table 3.4). This means that 68% of the variance of the participants' scores in the 7-Item BBS 3P can be attributed to factors other than those captured by the Mini-BESTest. Conversely, the BBS assists in explaining 75% of the variance in the participants' scores in the 7-Item BBS 3P, as indicated by the highest r^2 value. Therefore, 25% of the variance in the participants' scores in the 7-Item BBS 3P can be attributed to factors other than those captured by the BBS.

Table 3.4 Pearson's correlation coefficient, coefficient of determination and percentage shared variance for total scores of balance measures

	BBS			Mini BESTest		
	r	r ²	%	r	r ²	%
7-Item BBS 3P (0-14)	0.86	0.75	75	0.56	0.32	32
Mini-BESTest (0-28)	0.74	0.54	54			

BBS = Berg Balance Scale; 7-Item BBS 3P = 7-Item 3-Level Berg Balance Scale; Mini-BESTest = Mini Balance Evaluation Systems Test; r = Pearson's correlation coefficient; r^2 = coefficient of determination; % = percentage shared variance

3.6 Linear regression analysis for use of walking stick and balance

Use of a walking stick only explained 19% of the variance in participants' Mini-BESTest scores (lowest r^2 value for walking stick), however 46% of the variance can be explained in participants' BBS scores (highest r^2 value for walking stick) (Table 3.5). Therefore, 54 – 81% of the variance in participants' scores in the balance measures used in this study can be attributed to factors other than those explained by use of walking stick.

Table 3.5 Pearson's correlation coefficient, coefficient of determination and percentage shared variance for use of walking stick and balance

	7-Item BBS 3P			BBS			Mini-BESTest		
	r	r²	%	r	r²	%	r	r²	%
Walking stick	0.63	0.39	39	0.68	0.46	46	0.44	0.19	19

BBS = Berg Balance Scale; 7-Item BBS 3P = 7-Item 3-Level Berg Balance Scale; Mini-BESTest = Mini Balance Evaluation Systems Test; r = Pearson's correlation coefficient; r² = coefficient of determination; % = percentage shared variance

3.7 Summary of results

- Significantly high correlations were observed between the 7-Item BBS 3P and BBS and between the BBS and Mini-BESTest
- Significantly moderate correlations were observed between the 7-Item BBS 3P and Mini-BESTest and for use of walking stick with 7-Item BBS 3P and BBS.
- A significantly low correlation was observed between use of walking stick and Mini-BESTest
- BBS could assist in the explanation of a higher percentage of variance in the 7-Item BBS 3P than the Mini-BESTest
- Use of walking stick for baseline mobility only explained a low percentage of variance on balance outcome measures

CHAPTER 4 DISCUSSION

The results of this study have provided new and clinically relevant information regarding the concurrent validity of the 7-Item BBS 3P with other clinical measures of balance in elderly community-dwelling adults. This supports the use of the 7-Item BBS 3P as a single measure of balance or as part of a multifactorial balance assessment. The sample size ($n = 30$) was sufficiently powered to detect significant differences ($p \leq 0.05$) in all correlations. Results will be analysed further to explore the correlations between each of the outcome measures and between use of a walking stick for baseline mobility and each outcome measure. The explained variance between each of the outcome measures and between use of a walking stick for baseline mobility and each measure will also be explored.

4.1 Participant characteristics

This study aimed to include a broad spectrum of elderly community-dwelling adults which would be representative of this population. However the study design necessitated implementation of certain inclusion and exclusion criteria as certain balance tasks were contraindicated due to lower limb joint replacements. The exclusion of neurological co-morbidities known to affect balance may have also affected results as the study was not powered for this (Shumway-Cook et al. 1997). The inclusion criteria of greater than or equal to 24 points on the MMSE, was employed to indicate the exclusion of dementia (Folstein et al. 1975; Desai et al. 2010; Wrisley and Kumar. 2010; Hou et al. 2011).

The mean age in this study sample fell within the standard deviation limits of previously published data for elderly community-dwelling adults (Shumway-Cook et al. 1997; Boulgarides et al. 2003; Muir et al. 2008; Stevenson et al. 2010; Nguyen et al. 2012). A similar trend was observed for the mean number of co-morbidities in this study (Berg et al. 1995; Stevenson et al. 2010). However, the population of the Berg et al. (1995) study consisted of elderly adults living in a seniors' residence, therefore results should be interpreted with caution.

The most common conditions identified in the community-dwelling elderly in the current study included HTN, OA, Cardiovascular disease and Diabetes which is in keeping with previous published research (Steffen et al. 2005; Wang et al. 2006; Stevenson et al. 2010). In the current study, 57% of participants (n=17) had HTN and 20% had diabetes (n=6). It has been demonstrated that older people with diabetes and HTN may also have diminished sensation in the lower limbs and associated retinopathies which may have an effect on balance (Jampel. 2001; Gulbandilar et al. 2008). Proprioceptive input from the lower limbs is an important contributor to standing balance as its threshold is lower than the visual and vestibular thresholds (Fitzpatrick and McCloskey. 1994).

Degeneration of the cervical spine from spondylosis and OA may also result in poor postural control and therefore increase risk of falling due to mechanoreceptor damage in the apophyseal joints (Wyke. 1979). In the current study, 40% of participants had OA (n=12). Vision may be used to compensate for reduced proprioceptive input or the individual may 'stiffen their posture' while concentrating on the task of standing (Berg et al. 1992b).

The mean number of medications used by participants in the current study falls within the standard deviation limits of published data for elderly community-dwelling adults (9.6 ± 3.5) (Conradsson et al. 2007). However, it exceeds that observed in other published studies (1.7 ± 0.2 – 3.8 ± 2.8) (Steffen et al. 2002; Boulgarides et al. 2003; Stevenson et al. 2010). Polypharmacy affected 70% ($n=21$) of the participants in the current study. However, the impact of polypharmacy cannot be fully ascertained as fall history was not examined in the current study. Future research investigating the effect of polypharmacy on falls risk, using the 7-Item BBS 3P, may provide new clinically relevant information.

4.2 Correlation between the 7-Item BBS 3P and the BBS

A significantly high correlation was demonstrated between the 7-Item BBS 3P and the BBS ($\rho = 0.84$, $p < 0.01$). This correlation was not as high as one might expect (greater than or equal to 0.9) despite the seven items of the 7-Item BBS 3P having originated from the BBS. The combined level of one point on the 7-Item BBS 3P was scored when a participant met the criteria for the second, third or fourth but not the fifth level on the original BBS. The lower than expected correlation may be due to the reduction grading levels per item (five to three), as the 7-Item BBS 3P may have scored the subject lower than the BBS for completion of the same balance task. For example, for the tandem stance task, a participant who could place one foot ahead independently and hold for 30 seconds on the 7-Item BBS 3P, attained the same score as another participant that needed help to step and could only hold for 15 seconds on the BBS.

A very high correlation was previously demonstrated between the 7-Item BBS 3P and the BBS in 113 people with stroke ($r = 0.99$) (Chou et al. 2006). However, only the original BBS was performed in the Chou et al. (2006) study and the scores for the 7-Item BBS 3P were subsequently extracted from the performance of the BBS. This may explain the very high correlation between the two measures as the 7-item BBS 3P was not performed separately in its entirety. Three other studies also employed the same technique of extracting scores from the BBS (Wang et al. 2004; Jogi et al. 2010; Liaw et al. 2012). A strong correlation ($\rho = 0.96$, $p < 0.01$) and excellent test-retest reliability (ICC = 0.99, 95% CI = 0.98-0.99) was demonstrated for the 3-level 14 item BBS (BBS 3P) in people with stroke (Wang et al. 2004; Liaw et al. 2012). The 7-Item 5-level BBS demonstrated a very strong correlation with the BBS in 54 participants with total hip and knee arthroplasty before and after a five to seven week home based exercise program ($r = 0.92$, CI: 0.86-0.95 and $r = 0.97$, CI: 0.95-0.98 respectively) (Jogi et al. 2010). The results of the aforementioned studies add support to the demonstration of a high correlation between the 7-Item BBS 3P and the BBS in the current study

4.3 Correlation between the BBS and Mini-BESTest

A high correlation was observed between the BBS and Mini-BESTest in this study ($\rho = 0.74$, $p < 0.01$). Despite an absence of published correlations between the Mini-BESTest and the BBS in the elderly, high correlations have been demonstrated in a variety of other populations, which supported the Mini-BESTest results in this study (Bergstrom et al. 2012; King et al. 2012; Godi et al. 2013).

The Mini-BESTest and BBS both incorporate static and dynamic tasks such as STS, unsupported standing with feet together and SLS. The BBS, however, does not include other important aspects of dynamic balance control, for example, examination of an individual's ability to respond to postural perturbations, stand on a compliant or inclined surface or walk while performing a cognitive task. This is because the BBS is predominantly a measure of static balance (Franchignoni et al. 2010). A significant correlation was demonstrated between the static or 'maintaining a position' components and mean velocity of centre of pressure (CoP) in the anterior-posterior direction as measured by a force platform ($\rho = -0.50$, $p < 0.05$) in 20 participants with stroke (mean age = 50.1 years, SD = 9.8) (Frkyberg et al. 2007). The 'maintaining a position' tasks consisted of standing and sitting unsupported, standing with eyes closed and with feet together respectively, tandem stance and SLS. However, it was identified that the mean velocity of the CoP's displacement can be quite low, even in an individual with a considerable postural control disorder. The difference in static and dynamic components between the two measures, may explain why a correlation of greater than 0.9 was not observed in the current study.

The Mini-BESTest also correlated highly with the BBS in 93 participants with various balance disorders (mean age = 66.1 years, SD = 13.1) ($r = 0.85$, 95% CI = 0.78-0.90) (Godi et al. 2013). Despite the absence of a community-dwelling elderly population in the aforementioned study, it does however encompass a diverse range of conditions which adds support to the high correlation between the measures in the current study. The Mini-BESTest was also found to correlate highly with the BBS in people with Parkinson's disease ($\rho = 0.94$, $p < 0.01$; $\rho = 0.79$, $p < 0.01$) and stroke ($\rho = 0.83$, $p < 0.01$; $\rho = 0.86$, $p < 0.01$) (Bergstrom et al. 2012; King et al. 2012; Tsang et al. 2013).

It has been suggested that the Mini-BESTest may be more useful than the BBS in evaluating individuals with mild Parkinson's disease or more subtle balance deficits as it contains items that are able to challenge the individual, even with minimal balance impairment (Bergstrom et al. 2012; King et al. 2012; Godi et al. 2013). This may be reflected by the finding that no participant in the current study achieved maximum score in the Mini-BESTest. Therefore the BBS may be more appropriate in the identification of balance deficits in those individuals' with more severe Parkinson's disease or severely limited function (King et al. 2012; Godi et al. 2013). However, a score range of 0-32 was employed for the Mini-BESTest in the study by Bergstrom et al. (2012), which is incorrect. The Mini-BESTest has 14 items scored from 0-2 so the maximum score is 28, therefore these results should be interpreted with caution.

The high correlations between the BBS and Mini-BESTest demonstrated in the results of the aforementioned studies, add support to the demonstration of the high correlation observed between the measures in the current study. As the Mini-BESTest contains more "dynamic" components than the BBS, it may be used to compliment the BBS and provide a comprehensive assessment of balance.

4.4 Correlation between the 7-Item BBS 3P and the Mini-BESTest

A significantly moderate correlation was demonstrated between the 7-Item BBS 3P and the Mini-BESTest ($\rho = 0.57$, $p \leq 0.01$), which was lower than the correlation observed between the BBS and the Mini-BESTest ($\rho = 0.74$, $p < 0.01$). This may be due to the Mini BESTest sharing many components with the BBS (King et al. 2012). The 7-Item BBS 3P also contains fewer items than the BBS, which may explain why the correlation

between the 7-Item BBS 3P and Mini-BESTest was lower. Published correlational studies between the 7-Item BBS 3P and Mini-BESTest have not been established in a community-dwelling population, therefore a comparative analysis was not possible.

4.5 Comparison of balance outcome measures with published cut-off and normative data

4.5.1 *The Berg Balance Scale (BBS)*

Mean scores for the BBS in this study sample were similar to those documented in existing literature for other community-dwelling older adults (Table 4.1) (Steffen et al. 2002; Steffen and Mollinger. 2005). The oldest participant in the study, who used a walking stick for mobility, achieved the lowest score of 43 points. This participant also had diabetes and glaucoma. This may have resulted in diminished sensation in the lower limbs and poor eyesight, resulting in increased difficulty in placing feet to attain a task position or locate objects to facilitate transfers, stepping and reaching (Jampel, 2001; Gulbandilar et al. 2008).

A ceiling effect was noted in 10% ($n = 3$) of participants in the current study where the maximum BBS score of 56/56 was achieved. Therefore, the BBS may be considered an acceptable measure in the current study, as less than 15% of participants achieved the highest score (McHorney and Tarlov, 1995). The findings of a ceiling effect in existing literature has also been found in 3-36% of elderly community-dwelling adults (Steffen and Mollinger. 2005; Wang et al. 2006; Salavati et al. 2012).

In this study, 97% of participants had scores of 45 or above which indicated a low risk of falling. However, Shumway-Cook et al. (1997) further analysed fall risk by BBS score range whereby each point drop in the range of 56-54 was associated with a 3-4% increase in fall risk. This indicated that 50% of participants who had achieved a score within the highest range of 54-56 points, were in fact at a 3-4% risk of fall with each point drop in this range. However, identification of falls risk depended on the interaction between many factors, which became increasingly difficult to predict in older adults that had a high level of activity and independence (Boulgarides et al. 2003).

4.5.2 The 7-Item BBS 3P

The lowest score of nine points on the 0-14 scale of the 7-Item BBS 3P was achieved by three participants, all of whom used a walking stick for mobility. Two of these participants were diabetic, which may have resulted in impaired circulation/sensation in the lower limbs (Gulbandilar et al. 2008).

For the purposes of comparison with published data the mean values of the linearly transformed 7-Item BBS 3P will be used. This is because published cut-off and normative data for the 7-Item BBS 3P have not been established in the community-dwelling elderly population. The linearly transformed mean of the 7-Item BBS 3P in this study (48.27) differs to the 7-Item BBS 3P mean (22.1) in the Chou et al. (2006) study. However, the population of interest in the study by Chou et al. (2006) consisted of people with stroke therefore direct comparisons cannot be drawn from these results.

A mean difference of 3.46 points was observed between the values of the linearly transformed 7-Item BBS 3P and the BBS in the current study (48.27 and 51.73 points respectively). This is in contrast to a larger scale study by Chou et al. (2006) which resulted in a mean difference of 1.2 points between the values of the linearly transformed 7-Item BBS 3P and the BBS (22.1 and 23.2 respectively). However, the scores for the 7-Item BBS 3P were subsequently extracted from the single performance of the BBS in the study by Chou et al. (2006). Therefore the results must be interpreted with caution as the 7-item BBS 3P was not performed separately in its entirety and the population consisted of people with stroke. The 7-Item BBS 3P in the current study was completed separately to the BBS to ascertain a more accurate correlation between the two measures.

It must be noted that a participant's score obtained on the 7-Item BBS 3P, may result in a corresponding score difference of up to seven points on the BBS (Figure 3.6). This was large and exceeded the MDC range of 3.3-6.3 points in the BBS for elderly people (Donoghue et al. 2009). This may suggest that the two scales cannot be used interchangeably and that further research needs to be conducted to establish normative, MDC and cut-off data for the 7-Item BBS 3P.

4.5.3 The Mini-BESTest

To the author's knowledge, there are no normative or cut-off data in existence for the Mini-BESTest in the community-dwelling elderly population (aged greater than 65 years). However, median values for the Mini-BESTest in the community-dwelling

adults aged 60.2 ± 9.3 years have been established in a study by Tsang et al. (2013) (Table 4.1).

The lowest score of 13 points on the 0-28 scale of the Mini-BESTest was achieved by one participant, who did not use a walking stick for mobility. However, this person had multi-level lumbar spondylosis, which may have resulted in reduced angular velocity of the lower trunk. This subsequently may have affected the participant's ability to complete the dynamic tasks of the Mini-BESTest (Gill et al. 2001). Part of the dynamic assessment of the Mini-BESTest incorporates head turns while mobilising, which may therefore challenge the vestibular system. The role of the vestibular system in balance is to monitor and correct head position and motion via vestibulocular and vestibulospinal pathways (Sturnieks et al. 2008). Abnormalities in the semi-circular canals and otolith organs which mediate the Vestibulo-ocular reflex (VOR) may result in postural instability and a broad based ataxic gait pattern resulting in lower scores in this section of the Mini-BESTest (Tian et al. 2002).

Median score for the Mini-BESTest in the current study sample was less than the median score of 27 demonstrated in community-dwelling adults aged 60.2 ± 9.3 years (Tsang et al. 2013). However, the population in the study by Tsang et al. (2013) was younger than the current study which may account for the lower median scores seen in the Mini-BESTest.

Table 4.1 Published cut off values and normative values for balance measures

Balance Measure (Range)	Published cut-off values for increased risk of falling in the elderly (Author)	Published normative values Mean (SD); Population (Age); (n); Author
BBS (0-56)	< 45 (Berg et al. 1992a; Bogle Thorbahn and Newton, 1996; Donoghue et al, 2009)	a) 53.33 (2.5); Community-dwelling (60-89 years); (n=96); Steffen et al. (2002) b) 52.5 (3.5); Community-dwelling (60-80+ years); (n=59); Steffen and Mollinger. (2005)
Mini-BESTest (0-28)	Not established	27* (26-27)**; Community-dwelling (60.2±9.3 years); (n=48); Tsang et al. (2013)
7-item BBS 3P (0-14)	Not established	Not established

BBS = Berg Balance Scale; 7-Item BBS 3P = Seven Item Three Level Berg Balance Scale; Mini-BESTest = Mini Balance Evaluation Systems Test; n=number of participants; SD=Standard deviation * Median value ** Interquartile range (IRQ)

4.6 Decline in balance with use of walking stick for baseline mobility

4.6.1 BBS

Lower mean BBS scores have been observed in individuals who use a walking stick versus independent mobility (Berg et al, 1992a; Berg et al, 1992b). In the current study, mean BBS scores for participants that used a walking stick (n=6) to mobilise at baseline was lower (mean=46.67, SD=2.88) than participants that mobilised independently (n=24; mean=53, SD=2.86). The mean BBS score obtained for use of a walking stick in the current study fell within the standard deviation limits of normative values (Table 4.2) (Berg et al. 1992a; Berg et al. 1992b).

Mean BBS score in participants who mobilised independently in the current study, satisfied the standard deviation limits of published normative data (49.6 ± 5.6) (Berg et al. 1992a). However, the mean BBS score just exceeded the higher end of the 95% CI of Berg et al. (1992b) (44.8-49.6). This may be due to the lower mean age of participants in the current study (79.57 years) than that of participants' in the Berg et al. (1992b) study (83.0 years). There were also a greater number of participants' that mobilised independently in the current study sample (24 versus 10).

Table 4.2 Published values for independent or use of a walking stick for baseline mobility

	Published values for walking stick in the elderly Mean (SD) (author) (n)	Published values for independent mobility in the elderly Mean (SD) (author) (n)
7-Item BBS 3P (0-14)	Not established	Not established
BBS (0-56)	(a) 48.3 (3.2) (outdoors) (n = 26) 45.3 (3.4) (indoors) (n = 29) (Berg et al. 1992a) (b) 39.0 (95% CI = 32.6-45.4) (n = 9) (Berg et al. 1992b)	(a) 49.6 (5.6) (n = 49) (Berg et al. 1992a) (b) 47.2 (95% CI = 44.8-49.6) (n = 10) (Berg et al. 1992b)
Mini-BESTest (0-28)	Not established	Not established

BBS = Berg Balance Scale; 7-Item BBS 3P = Seven Item Three Level Berg Balance Scale; Mini-BESTest = Mini Balance Evaluation Systems Test; n=number of participants; SD=Standard deviation; 95% CI=95% Confidence Interval

4.6.2 7-Item BBS 3P

In the 7-Item BBS 3P, mean scores for participants who used a walking stick ($n=6$) to mobilise at baseline was lower (mean=10, $SD=1.27$) than participants that mobilised independently ($n=24$; mean=12.58, $SD=1.35$). As this study is the first to examine concurrent validity of the 7-Item BBS 3P in the community-dwelling elderly, to this author's knowledge, there is no existing published literature to draw comparisons with.

As such data has been published for the BBS, the linearly transformed 7-Item BBS 3P mean will be used to draw comparisons from. Therefore, the mean score obtained for use of a walking stick in the linearly transformed 7-Item BBS 3P (40 ± 4.62), satisfied the 95% CI limits of published data (Berg et al. 1992b) (Table 4.2). However, it was lower than the 95% CI in the study by Berg et al. (1992a). This may be due to the low number of participants who used a walking stick for baseline mobility in the current study sample, therefore results should be interpreted with caution.

Mean scores for the linearly transformed 7-Item BBS 3P in participants that mobilised independently at baseline (50.33 ± 5.4), satisfied the standard deviation limit and 95% CI range in published data (Berg et al. 1992a; Berg et al. 1992b). However, as these 7-Item BBS 3P mean scores have been linearly transformed to make comparisons with mean BBS scores, caution must be taken when interpreting these results.

4.6.3 Mini-BESTest

Mini-BESTest mean scores in participants who used a walking stick to mobilise at baseline was lower (18.17) than participants that mobilised independently (21.92). To the author's knowledge, there is no existing published evidence for the Mini-BESTest from which to draw comparisons for use of a walking aid in the elderly community-dwelling population.

Older adults tend to mobilise with a slower velocity and cadence, shorter and wider step length and increased time spent in double limb support (Berg et al. 1992b; Sturnieks et al. 2008; Park et al. 2013). This can be further challenged when the individual crosses an obstacle, as time spent in single limb support is increased. Therefore, they are less capable in the avoidance of an obstacle, for example, sidestepping, stopping and turning which results in a higher risk of falling (Berg et al. 1992b; Park et al. 2013). Reduced visual input and longer response times may also result in impaired proactive and reactive strategies in the avoidance of obstacles due to misjudgement of depth and distance (Lord. 2006). Use of a walking stick may provide assistance with 'double limb' support, particularly when an individual is forced into single limb support to step over an obstacle (Berg et al. 1992a; Kuys et al. 2011; Park et al. 2013).

Part of the reactive balance assessment in the Mini-BESTest involves displacement of the COM in relation to the BOS. Therefore, when the COM is moved towards the limits of stability, either voluntarily or in response to an external perturbation, a compensatory step may need to be taken to increase the BOS. The performance of this is significantly

slower in older individuals which may have resulted in lower scores in this section of the Mini-BESTest in the current study (Stelmach et al. 1989; Sturnieks et al. 2008).

Poor response times may also be attributed to a slower generation of joint movements. This can be as a result of strength loss, longer latencies in reflexive and voluntary muscle response, neuronal or myelin loss, increased joint stiffness and lower peak ankle movement in the stance limb (Berg et al. 1992b; Pijnappels et al. 2004; Sturnieks et al. 2008; Kuys et al. 2011). It is this reduced capacity for rapid generation of force that may limit an individual's quick response to a loss of balance and therefore result in an increased risk of falling (Sturnieks et al. 2008). Use of a walking stick may therefore increase proprioceptive input through the upper limb by increasing the BOS. However it must be stated that the number of participants that used a walking stick for baseline mobility in the study sample was small, therefore results should be interpreted with caution.

4.7 The 7-Item BBS 3P as a screening tool for impaired balance

The significantly high correlation of the 7-Item BBS 3P with the BBS supports its use as a viable screening tool for balance impairment. The BBS explained 75% of the variance in 7-Item BBS 3P scores, leaving only 25% of the variance due to other factors. These may have been influenced by the fewer number of items being tested or reduced scaling level from five to three per item in the 7-Item BBS 3P. Conversely, while the Mini-BESTest also correlated significantly with the 7-Item BBS 3P, it only explained 32% of the variance in the 7-Item BBS 3P, leaving 68% of the variance in 7-Item BBS 3P scores due to other factors. This may be due to a higher content of

dynamic balance elements in the Mini-BESTest than the 7-Item BBS 3P (Duncan et al. 2012; King et al. 2012).

4.8 Shared variance between use of walking stick and balance

While use of walking stick for baseline mobility correlated significantly with all balance measures, the correlations ($\rho=0.47-0.61$, $p<0.05$) were weak to moderate. Use of a walking stick for baseline mobility demonstrated the highest explained variance in the BBS. However this still left 54% of the variance due to other factors. Previous research has also demonstrated lower mean BBS scores in individuals that use a walking stick versus independent mobility (Berg et al, 1992a; Berg et al, 1992b).

4.9 Clinical implications

The results of this study support the use of the 7-Item BBS 3P as a screening tool for balance ability in the community-dwelling elderly, as demonstrated by the significant correlations with the BBS and Mini-BESTest ($\rho= 0.84$ and 0.57 respectively, $p \leq 0.01$). Use of the Mini-BESTest in the community-dwelling elderly population was also supported due to the high correlation with the BBS ($\rho=0.74$, $p \leq 0.01$).

The 7-Item BBS 3P and BBS cannot be used interchangeably as demonstrated by the correlation and BBS MDC values. The BBS only explained 75% of the variance in scores of the 7-Item BBS 3P, with 25% of the variance explained by other factors. This may be due to the reduction in items or more likely the reduction in levels of scaling per

item in the 7-Item BBS 3P, as participants may have been graded lower in the 7-Item BBS 3P than their actual ability.

Furthermore, despite significant correlations between mean scores for use of a walking stick and balance, these correlations were weak to moderate ($\rho=0.47-0.61$, $p<0.05$). Therefore, use of a walking stick for baseline mobility cannot be used as an indication of an individual's balance. Although this study recommends the use of the 7-Item BBS 3P as a screening tool for balance in the community-dwelling elderly, further research is needed to establish normative, MDC and cut-off data for this measure.

4.10 Study limitations

There are several limitations that must be noted:

- Despite assessor competency with the seven items from the BBS, the items in the 7-Item BBS 3P had been revised from a five level to a three level scaling format. Therefore, unfamiliarity with a new format of scaling may have affected the grading of each item in the 7-Item BBS 3P, despite adherence to the standardised instructions of this scale.
- The primary investigator conducted all measures on participants, therefore, assessor bias may have been a factor. However, this was minimised by strict adherence to the standardised instructions contained within each measure and a second assessor (blinded to the participant's identity and performance of the measure) totalled up the score results to minimise recall bias from the first assessor.

- As this study was cross sectional, it only involved the assessment of participants at one point in time. Therefore, it did not account for external factors that may have impacted on the participants' balance performance. Efforts were made to standardise testing procedures and provide rest periods at the participant's discretion.
- The recruited participants were relatively mobile and community-dwelling therefore the findings cannot be generalised to those who are severely impaired in their mobility or are in hospital or residential settings.
- Individuals post fracture and THR, common in the community-dwelling elderly population, were also excluded from the study. This may have an impact on the external validity of the study.
- Despite the study population consisting of elderly adults who lived in the community, the majority of participants attended day care centres and may have had greater access to other services for example, referral to other allied health services including physiotherapy, public health nursing and occupational therapy. This may have an effect on the external validity of the study, as those individuals who lack access to these services were not included in the study.
- All the measures used in this study assessed functional balance only. The psychological consequences secondary to a history of falls or FOF were not assessed.
- All assessments were conducted in randomised order, however as all outcome measures were completed within one visit, a learning or fatigue effect of tasks common to the outcome measures, may have occurred.

4.11 Recommendations for future studies

Based on previous research and the findings of the current study, the following recommendations aim to highlight opportunities for future research. For example, this study may be repeated:

- In an elderly population that reside in residential settings to fully validate its use in this population.
- In a larger sample which may provide more definitive data for comparison to normative and cut-off data, particularly in individuals that require a walking stick for baseline mobility.
- With a five level version of the 7-Item BBS 3P, which may improve the psychometric properties of the test while maintaining the completion time of the shorter version of the BBS.
- To include the assessment of the role of psychological factors on balance, which are not quantifiable via functional measures.

CHAPTER 5 CONCLUSION

This study investigated the concurrent validity of the 7-item BBS-3P with other clinical measures of balance using a convenience sample of elderly community-dwelling adults from two physiotherapy departments and two day care centres in Ireland. The results confirm that the 7-Item BBS 3P correlated highly with the BBS and moderately with the Mini BESTest in a sample of community-dwelling elderly adults. Therefore the 7-Item BBS 3P measures the same functional construct of balance as the BBS.

Despite weak to moderate correlations between use of a walking stick for baseline mobility and balance measures, lower mean BBS scores in individuals that use a walking stick have also been demonstrated by previous research. The balance assessments used in this study encompass both static and dynamic elements of functional balance, reflective of activities of daily living. The significant correlations observed between balance measures highlights the importance of functional balance control in the elderly population for completion of activities of daily living. This finding has important clinical implications for those involved in the design and implementation of balance re-education, to reduce the risk of falls in the elderly population as identified by particular threshold or cut-off balance scores achieved.

The significantly high correlations observed are sufficiently strong to warrant the 7-Item BBS 3P to be used as a screening tool for balance impairment in the elderly. However, the 7-Item BBS 3P and BBS cannot be used interchangeably as demonstrated by the correlation values. This is augmented by the finding that a participant's score obtained on the 7-Item BBS 3P, may result in a corresponding score difference of up to seven

points on the BBS. This was large and exceeded the BBS MDC range for elderly people. Further research needs to be conducted to establish normative, MDC and cut-off data for the 7-Item BBS 3P. Despite observing significant correlations between the 7-Item BBS 3P and the Mini BESTest, the strength of the correlation was only moderate, which was conceivably reflective of the greater dynamic component contained within the Mini BESTest. Therefore, a multifactorial approach to balance screening and treatment is vital to minimise the potential detrimental and economic effects that may result from unidentified and untreated balance impairment in this vulnerable population of community-dwelling elderly.

Word Count: 13615

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VOLUNTEERS REQUIRED

Would you like to help out in
a research project looking at
balance tests used in
physiotherapy on patients
with balance difficulties?

Do you have balance issues and be willing
to take part in having your balance assessed
by a physiotherapist?

If you would like to volunteer in taking part in this study please contact a member of staff who will give you an information leaflet outlining the study. Alternatively, please contact Sinéad Considine on 0214777180 or leave your name and number at the physiotherapy reception.

Appendix 2a



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Liz O' Sullivan,
Physiotherapy Manager Cork South
Community Physiotherapy dept
St Finbarrs Hospital,
Cork.
Tel 021 4923415
Mob; 087 6672664)
E-mail ; liz.osullivan1@hse.ie
Nov 25th 2013 .

Re; MSc project **"To investigate the concurrent validity of the 7-item BBS-3P with other clinical measures of balance in elderly community-dwelling adults"**

Dear Colleagues at UCC,

I , Liz O ' Sullivan , Physiotherapy Manager Cork South PCC grant permission to our full time staff grade physiotherapist Sinead Considine MISCP to undertake this study as part of her MSC research project with consenting patients at the following Cork HSE sites ;

1. Kinsale Community Hospital, Kinsale, Co. Cork;
2. Blackrock Hall Primary Care, Mahon, Cork and
3. Turners Cross Day Care Centre, Turners Cross, Cork.

Liz o Sullivan, MISCP.

A handwritten signature in black ink, appearing to read 'Liz O'Sullivan', written over a horizontal line.

Date 25/11/13.

Appendix 2b



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Physiotherapy Department,
Kerry General Hospital,
Tralee,
Co. Kerry.

17th October 2013.

Ethics Board
Cork University Hospital.
Wilton
Cork

Re: Ethics submission on behalf of Sinead Considine
MSc project "To investigate the concurrent validity of the 7-item
BBS-3P with other clinical measures of balance in elderly
community-dwelling adults"

Dear Colleague,

I am confirming that Sinead can recruit clients for the above study from the
Physiotherapy Departments both in Kerry General Hospital and Tralee
Community Nursing Unit.
Please let me know if you need more information.

Regards

Eibhlís Cahalane

Eibhlís Cahalane
A/Physiotherapy Manager

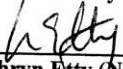


DATE: 22/10/2012

To whom it may concern,

Sinead Considine has been granted permission to access Client's who attend Kinsale & District Day Care Centre for participation in her MSc research project. Please don't hesitate to contact me should you require any further information.

Yours Sincerely


Kathryn Etty (Nurse Co-Ordinator)

Kinsale & District Day Care Centre
Rathbeg, Kinsale, Co. Cork

Turner's Cross Social Services Ltd.

Co. No 045294 CHY14066
63d Collier Road Cork Tel 021-4023436

23/10/13

To whom it may concern,

This is to certify that Sinéad Considine has sought, & been granted permission to recruit elderly community dwelling adults for her study.

If you have any queries please do not hesitate to contact me.

Yours sincerely,
Kathleen Mullane
Nurse Manager

Appendix 3a

Form 1

UNIVERSITY COLLEGE CORK Clinical Research Ethics Committee of the Cork Teaching Hospitals

PROTOCOL SUBMISSION FORM

All items must be completed as indicated; incomplete applications will be returned. A protocol application must include:

1. Protocol Submission Form (pages 1-4) – **Original and seven copies. Original must be signed by the Chief Investigator. There can only be one Chief Investigator and he/she must be a Consultant or Member of Faculty. Hand written forms will not be accepted.**
2. Consent Form (the standard Ethics Committee format) – **Eight copies.**
3. Detailed Protocol including instruments involved – **Eight Copies,**
4. Details of insurance policies in place to cover the study.
5. Curriculum Vitae of Chief Investigator (2 page document only) - **One copy.**

The complete application package must be received in the Ethics Committee office prior to or before 4.30pm on the deadline date in order to ensure review the next month. The Ethics Committee office is located at Lancaster Hall, 6 Little Hanover Street, Cork. The telephone number is (021) 4901901 and fax number is (021) 4901919. **Replies will be sent to the Study Chief Investigator.**

Chief Investigator

Name of Chief Investigator: Ms. Liz O'Sullivan

Appointment: Physiotherapy Manager

Department: Physiotherapy Department,

Office Address: Physiotherapy Department, Coolnagarrane, Hospital Grounds, Skibbereen, Co. Cork

Telephone No : 021 4923415

Protocol Details

Protocol Number (if applicable):

Protocol Title: To investigate the concurrent validity of the 7-item BBS-3P with other clinical measures of balance in elderly community dwelling adults.

Site(s) of Performance: Kerry General Hospital, Tralee, Co. Kerry; Community Nursing Unit, Tralee, Co. Kerry; Blackrock Hall, Mahon Primary Care Centre, Mahon, Co. Cork; Kinsale Community Hospital, Kinsale, Co. Cork and Turners Cross Day Care Centre, Turners Cross, Co. Cork

Co-investigators

Only the co-investigators listed may perform the procedures indicated on this protocol. They may NOT amend the protocol.

Names & Appointments:

Co-Investigator: Sinéad Considine, Physiotherapist, Health Services Executive (HSE), Cork South Lee Community

Project Supervisor: Dr. Helen French, Lecturer in Physiotherapy, Royal College of Surgeons in Ireland, 123 St. Stephens Green, Dublin 2. Telephone: 01 4022258

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Is this protocol part of an active or pending externally funded project: Yes ☐ No ☒

If yes, complete the following:

Names of Agency/Sponsor:
Address of Agency/Sponsor:
Title of Grant Proposal:
Does the Chief Investigator personally gain financially from this study: Yes <input type="checkbox"/> No <input type="checkbox"/>
Are there any additional cost implications for the hospital management beyond standard of care:
Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes please specify

SPECIAL CONSIDERATIONS

Is this study is part of a **multi-centre** project: Yes ☐ No ☒

Does this study involve **laboratory/clinical procedures** NOT part of ordinary management: Yes ☐ No ☒

Does this study involve the clinical experimental use of **radiation or radioisotopes**: Yes ☐ No ☒

Does this study involve the use of **biohazardous or infectious radioisotopes**: Yes ☐ No ☒

If yes, please explain:

Are human subjects from the following **special population(s)** involved in this study: *Tick where appropriate*

Infants (<1 Year)	<input type="checkbox"/>	Children(1-17 years)	<input type="checkbox"/>
Elderly (>59 years)	<input checked="" type="checkbox"/>	Pregnant Women	<input type="checkbox"/>
Prisoners	<input type="checkbox"/>	Mentally Disabled	<input type="checkbox"/>
Mentally Retarded	<input type="checkbox"/>	None of these	<input type="checkbox"/>

No investigator shall recruit from a student group where he/she, or any of the co-investigators, have material influence over the assessment of academic performance of that student group.

PRECODED STUDY DESCRIPTION For each of the categories below, please select the item(s) which best describe(s) your study. You may tick up to two items for each category.

Type of study:

Behavioural-Social	<input type="checkbox"/>	Compassionate	<input type="checkbox"/>	Descriptive	<input type="checkbox"/>
Diagnostic	<input type="checkbox"/>	Educational	<input checked="" type="checkbox"/>	Epidemiologic	<input type="checkbox"/>
Preventive	<input type="checkbox"/>	Therapeutic	<input type="checkbox"/>		

Other: _____

Organ System(s):

Not Applicable	<input type="checkbox"/>	Breast	<input type="checkbox"/>	Cardiovascular	<input type="checkbox"/>
Dermatologic	<input type="checkbox"/>	Endocrine/Metabolic	<input type="checkbox"/>	Gastrointestinal/Hepatic	<input type="checkbox"/>
Haematologic	<input type="checkbox"/>	Musculo-skeletal	<input checked="" type="checkbox"/>	Neurologic	<input type="checkbox"/>
Ophthalmologic	<input type="checkbox"/>	Otolaryngologic	<input type="checkbox"/>	Pulmonary	<input type="checkbox"/>
Renal	<input type="checkbox"/>	Reproductive	<input type="checkbox"/>	Urinary tract	<input type="checkbox"/>

Cells, blood, other body fluids or tissues only ☐

Other : _____

Type of Disorder:

Not Applicable	<input checked="" type="checkbox"/>	Congenital	<input type="checkbox"/>	Degenerative	<input type="checkbox"/>
Infectious	<input type="checkbox"/>	Immunologic	<input type="checkbox"/>	Malignant	<input type="checkbox"/>
Metabolic/Endocrine	<input type="checkbox"/>	Normal Physiologic	<input type="checkbox"/>	Psychiatric	<input type="checkbox"/>
		Traumatic	<input type="checkbox"/>		

Other : _____

Type of Drug/Device:

Not Applicable	<input checked="" type="checkbox"/>	Analgesics	<input type="checkbox"/>	Anaesthetics	<input type="checkbox"/>
Anti-asthma/allergy	<input type="checkbox"/>	Anticoagulant	<input type="checkbox"/>	Anti-infectives	<input type="checkbox"/>
Anti-inflammatory/Anticonvulsants	<input type="checkbox"/>	Biologicals/Vaccines	<input type="checkbox"/>	Blood Components	<input type="checkbox"/>
Cardiovascular/Antihypertensive	<input type="checkbox"/>	Chemotherapeutic Agents	<input type="checkbox"/>	Contraceptives	<input type="checkbox"/>
Contrast Media	<input type="checkbox"/>	Dermatologics	<input type="checkbox"/>	Diagnostics	<input type="checkbox"/>
Hormones	<input type="checkbox"/>	Immunosuppressives	<input type="checkbox"/>	Vitamins	<input type="checkbox"/>

Sedatives/Antidepressants/Tranquilizers ☐ Other: _____

Purpose of Investigation: Research has shown that impaired balance is a major factor associated with falls, fear of falling, disability, institutionalisation and death. One in three people over the age of 65 and 1 in 2 people over 85 years fall every year in Ireland (National Steering Group, 2008). Two-thirds of people over 65 years fall again within 6 months and the burden of falls and related injuries could double over the next 25 years as Ireland's population ages (National Steering Group, 2008). This places an increasing demand and cost on the public health system. It is estimated that the current yearly economic cost of falls in older people is ~€400 million which could increase to €2 billion in the next 25 years unless effective falls prevention strategies are implemented (National Steering Group, 2008). It is therefore of upmost importance that balance deficits are identified early and treated effectively. A psychometrically sound balance assessment instrument is useful to ascertain balance performance of older adults, monitor changes in performance and identify those at risk of deterioration early and treat accordingly. The Berg Balance Scale (BBS) was originally developed to assess balance performance in geriatric people (Berg et al, 1989). The BBS consists of 14 items of static and functional tasks scored on a 5 point scale and total score is out of 56, with higher scores indicating better balance. Wang et al (2004), developed a modified 3-level 14-item BBS (BBS-3P) and compared it to the original BBS in people with stroke and it was found that the psychometric properties of the BBS-3P were comparable to the non-truncated scale. However, the BBS takes approximately 20 minutes to complete and the high internal consistency of the BBS as found by a Cronbach α co-efficient of 0.98, indicated some item redundancy (Mao et al, 2002). Therefore, Chou et al, (2006), developed further simplification of this measure which included a reduction of items tested and a reduction in levels of scaling. The authors found that the 7-item 3-level BBS (7-item BBS-3P) was simpler and faster to complete and may be used interchangeably with the original BBS in people with stroke as they were psychometrically similar. It only requires basic training and minimal equipment and is less time consuming for both the clinician and patient in a busy clinical environment. However, the relationship between the 7-item BBS-3P and balance is not well researched. Studies to date have only assessed the 7-item BBS-3P in stroke (Wang et al, 2004; Chou et al, 2006, Liaw et al, 2012). No study has investigated the use of the 7-item BBS-3P in elderly community dwelling adults. Therefore, the purpose of this study is to investigate the concurrent validity of the 7-item BBS-3P with other clinical measures of balance in elderly community dwelling adults.

Procedures to which humans will be subjected: Participants will undergo a one-off assessment. Firstly they will be screened for cognitive impairment using the Mini Mental State Exam (MMSE). Participants scoring less than 24 will be excluded as scores below 24 indicate cognitive impairment (Tombaugh and McIntyre, 1992). Written informed consent will be obtained from those who have satisfied the inclusion and exclusion criteria and data collection will include gender, height, weight, age, medical and medication history, residential status and three balance outcome measures. Volunteers will be advised that participation is entirely voluntarily and withdrawal is permitted at any time, without having to give a reason and without any personal consequence. Recruitment and testing will take place in the following out patient physiotherapy departments: Kerry General Hospital (KGH), Tralee, Co. Kerry; Community Nursing Unit (CNU), Tralee, Co. Kerry; Mahon Primary Care Centre, Blackrock Hall, Mahon, Co. Cork; Kinsale Community Hospital, Kinsale, Co. Cork and Turners Cross Day Care Centre, Turners Cross, Co. Cork. Participants will be asked to attend on a single occasion and all balance assessments will be conducted on that day, lasting approximately an hour in total. Two assessors will be involved in the study: first assessor will collect the data and the second assessor will total up the score results to eliminate any recall bias from the first assessor. Three balance outcome measures will be used: Berg Balance Score (BBS), 7-item BBS-3P and Mini BESTest. All balance tests will be performed in a randomised order according to standardised procedures and instructions. The BBS consists of 14 items of static and functional tasks and it measures the participant's ability to maintain their balance during static postures or while performing various functional movements for a specified duration of time (Blum and Korner-Bitensky, 2008). The items range in difficulty from sitting unsupported for two- minutes to standing on one foot for ten seconds. Scoring criteria is graded on a 5 point scale (0-1-2-3-4): 0=unable to perform; 4=able to perform independently. Total score is out of 56, with higher scores indicating better balance and it takes approximately 20 minutes to administer.

Procedures to which humans will be subjected continued: The 7-item BBS-3P is also a functional based performance measure and it consists of 7 items from the original BBS: reaching forward with outstretched arm, standing with eyes closed, standing with one foot in front, turning to look behind, retrieving object from floor, standing on 1 foot, sitting to standing (Chou et al, 2006). Scoring criteria has been collapsed from 5 levels (0-1-2-3-4) to 3 levels (0-1-2). Total score is out of 14, with higher scores indicating better balance and it takes less than 10 minutes to administer.

The Mini-BESTest is a 14-item comprehensive balance test developed to identify postural control systems that underlie poor functional balance (Franchiogni et al, 2010). It measures transitions and anticipatory postural adjustments, responses to external perturbations, sensory orientation & stability in gait. Scoring criteria is graded 0 (unable to perform or requires help) to 2 (normal performance), total score is out of 28 with higher scores indicating better balance and it takes approximately 15 minutes to complete.

Potential benefits to subjects and/or society: There will be no direct benefit to the participants taking part however if the 7-item BBS-3P is found to be valid, it may be of benefit to the physiotherapist in assessing an elderly person's balance and also be of benefit to the person that is being tested in helping to identify their falls risk and focus treatment on specific balance domains within the assessment measure. The 7-item BBS-3P takes less than 10 minutes to complete allowing for time efficient assessment of balance in a busy clinical setting.

Potential risks to subjects and precautions taken to minimise risk: There is a minimal risk that a participant may lose their balance and fall during testing. However, the participants will be supervised at all times and testing will be conducted in a safe environment. Participants will also be asked to wear a safety belt around their waist during the balance tests in the event they fall and need guidance towards the floor. In the unlikely event that a participant falls, the Chief Investigator and the patient's GP will be notified and the appropriate medical attention obtained if required. Rest periods will also be provided as required by the participant. The participant's cognition will also be assessed to ascertain that they are able to understand and follow instructions. Participants will also be screened for exclusion criteria to identify any medical conditions that may affect their balance or compromise their health status during testing.

Alternative procedures, if any, available to subjects: Not Applicable

Subjects: A convenience sample of 30 community-dwelling elderly participants will be required for the study. Volunteers will be recruited through local advertisements (poster and verbal), in physiotherapy out-patient departments (OPD) in: Kerry General Hospital (KGH), Tralee, Co. Kerry, Community Nursing Unit (CNU), Tralee, Co. Kerry, Mahon Primary Day Care Centre, Blackrock Hall, Mahon, Co. Cork, Kinsale Community Hospital, Kinsale, Co. Cork and Turners Cross Day Care Centre, Turners Cross, Co. Cork. Testing will take place in physiotherapy OPD in: KGH, Tralee, Co. Kerry, CNU, Tralee, Co. Kerry, Mahon Primary Day Care Centre, Blackrock Hall, Mahon, Co. Cork, Kinsale Community Hospital, Kinsale, Co. Cork and Turners Cross Day Care Centre, Turners Cross, Co. Cork. Inclusion criteria: Aged 65 years or older, living at home, independently mobile \pm walking stick > 6 meters and ≥ 24 on the MMSE. Exclusion criteria: unstable cardiac conditions, unstable hypertension (HTN) or Orthostatic hypotension that may affect the safety of the participant's health status during testing; Cerebrovascular Accident (CVA) or Peripheral Neuropathy as residual weakness or decreased sensitivity may affect balance, Total Hip Replacement, recent lower limb fractures and less than 90° shoulder flexion, as 90° is required to complete the functional reach test in the BBS.

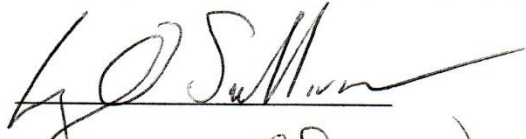
Will there be payment to subjects? Yes ☐ No ☒ If Yes how much? _____
If so, how much?

Methods used to ensure confidentiality of data: All information obtained will be kept anonymous and confidential by assigned identification numbers on all data recording sheets. Data recording sheets will only have a study identification number located on them. Information obtained from the data recording sheets will be imputed onto excel spreadsheets for statistical analysis via SPSS (a statistical computer package) on a password protected laptop. All data will remain confidential. Data recording sheets and the password protected laptop will be stored securely in a locked drawer in the physiotherapy department only accessible to the principal investigator: Sinéad Considine. Data will be stored securely for 5 years upon which it will be destroyed.

Declaration of the Chief Investigator

I certify that the protocol and method of obtaining informed consent as approved by the Ethics Committee will be followed during the period of this research project. Any changes of protocol, PI or consent will be submitted for Ethics Committee review and approval prior to implementation. Any adverse reactions will be promptly reported to the Ethics Committee office. This research will be carried out only by the approved Chief Investigator and co-investigators. All records of this research will be maintained as required by the Department of Health & Children.

Signature Chief Investigator:



Print Name:

Liz O'Sullivan

Date: (dd/mm/yyyy)

13/09/13

UNIVERSITY COLLEGE CORK

Clinical Research Ethics Committee Of The Cork Teaching Hospitals

AMENDMENT SUBMISSION FORM

When any revision to an approved research protocol, written consent form and/or advertisement for subject recruitment is desired, an amendment must be filed with the Ethics Committee. The amendment submission form must be completed indicating the changes; revisions may be within the protocol itself, the written consent form or the advertisement. The form should explain what changes have been made and the rationale for the change. Eight copies of the revised pertinent original documents (protocol, consent form, and/or advertisement) with new version numbers should also be submitted with the changes identified using a highlighter pen. A cover letter or additional information may also be attached, as necessary.

Amendments to approved protocols may not be initiated until Ethics Committee approval has been obtained, except when necessary to eliminate apparent immediate hazards to the subject. Amendments usually require full Board review at the scheduled monthly meetings; therefore, the submission deadlines must be met. The Ethics Committee reserves the right to determine whether proposed changes are substantive and to request further information or a new protocol submission, as appropriate. **The title on the amendment must be exactly the same as the title on the original submission.**

Chief Investigator: Ms. Liz O'Sullivan

Department: Physiotherapy Department, Coolnagarrane, Hospital Grounds, Skibbereen, Co. Cork

Protocol Title: To investigate the concurrent validity of the 7-item BBS-3P with other clinical measures of balance in elderly community dwelling adults.

The following changes are proposed for this protocol:

Chief Investigator	<input type="checkbox"/>	Co-investigator(s)	<input type="checkbox"/>
Dosage	<input type="checkbox"/>	Treatment Procedures	<input type="checkbox"/>
Drug/Device	<input type="checkbox"/>	Study Population	<input type="checkbox"/>
Number of Subjects	<input type="checkbox"/>	Risks	<input type="checkbox"/>
Advertisement	<input type="checkbox"/>	Editorial Corrections	<input checked="" type="checkbox"/>
Other	<u>Project Supervisor</u>		

Is a revised protocol necessary as a result of this amendment?
If yes, please attach a revised protocol to this amendment.

Yes ☐ No ☒

Is a revised consent form necessary as a result of this amendment?
If yes, please attach a revised consent form to this amendment.

Yes ☒ No ☐

Is a revised advertisement necessary as a result of this amendment?
If yes, please attach a revised advertisement to this amendment.

Yes ☐ No ☒

Please list the specific changes from the previously approved protocol and provide sufficient rationale for each change to allow the committee to make a decision. Use additional pages as necessary.

1. Other: Project Supervisor

This research module is being undertaken by Co-Investigator: Sinead Considine as part of an MSc in Neurology and Gerontology, Royal College of Surgeons in Ireland (RCSI), 123 St. Stephen's Green, Dublin 2.

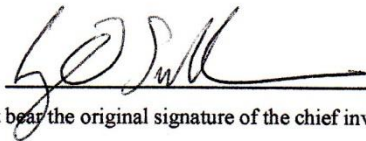
As the project supervisor for this research module in the RCSI, an amendment is to be submitted requesting that Dr. Helen French, Lecturer in Physiotherapy, Royal College of Surgeons in Ireland (RCSI), 123 St. Stephen's Green, Dublin 2 be included on the protocol amendment submission form, Participant Information Leaflet and Consent Form.

If this application is successful, the study protocol would therefore consist of Dr. Helen French as the Project Supervisor, Ms. Sinead Considine as the Co-Investigator and Ms. Liz O'Sullivan as the Chief Investigator.

2. Editorial Corrections (Patient Information Leaflet)

This study will take place from November 2013 to March 2014.

Investigator



(This form must bear the original signature of the chief investigator)

Date

22/1/14

Appendix 4a



Tel: + 353-21-490 1901
Fax: + 353-21-490 1919

Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

COISTE ÉITICE UM THAIGHDE CLINICIUIL **Clinical Research Ethics Committee**

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

Our ref: ECM 3 (jj) 03/12/13

15th November 2013

Ms Liz O'Sullivan
Physiotherapy Manager
Coolnagarrane
Hospital Grounds
Skibbereen
Co Cork

Re: To investigate the concurrent validity of the 7-item BBS-3P with other clinical measures of balance in elderly community dwelling adults.

Dear Ms O'Sullivan

The Chairman approved the following:

- Revised Application Form
- Revised Patient Information Leaflet
- Revised Consent Form

I acknowledge receipt of a letter dated 25th November 2013 from Sinead Considine, the co-investigator involved in this study. In the letter Sinead seems unhappy with our requests for amendments and with what she refers to as the lack of progress regarding ethical approval. On this, I would like to point out that all of the changes required were requested in our letter dated 23rd September 2013. Had we received all of those amendments in the November submission, full approval to begin the research would have been granted on November 15th. I am sure you will appreciate that we cannot approve any document which may be misleading to a study participant.

It appears that Sinead did not understand our request to change the wording of the following sentence "***I am aware of the potential risks of this research study and that if I fall during this study that my GP will be contact on my behalf***". I apologise for the lack of clarity but I presumed that on reading it again the error would be immediately apparent and therefore did not feel the need to have to point out that the sentence should read "I am aware of the potential risks of this research study and that if I fall during this study that my GP will be **contacted** on my behalf".

Full approval is now granted to begin this study and I wish Sinead the best of luck with the research.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant

Appendix 4b



Tel: + 353-21-490 1901
Fax: + 353-21-490 1919

Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

COISTE EITICE UM THAIGHDE CLINICIÚIL Clinical Research Ethics Committee

Lancaster Hall,
6 Little Hanover Street,
Cork,
Ireland.

4th February 2014

Our ref: ECM 3 (jj) 04/03/14

Ms Liz O'Sullivan
Physiotherapy Manager
Coolnagarrane
Hospital Grounds
Skibbereen
Co Cork

Re: To investigate the concurrent validity of the 7-item BBS-3P with other clinical measures of balance in elderly community dwelling adults.

Dear Ms O'Sullivan

The Chairman approved the following:

- Revised Study Protocol Version 2.

Full approval is now granted to begin this study.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.

Appendix 5



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Participant Information Leaflet



Study Title

To investigate the concurrent validity of the 7-item BBS 3P with other clinical measures of balance in elderly community dwelling adults

Chief Investigator: Ms. Liz O'Sullivan
Physiotherapy Manager, Coolnagarrane, Hospital Grounds, Skibbereen, Co. Cork
Telephone: 021 4923415

Co-Investigator: Sinéad Considine,
Physiotherapist in Kinsale Community Hospital, Kinsale, Co. Cork/ MSc student in
Neurology and Gerontology, Royal College of Surgeons in Ireland (RCSI)
Telephone: 021 4777180 (work); 087 9476150 (mobile)

Project Supervisor: Dr. Helen French,
Lecturer in Physiotherapy, Royal College of Surgeons in Ireland, 123 St. Stephen's Green,
Dublin 2.
Telephone: 01 4022258

You are being invited to take part in a clinical research study which is taking place in the Health Service Executive (HSE) regions of Cork South Lee and Kerry as part of an MSc in Physiotherapy at RCSI. You will be invited to attend one location in Co. Cork or Co. Kerry. You may decide to attend Kinsale Community Hospital/Turners Cross Day Care Centre/Blackrock Hall Primary Care Centre in Co. Cork or Kerry General Hospital, Tralee in Co. Kerry for participation in this study. Please read this information leaflet carefully and if you wish you may discuss it with your GP, family or friends before deciding to take part. Please take the time to ask questions and do not feel rushed or obliged to make an immediate decision. You should clearly understand the risks and benefits of participating in this study so that you can make a decision that is right for you. This process is known as informed consent.

You are not obliged to take part in this study and if you decide not to take part, your treatment or future care at the hospital will not be affected in any way. Withdrawal is permitted at any time, to include before or during the study, without having to give a reason and without any personal consequence.

PIL V4

Why is this study being done?

People with reduced balance are at a higher risk of falls, particularly in the elderly because of decreased muscle strength and slower balance reactions. This group of people may be sent to a physiotherapist for assessment and treatment to help improve their balance and prevent falls. Part of the physiotherapist's assessment may involve the use of a measurement tool to identify those who are at risk of falls. The Berg Balance Scale (BBS) is currently used to assess an individual's level of balance. However, a quicker, short version of this is available called the 7-item BBS-3P but it is not clear if it is useful for measuring balance for older people. Therefore, this study is being carried out to ascertain if this new balance assessment tool, the 7-item BBS-3P, will measure balance in the same way as the BBS.

Who is organising and funding this study?

Sinéad Considine, a physiotherapist in Kinsale Community Hospital is carrying out this study as part of a Masters in neurology and gerontology in the Royal College of Surgeons in Ireland and will be covering all costs. There is no funding for this study.

How will this study be carried out?

This study will take place from November 2013 to March 2014. If you agree to take part, you will be asked to attend the day care centre/physiotherapy department for a once off assessment of your balance which should take around 45-50 minutes. We will assess your ability to understand instructions and asked questions regarding your medical history that may affect your balance. You will also be asked your date of birth and any medications that you are taking. We will measure your height and weight and then the balance measurements will then be carried out.

What will happen to me if I agree to take part?

If you agree to take part, you will be asked to attend on one occasion and all measurements will be conducted that day. You will not have to re-attend on another day for testing. Ms. Sinéad Considine will contact you to make an appointment at a time that is convenient for you. You will be asked to wear comfortable clothing and footwear. Balance will then be measured using three tests:

Berg Balance Scale (BBS): this contains 14 tests of balance which range in difficulty from sitting with no back support to standing on one leg for ten seconds.

7-item BBS-3P: this contains 7 tests of balance ranging in difficulty from standing from a sitting position to standing on one leg for ten seconds

Mini-BESTest: this contains 14 tests of balance that range from standing from a sitting position to standing on a soft surface with your eyes closed.

You will be supervised to ensure your safety at all times during testing. Your balance results will be sent to your GP.

Benefits

There is no direct benefit to you for participating in this study however the results may help others who have balance impairments in the future. It may allow physiotherapists to use a test that takes less time to perform. This would mean less of the patients' time also.

Risks

There is a minimal risk that you may lose your balance and fall during testing. However, you will be supervised at all times and testing will be done in a safe environment. You will also be asked to wear a safety belt around your waist during the balance tests.

Confidentiality issues

Your information will remain confidential and anonymous. Your name, personal information and results will be given a code number. This is done to protect your identity of which will only be known to the co-investigator. Data and the code number without the participants name will be transferred to a computer statistical package. Data will remain confidential and securely stored on a password protected computer for 5 years upon which it will be destroyed.

What if something goes wrong?

If you fall or experience any health related issue during the study you will receive the appropriate medical attention and your GP will be contacted.

If you require further information?

If you have any further questions about the study or should you wish to withdraw from the study, you may do so without any personal consequence or justification of your decision.

For any additional information, please contact:

Sinéad Considine
Address: Physiotherapy Department,
Kinsale Community Hospital,
Kinsale,
Co. Cork
Phone: 0667184280

Ms. Liz O'Sullivan
Physiotherapy Manager,
Coolnagarrane,
Hospital Grounds
Skibbereen,
Co. Cork
Phone: 021 4923415
Co. Cork

Dr. Helen French,
Lecturer in Physiotherapy,
Royal College of Surgeons in Ireland,
123 St. Stephen's Green,
Dublin 2.
Telephone: 01 4022258

Appendix 6



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Consent Form



Project Title

To investigate the concurrent validity of the 7-item BBS-3P with other clinical measures of balance in elderly community dwelling adults

Chief Investigator: Ms. Liz O'Sullivan, Physiotherapy Manager, Coolnagarrane, Hospital Grounds, Skibbereen, Co. Cork. Telephone: 021 4923415

Co-Investigator: Sinéad Considine, Physiotherapy Department, Kinsale Community Hospital, Kinsale, Co. Cork. Telephone: 021 4777180

Project Supervisor: Dr. Helen French, Lecturer in Physiotherapy, Royal College of Surgeons in Ireland, 123 St. Stephen's Green, Dublin 2. Telephone: 01 4022258

Please tick the appropriate answer:

I confirm that I have read and understood the participant information leaflet dated _____ attached, and that I have had ample opportunity to ask questions, all of which have been satisfactorily answered. ☐ Yes ☐ No

I understand that my participation in this study is entirely **voluntary** and that I may withdraw at any time, without giving reason, and without this decision affecting my future treatment or medical care. ☐ Yes ☐ No

I understand that my information will remain confidential and anonymous. I understand that my name, personal information and results will be given a code number. This is done to protect my identity of which will only be known to the co-investigator. I understand that data will remain confidential and securely stored on a password protected computer for 5 years upon which it will be destroyed. ☐ Yes ☐ No

Consent Form V4

I am aware that if I fall or experience any health related issue during the study that I will receive the appropriate medical attention and my GP will be contacted.

☐ Yes

☐ No

I have been given a copy of the Patient Information Leaflet and this consent form for my records

☐ Yes

☐ No

Participant Signature: _____

Name in Block Capitals: _____

Date: _____

To be completed by the co-investigator:

I the undersigned have taken the time to fully explain to the above participant the nature and purpose of this study in a manner that he/she could understand. I have explained the test procedures, risks involved and possible benefits and have invited him/her to ask any questions on any aspect of the study that concerned him/her

Research Investigator Signature: _____

Name in Block Capitals: _____

Qualification: _____

Date: _____

Appendix 7

Data Collection Form

To investigate the concurrent validity of the 7-item BBS-3P with other clinical measures of balance in elderly community dwelling adults

Identification Code Number: _____

Date: _____

Demographics:

Age: _____

Gender: Male ☐ Female ☐

Weight: _____

Height: _____

Mobility: Independent ☐ Walking Stick ☐

PMHx: _____

Medications: _____

Outcome measurement scores

Mini Mental State Examination Score: _____ /30

Berg Balance Score: _____ /56

7-item BBS-3P: _____ /14

Mini-BESTest: _____ /28

Appendix 8

Physiotherapy Department,
Kinsale Community Hospital,
Kinsale,
Co. Cork
Date:

Dr. _____

Address: _____

Patient's name: _____

Patient's Address: _____

Dear Dr. _____,

My name is Sinéad Considine and I am a physiotherapist in Kinsale Community Hospital and Tuners Cross Day Care Centre (HSE – Cork South Lee). I am currently undertaking an MSc in Neurology and Gerontology at the Royal College of Surgeons in Ireland and I am conducting a study to investigate the validity of a shortened version of the Berg Balance Scale (BBS) known as the 7-item BBS-3P, with other clinical measures of balance in elderly community-dwelling adults. Balance outcome measures are frequently used by physiotherapists to assess the falls risk of a patient. The BBS includes 14 functional and static items scored on a 5-level scale, it takes approximately 20 minutes to administer and total score is out of 56 with higher scores indicating better balance. The 7-item BBS-3P includes 7 balance tasks scored on a 3-level assessment scale and it takes less than 10 minutes to complete, however the 7-item BBS-3P has yet to be validated in the elderly community dwelling population. The title of my study therefore is:

“To investigate the concurrent validity of the 7-item BBS-3P with other clinical measures of balance in elderly community dwelling adults”

I wish to advise you that your patient _____ has been recruited to the study.

Participation in this study involves screening for inclusion and exclusion criteria, obtaining medical and medication history, age, weight, height, gender, mobility status and balance. Collection of this data will take approximately 1 hour in total. I have 6 years' experience in conducting balance outcome measures and therefore I am competent in conducting them for this study. There is a minimal risk that the participant could fall during the assessment, however participants will be closely supervised during testing and will also be wearing a safety belt. In the event that something unexpected does happen during the study, you will be notified. Results of the participants balance outcome measures can be arranged to be sent to you for your records.

My contact e mail is sineadconsidine@rcsi.ie, work phone number: 021 4777180 and mobile: 087 9476150

My supervisor is Dr. Helen French, Lecturer in Physiotherapy, Royal College of Surgeons in Ireland. Telephone: 01 402 2258

If you have any further questions, please do not hesitate to contact me.

Yours Sincerely

Sinéad Considine (MISCP)

Appendix 9a



OCCUPATIONAL THERAPY DEPARTMENT

Participant Number: _____

Folstein Mini Mental State Examination (MMSE) Adapted by the Mercers Institute

CONSULTANT

		SCORE			
		Dates of Assessments			
1) Orientation (Max. Score = 10)		Day.....			
		Month.....			
		Date.....			
		Year.....			
		Town.....			
		Hospital.....			
		Floor/Ward.....			
		St. Patrick's Day.....			
		Taoiseach.....			
		President.....			
		Orientation Score /10	/ 10	/ 10	/ 10
2) Registration (Max. Score = 3)					
Say "Ball", "Flag" and "Tree" clearly and slowly for about 1 second each. After you have said all 3 words, ask the subject to repeat them. This first repetition determines the score (0-3) but keep saying them (up to 6 trials) until the subject can repeat all 3 words. If he/ she does not eventually learn all 3, recall cannot be meaningfully tested.		Ball			
		Flag			
		Tree			
		Registration Score /3	/ 3	/ 3	/ 3
		Record No. of Trials _____	_____	_____	_____
3) Attention and Calculation (Max. Score = 5)					
(A) Ask the subject to begin at 100 and count backwards by 7. Stop after 5 subtractions (93, 86, 79, 72, 65). Score 1 point for each correct no.		93, 86, 79, 72, 65			
		Score /5	/ 5	/ 5	/ 5
OR		OR	OR	OR	OR
(B) Ask the subject to spell the word "world" backwards. The score is 1 point for each correctly placed letter e.g. DLROW = 5: DLWOR = 3. Record how the subject spelled the word backwards.		_____			
		Attn./ Calcn. Score /5	/ 5	/ 5	/ 5
4) Recall (Max. Score = 3)					
Ask the subject to recall the 3 words you previously asked him/ her to remember.		Ball / Flag / Tree			
		Recall Score /3	/ 3	/ 3	/ 3

Participant Number: _____

SUBTOTAL Assessment Dates		/ 21	/ 21	/ 21	/ 21
5) Language and Parietal Functions (Max. score = 9)					
<p>Naming: Show the subject a wrist watch and ask "what is this?" Repeat for pencil. 1 point for each item named correctly.</p> <p>Repetition: Ask the subject to repeat "no ifs, ands or buts"</p> <p>3 Stage Command: Show the subject a piece of paper and say "take this paper in your right hand, fold it over in half and put it on the floor". Score 1 point for each action performed correctly.</p> <p>Reading: Ask the subject to read "close your eyes" and do what it tells you to do. Only score correct if he/she actually closes his/her eyes.</p> <p>Writing: On a blank piece of paper ask him/her to write a sentence. It must be written spontaneously. It must contain a subject and make sense. Correct grammar and punctuation are not necessary.</p> <p>Copying: Ask the subject to copy the intersecting pentagons. Ask the subject to copy it exactly as it is. All 10 angles must be Present and the 2 must intersect to score 1 point. Tremor and rotation are ignored.</p>	Watch / Pencil				
	Naming Score	/ 2	/ 2	/ 2	/ 2
	Repetition Score	/ 1	/ 1	/ 1	/ 1
	Takes in right hand Folds in half Puts on floor				
	3 Stage Command Score	/ 3	/ 3	/ 3	/ 3
	Closes his/her eyes				
	Reading Score	/ 1	/ 1	/ 1	/ 1
	Writes a sentence				
	Writing Score	/ 1	/ 1	/ 1	/ 1
	Draws pentagon.				
	Copying Score	/ 1	/ 1	/ 1	/ 1
Lang. / Parietal Subtotal		/ 9	/ 9	/ 9	/ 9
MMSE TOTAL		/ 30	/ 30	/ 30	/ 30

Please note age patient finished school _____
 Rate subjects level of consciousness Stupor _____ Drowsy _____ Alert _____
 Rate subjects level of motivation High _____ Medium _____ Low _____

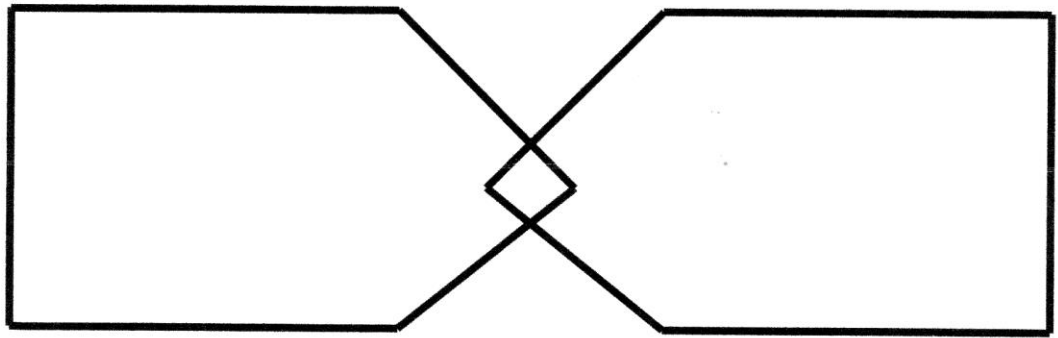
Interpretation of MMSE

Method	Score	Interpretation
Single Cut-off	<24	Abnormal
Range	<21	Increased odds of dementia
	>25	Decreased odds of dementia
Education	21	Abnormal for completing primary ed.
	<23	Abnormal for secondary ed.
	<24	Abnormal for 3 rd level ed.
Severity	24-30	Questionably significant
	20-25	Indicates mild impairment
	10-20	Indicates moderate impairment
	0-10	Indicates severe impairment

Print Name _____ Signature _____ Date: _____
 Print Name _____ Signature _____ Date: _____
 Print Name _____ Signature _____ Date: _____

Participant Number: _____

CLOSE YOUR EYES



Appendix 9b

Berg Balance Scale

Participant Number: _____ Date: _____

ITEM DESCRIPTION	SCORE (0-4)
Sitting to standing	_____
Standing unsupported	_____
Sitting unsupported	_____
Standing to sitting	_____
Transfers	_____
Standing with eyes closed	_____
Standing with feet together	_____
Reaching forward with outstretched arm	_____
Retrieving object from floor	_____
Turning to look behind	_____
Turning 360 degrees	_____
Placing alternate foot on stool	_____
Standing with one foot in front	_____
Standing on one foot	_____
Total	_____

GENERAL INSTRUCTIONS

Please demonstrate each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item.

In most items, the subject is asked to maintain a given position for a specific time. Progressively more points are deducted if:

- the time or distance requirements are not met
- the subject's performance warrants supervision
- the subject touches an external support or receives assistance from the examiner

Subject should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.

Equipment required for testing is a stopwatch or watch with a second hand, and a ruler or other indicator of 2, 5, and 10 inches (5, 12.5 and 25cm). Chairs used during testing should be a reasonable height. Either a step or a stool of average step height may be used for item # 12.

Berg Balance Scale

SITTING TO STANDING

INSTRUCTIONS: Please stand up. Try not to use your hand for support.

- () 4 able to stand without using hands and stabilize independently
- () 3 able to stand independently using hands
- () 2 able to stand using hands after several tries
- () 1 needs minimal aid to stand or stabilize
- () 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED

INSTRUCTIONS: Please stand for two minutes without holding on.

- () 4 able to stand safely for 2 minutes
- () 3 able to stand 2 minutes with supervision
- () 2 able to stand 30 seconds unsupported
- () 1 needs several tries to stand 30 seconds unsupported
- () 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL

INSTRUCTIONS: Please sit with arms folded for 2 minutes.

- () 4 able to sit safely and securely for 2 minutes
- () 3 able to sit 2 minutes under supervision
- () 2 able to sit 30 seconds
- () 1 able to sit 10 seconds
- () 0 unable to sit without support 10 seconds

STANDING TO SITTING

INSTRUCTIONS: Please sit down.

- () 4 sits safely with minimal use of hands
- () 3 controls descent by using hands
- () 2 uses back of legs against chair to control descent
- () 1 sits independently but has uncontrolled descent
- () 0 needs assist to sit

TRANSFERS

INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.

- () 4 able to transfer safely with minor use of hands
- () 3 able to transfer safely definite need of hands
- () 2 able to transfer with verbal cuing and/or supervision
- () 1 needs one person to assist
- () 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED

INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.

- () 4 able to stand 10 seconds safely
- () 3 able to stand 10 seconds with supervision
- () 2 able to stand 3 seconds
- () 1 unable to keep eyes closed 3 seconds but stays safely
- () 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER

INSTRUCTIONS: Place your feet together and stand without holding on.

- () 4 able to place feet together independently and stand 1 minute safely
- () 3 able to place feet together independently and stand 1 minute with supervision
- () 2 able to place feet together independently but unable to hold for 30 seconds
- () 1 needs help to attain position but able to stand 15 seconds feet together
- () 0 needs help to attain position and unable to hold for 15 seconds

Berg Balance Scale continued.....

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING

INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

- () 4 can reach forward confidently 25 cm (10 inches)
- () 3 can reach forward 12 cm (5 inches)
- () 2 can reach forward 5 cm (2 inches)
- () 1 reaches forward but needs supervision
- () 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION

INSTRUCTIONS: Pick up the shoe/slipper, which is place in front of your feet.

- () 4 able to pick up slipper safely and easily
- () 3 able to pick up slipper but needs supervision
- () 2 unable to pick up but reaches 2-5 cm(1-2 inches) from slipper and keeps balance independently
- () 1 unable to pick up and needs supervision while trying
- () 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING

INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.

- () 4 looks behind from both sides and weight shifts well
- () 3 looks behind one side only other side shows less weight shift
- () 2 turns sideways only but maintains balance
- () 1 needs supervision when turning
- () 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES

INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.

- () 4 able to turn 360 degrees safely in 4 seconds or less
- () 3 able to turn 360 degrees safely one side only 4 seconds or less
- () 2 able to turn 360 degrees safely but slowly
- () 1 needs close supervision or verbal cuing
- () 0 needs assistance while turning

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED

INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touch the step/stool four times.

- () 4 able to stand independently and safely and complete 8 steps in 20 seconds
- () 3 able to stand independently and complete 8 steps in > 20 seconds
- () 2 able to complete 4 steps without aid with supervision
- () 1 able to complete > 2 steps needs minimal assist
- () 0 needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT

INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)

- () 4 able to place foot tandem independently and hold 30 seconds
- () 3 able to place foot ahead independently and hold 30 seconds
- () 2 able to take small step independently and hold 30 seconds
- () 1 needs help to step but can hold 15 seconds
- () 0 loses balance while stepping or standing

STANDING ON ONE LEG

INSTRUCTIONS: Stand on one leg as long as you can without holding on.

- () 4 able to lift leg independently and hold > 10 seconds
- () 3 able to lift leg independently and hold 5-10 seconds
- () 2 able to lift leg independently and hold ≥ 3 seconds
- () 1 tries to lift leg unable to hold 3 seconds but remains standing independently.
- () 0 unable to try of needs assist to prevent fall

() TOTAL SCORE (Maximum = 56)

Appendix 9c

7-Item - Berg Balance Scale – 3 Points (7-Item BBS-3P)

Department of Physiotherapy

Participant Number:	CHI:
Physiotherapist (Signature & PRINT)	
Diagnosis	Ward/Location
	Consultant/GP

ITEM DESCRIPTION

DATE

1. SITTING TO STANDING

Able to stand without using hands and stabilise independently	2					
Able to stand using hands after several tries	1					
Needs moderate or maximal assistance to stand	0					

6. STANDING UNSUPPORTED WITH EYES CLOSED

Able to stand for 10 seconds safely	2					
Able to stand for 3 seconds	1					
Needs help to keep from falling	0					

8. REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING

Can reach forward confidently >25cm (10")	2					
Can reach forward safely >5cm (2")	1					
Loses balance while trying / requires external support	0					

9. PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION

Able to pick up slipper safely and easily	2					
No pick up but 2-5cm (1-2") from slipper keeping balance independently	1					
Unable to try/needs assistance to keep from losing balance or falling	0					

10. TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING

Looks behind from both sides and weight shifts well	2					
Turns sideways only but maintains balance	1					
Needs assistance to keep from losing balance or falling	0					

13. STANDING UNSUPPORTED ONE FOOT IN FRONT

Able to place foot in tandem independently and hold for 30 seconds	2					
Able to take small step independently and hold for 30 seconds	1					
Loses balance while stepping or standing	0					

Indicate which foot is in front

Left						
Right						

14. STANDING ON ONE LEG

Able to lift leg independently and hold for >10 seconds	2					
Able to lift leg independently and hold for = or >3 seconds	1					
Unable to try or needs assistance to prevent fall	0					

Indicate which leg is lifted

Left						
Right						

Total Score (Maximum = 14)

Signature (Print)

Reference:

Chou C-Y, Chien C-W, Hsueh I-P, Sheu C-F, Wang C-H, Hsieh C-L (2006) Developing a Short Form of the Berg Balance Scale for People With Stroke. *Physical Therapy* 86(2), 195-204.

Appendix 9d

Mini-BESTest: Balance Evaluation Systems Test

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ANTICIPATORY

SUB SCORE: /6

1. SIT TO STAND

Instruction: "Cross your arms across your chest. Try not to use your hands unless you must. Do not let your legs lean against the back of the chair when you stand. Please stand up now."

(2) Normal: Comes to stand without use of hands and stabilizes independently.

(1) Moderate: Comes to stand WITH use of hands on first attempt.

(0) Severe: Unable to stand up from chair without assistance, OR needs several attempts with use of hands.

2. RISE TO TOES

Instruction: "Place your feet shoulder width apart. Place your hands on your hips. Try to rise as high as you can onto your toes. I will count out loud to 3 seconds. Try to hold this pose for at least 3 seconds. Look straight ahead. Rise now."

(2) Normal: Stable for 3 s with maximum height.

(1) Moderate: Heels up, but not full range (smaller than when holding hands), OR noticeable instability for 3 s.

(0) Severe: ≤ 3 s.

3. STAND ON ONE LEG

Instruction: "Look straight ahead. Keep your hands on your hips. Lift your leg off of the ground behind you without touching or resting your raised leg upon your other standing leg. Stay standing on one leg as long as you can. Look straight ahead. Lift now."

Left: Time in Seconds Trial 1: _____ Trial 2: _____

Right: Time in Seconds Trial 1: _____ Trial 2: _____

(2) Normal: 20 s.

(2) Normal: 20 s.

(1) Moderate: < 20 s.

(1) Moderate: < 20 s.

(0) Severe: Unable.

(0) Severe: Unable

To score each side separately use the trial with the longest time.

To calculate the sub-score and total score use the side [left or right] with the lowest numerical score [i.e. the worse side].

REACTIVE POSTURAL CONTROL

SUB SCORE: /6

4. COMPENSATORY STEPPING CORRECTION- FORWARD

Instruction: "Stand with your feet shoulder width apart, arms at your sides. Lean forward against my hands beyond your forward limits. When I let go, do whatever is necessary, including taking a step, to avoid a fall."

(2) Normal: Recovers independently with a single, large step (second realignment step is allowed).

(1) Moderate: More than one step used to recover equilibrium.

(0) Severe: No step, OR would fall if not caught, OR falls spontaneously.

5. COMPENSATORY STEPPING CORRECTION- BACKWARD

Instruction: "Stand with your feet shoulder width apart, arms at your sides. Lean backward against my hands beyond your backward limits. When I let go, do whatever is necessary, including taking a step, to avoid a fall."

(2) Normal: Recovers independently with a single, large step.

(1) Moderate: More than one step used to recover equilibrium.

(0) Severe: No step, OR would fall if not caught, OR falls spontaneously.

6. COMPENSATORY STEPPING CORRECTION- LATERAL

Instruction: "Stand with your feet together, arms down at your sides. Lean into my hand beyond your sideways limit. When I let go, do whatever is necessary, including taking a step, to avoid a fall."

Left

Right

(2) Normal: Recovers independently with 1 step (crossover or lateral OK).

(2) Normal: Recovers independently with 1 step (crossover or lateral OK).

(1) Moderate: Several steps to recover equilibrium.

(1) Moderate: Several steps to recover equilibrium.

(0) Severe: Falls, or cannot step.

(0) Severe: Falls, or cannot step.

Use the side with the lowest score to calculate sub-score and total score.

SENSORY ORIENTATION

SUB SCORE: /6

7. STANCE (FEET TOGETHER); EYES OPEN, FIRM SURFACE

Instruction: "Place your hands on your hips. Place your feet together until almost touching. Look straight ahead. Be as stable and still as possible, until I say stop."

Time in seconds: _____

(2) Normal: 30 s.

(1) Moderate: < 30 s.

(0) Severe: Unable.

8. STANCE (FEET TOGETHER); EYES CLOSED, FOAM SURFACE

Instruction: "Step onto the foam. Place your hands on your hips. Place your feet together until almost touching. Be as stable and still as possible, until I say stop. I will start timing when you close your eyes."

Time in seconds: _____

(2) Normal: 30 s.

(1) Moderate: < 30 s.

(0) Severe: Unable.

9. INCLINE- EYES CLOSED

Instruction: "Step onto the incline ramp. Please stand on the incline ramp with your toes toward the top. Place your feet shoulder width apart and have your arms down at your sides. I will start timing when you close your eyes."

Time in seconds: _____

(2) Normal: Stands independently 30 s and aligns with gravity.

(1) Moderate: Stands independently <30 s OR aligns with surface.

(0) Severe: Unable.

DYNAMIC GAIT

SUB SCORE: _____ / 10

10. CHANGE IN GAIT SPEED

Instruction: "Begin walking at your normal speed, when I tell you 'fast', walk as fast as you can. When I say 'slow', walk very slowly."

(2) Normal: Significantly changes walking speed without imbalance.

(1) Moderate: Unable to change walking speed or signs of imbalance.

(0) Severe: Unable to achieve significant change in walking speed AND signs of imbalance.

11. WALK WITH HEAD TURNS – HORIZONTAL

Instruction: "Begin walking at your normal speed, when I say 'right', turn your head and look to the right. When I say 'left' turn your head and look to the left. Try to keep yourself walking in a straight line."

(2) Normal: performs head turns with no change in gait speed and good balance.

(1) Moderate: performs head turns with reduction in gait speed.

(0) Severe: performs head turns with imbalance.

12. WALK WITH PIVOT TURNS

Instruction: "Begin walking at your normal speed. When I tell you to 'turn and stop', turn as quickly as you can, face the opposite direction, and stop. After the turn, your feet should be close together."

(2) Normal: Turns with feet close FAST (≤ 3 steps) with good balance.

(1) Moderate: Turns with feet close SLOW (≥ 4 steps) with good balance.

(0) Severe: Cannot turn with feet close at any speed without imbalance.

13. STEP OVER OBSTACLES

Instruction: "Begin walking at your normal speed. When you get to the box, step over it, not around it and keep walking."

(2) Normal: Able to step over box with minimal change of gait speed and with good balance.

(1) Moderate: Steps over box but touches box OR displays cautious behavior by slowing gait.

(0) Severe: Unable to step over box OR steps around box.

14. TIMED UP & GO WITH DUAL TASK [3 METER WALK]

Instruction TUG: "When I say 'Go', stand up from chair, walk at your normal speed across the tape on the floor, turn around, and come back to sit in the chair."

Instruction TUG with Dual Task: "Count backwards by threes starting at _____. When I say 'Go', stand up from chair, walk at your normal speed across the tape on the floor, turn around, and come back to sit in the chair. Continue counting backwards the entire time."

TUG: _____ seconds; Dual Task TUG: _____ seconds

(2) Normal: No noticeable change in sitting, standing or walking while backward counting when compared to TUG without Dual Task.

(1) Moderate: Dual Task affects either counting OR walking ($>10\%$) when compared to the TUG without Dual Task.

(0) Severe: Stops counting while walking OR stops walking while counting.

When scoring item 14, if subject's gait speed slows more than 10% between the TUG without and with a Dual Task the score should be decreased by a point.

TOTAL SCORE: _____ / 28

Mini-BESTest Instructions

Subject Conditions: Subject should be tested with flat-heeled shoes OR shoes and socks off.

Equipment: Temper® foam (also called T-foam™ 4 inches thick, medium density T41 firmness rating), chair without arm rests or whee incline ramp, stopwatch, a box (9" height) and a 3 meter distance measured out and marked on the floor with tape [from chair].

Scoring: The test has a maximum score of 28 points from 14 items that are each scored from 0-2.

"0" indicates the lowest level of function and "2" the highest level of function.

If a subject must use an assistive device for an item, score that item one category lower.

If a subject requires physical assistance to perform an item, score "0" for that item.

For **Item 3** (stand on one leg) and **Item 6** (compensatory stepping-lateral) only include the score for one side (the worse score).

For **Item 3** (stand on one leg) select the best time of the 2 trials [from a given side] for the score.

For **Item 14** (timed up & go with dual task) if a person's gait slows greater than 10% between the TUG without and with a dual task the score should be decreased by a point.

1. SIT TO STAND	Note the initiation of the movement, and the use of the subject's hands on the seat of the chair, the thighs, or the thrusting of the arms forward.
2. RISE TO TOES	Allow the subject two attempts. Score the best attempt. (If you suspect that subject is using less than full height, ask the subject to rise up while holding the examiners' hands.) Make sure the subject looks at a non-moving target 4-12 feet away.
3. STAND ON ONE LEG	Allow the subject two attempts and record the times. Record the number of seconds the subject can hold up to a maximum of 20 seconds. Stop timing when the subject moves hands off of hips or puts a foot down. Make sure the subject looks at a non-moving target 4-12 feet ahead. Repeat on other side.
4. COMPENSATORY STEPPING CORRECTION-FORWARD	Stand in front of the subject with one hand on each shoulder and ask the subject to lean forward (Make sure there is room for them to step forward). Require the subject to lean until the subject's shoulders and hips are in front of toes. After you feel the subject's body weight in your hands, very suddenly release your support. The test must elicit a step. NOTE: Be prepared to catch subject.
5. COMPENSATORY STEPPING CORRECTION - BACKWARD	Stand behind the subject with one hand on each scapula and ask the subject to lean backward (Make sure there is room for the subject to step backward.) Require the subject to lean until their shoulders and hips are in back of their heels. After you feel the subject's body weight in your hands, very suddenly release your support. Test must elicit a step. NOTE: Be prepared to catch subject.
6. COMPENSATORY STEPPING CORRECTION- LATERAL	Stand to the side of the subject, place one hand on the side of the subject's pelvis, and have the subject lean their whole body into your hands. Require the subject to lean until the midline of the pelvis is over the right (or left) foot and then suddenly release your hold. NOTE: Be prepared to catch subject.
7. STANCE (FEET TOGETHER); EYES OPEN, FIRM SURFACE	Record the time the subject was able to stand with feet together up to a maximum of 30 seconds. Make sure subject looks at a non-moving target 4-12 feet away.
8. STANCE (FEET TOGETHER); EYES CLOSED, FOAM SURFACE	Use medium density Temper® foam, 4 inches thick. Assist subject in stepping onto foam. Record the time the subject was able to stand in each condition to a maximum of 30 seconds. Have the subject step off of the foam between trials. Flip the foam over between each trial to ensure the foam has retained its shape.
9. INCLINE EYES CLOSED	Aid the subject onto the ramp. Once the subject closes eyes, begin timing and record time. Note if there is excessive sway.
10. CHANGE IN SPEED	Allow the subject to take 3-5 steps at normal speed, and then say "fast". After 3-5 fast steps, say "slow". Allow 3-5 slow steps before the subject stops walking.
11. WALK WITH HEAD TURNS-HORIZONTAL	Allow the subject to reach normal speed, and give the commands "right, left" every 3-5 steps. Score if you see a problem in either direction. If subject has severe cervical restrictions allow combined head and trunk movements.
12. WALK WITH PIVOT TURNS	Demonstrate a pivot turn. Once the subject is walking at normal speed, say "turn and stop." Count the number of steps from "turn" until the subject is stable. Imbalance may be indicated by wide stance, extra stepping or trunk motion.
13. STEP OVER OBSTACLES	Place the box (9 inches or 23 cm height) 10 feet away from where the subject will begin walking. Two shoeboxes taped together works well to create this apparatus.
14. TIMED UP & GO WITH DUAL TASK	Use the TUG time to determine the effects of dual tasking. The subject should walk a 3 meter distance. TUG: Have the subject sitting with the subject's back against the chair. The subject will be timed from the moment you say "Go" until the subject returns to sitting. Stop timing when the subject's buttocks hit the chair bottom and the subject's back is against the chair. The chair should be firm without arms. TUG With Dual Task: While sitting determine how fast and accurately the subject can count backwards by threes starting from a number between 100-90. Then, ask the subject to count from a different number and after a few numbers say "Go". Time the subject from the moment you say "Go" until the subject returns to the sitting position. Score dual task as affecting counting or walking if speed slows (>10%) from TUG and or new signs of imbalance.