The Concurrent Validity of the Dual-Task l-Test in Parkinson's Disease and its Predictive Ability in Identifying Falls

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THE CONCURRENT VALIDITY OF THE DUAL-TASK L-TEST IN PARKINSON'S DISEASE AND ITS PREDICTIVE ABILITY IN IDENTIFYING FALLS

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

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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 and 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

People with Parkinson's Disease (PD) often have difficulty completing dual-tasks due to reduced automaticity of movement, which consequently increases falls risk. Further outcome measures (OMs) are required to enable assessment of dual-task mobility.

Aims and Objectives

Primary aim: To establish the concurrent validity of the L-Test-MANUAL and L-Test-COGNITIVE with the TUG-MANUAL and TUG-COGNITIVE in participants with idiopathic PD. Secondary aim: To determine the predictive ability of the L-Test, L-Test-MANUAL and L-Test-COGNITIVE in identifying fallers.

Methods

Twenty-five patients with idiopathic PD were recruited to the study and categorised into faller (28%, n=7) or non-faller (72%, n=18) groups. Participants completed the following tests: L-Test-STANDARD, L-Test-MANUAL and L-Test-COGNITIVE, and TUG-STANDARD, TUG-MANUAL and TUG-COGNITIVE. Time taken to complete each of the tests was measured and dual-task cost (DTC) was calculated. Mean differences for fallers and non-fallers were calculated using independent t-tests or the Mann-Whitney U test. Spearman's Rank Order Correlation Coefficients were calculated to determine the relationship between the L-Test and TUG manual and cognitive dual-task conditions. Receiver operating characteristic (ROC) curve analyses with 95% CIs were used to describe model discrimination for each of the L-Test and

TUG conditions. The area under the curve (AUC), sensitivity and specificity values and cut-off scores were established for identifying fallers versus non-fallers.

Results

The L-Test-STANDARD, L-Test-MANUAL and L-Test-COGNITIVE correlated very strongly with the TUG-STANDARD, TUG-MANUAL and TUG-COGNITIVE (rho=0.94, $p<0.001$, rho=0.94, $p<0.001$ and rho-0.92, $p<0.001$ respectively). There was no significant difference between fallers and non-fallers in time taken to complete the tests ($p\leq0.05$) or in DTC scores ($p\leq0.05$). Inspection of boxplots and of 25^{th} and 75^{th} percentile scores provided no indication of either a ceiling or floor effect respectively. Univariate regression analysis demonstrated that none of the tests had the ability to distinguish between fallers and non-fallers ($p\leq0.05$). The L-Test and TUG single-task conditions had the greatest estimates of sensitivity (71.4% and 85.7% respectively) and specificity (72.2% and 61.1% respectively) in identifying falls risk. Cut-off scores were established for falls risk for the single-task L-Test (≤23 seconds) and the single-task TUG (≤9.2 seconds).

Conclusions

L-Test single and dual-task conditions were very strongly correlated with those of the TUG. There was no evidence of a ceiling effect for any of the tests this cohort of participants with mild-moderate PD. None of the L-Test or TUG conditions were able to distinguish between fallers and non-fallers.

Implications of Findings

The manual dual-task and cognitive-dual task L-Test conditions correlated very highly with the corresponding TUG conditions, indicating their suitability for use in PwP of mild-moderate disease severity in the assessment of dual-task mobility. However, none of the test conditions was able to distinguish between fallers and non-fallers in this study. Future studies with larger sample sizes and greater numbers of fallers are necessary to determine whether the L-Test dual-task conditions have the ability to identify fallers.

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LIST OF ABBREVIATIONS

AUC	Area under the curve
CI	Confidence Interval
CNS	Clinical Nurse Specialist
COSMIN	Consensus-based Standards for the selection of health status Measurement Instruments
CTT	Consecutive task-training group
DTC	Dual-task cost
DTD	Dual-task difficulty
DTI	Dual-task interference
DTT	Dual-task training
EPGPD	European Physiotherapy Guidelines for Parkinson's Disease
GDPR	General Data Protection Regulation
FICSIT-4	Frailty and Injuries Cooperative Studies of Intervention Techniques
HEA	Higher Education Authority
H&Y	Hoehn and Yahr
ICC	Intraclass Correlation Coefficient
IDT	Integrated dual-task training group
IQR	Inter-quartile range
MDC	Minimal Detectable Change
MMSE	Mini-Mental State Examination
N	Number
OM	Outcome measure
PI	Principal Investigator

PIL	Patient Information Leaflet
PD	Parkinson’s Disease
PwP	People with Parkinson’s Disease
QoL	Quality of life
RCSI	Royal College of Surgeons Ireland
RCT	Randomised clinical trial
REC	Research Ethics Committee
ROC	Receiver Operating Characteristic
SD	Standard deviation
SPSS	Statistical Package for the Social Sciences
TUG	Timed Up-and-Go
TUH	Tallaght University Hospital
UIN	Unique Identification Number
10MWT	10-metre walk test
2MWT	2-minute walk test

INTRODUCTION

Parkinson's Disease (PD) is the most common progressive, neuro-degenerative disorder second to Alzheimer's disease (Kalia and Lang, 2015). The classical parkinsonian motor symptoms of bradykinesia, rigidity, resting tremor, postural instability and gait impairment are well documented, arising due to dopamine depletion in the basal ganglia (Wu et al., 2015). While historically PD rehabilitation focused primarily on motor impairments, the condition is now increasingly recognised as heterogenous in nature, with clinically significant non-motor symptoms (Kalia and Lang, 2015). Cognitive impairment is an important non-motor symptom in PD which is consistently associated with falls (Canning et al., 2014; Evans et al., 2017) and there is increasing evidence for a link between cognitive impairment and mobility in PD (Allcock et al., 2009; Morris et al., 2017). Specifically, deficits in attention and executive function in PD are thought to increase falls risk (Allcock et al., 2009).

In daily life, tasks such as brushing teeth, driving, or walking while talking on the phone are performed 'automatically', requiring minimal cognitive resources, and are resistant to interference from outside stimuli (Wu et al., 2015). However, walking while performing a secondary, attention-demanding task necessitates divided attention and intact executive function (Swank and Criminger, 2020). The deficits in attention and executive function observed in PD are a consequence of reduced automaticity of movement, where automaticity is refers to the ability to perform a skilled movement without conscious attention or executive control (Cameron et al., 2010). Deficits in automaticity manifest in dual-task difficulty (DTD) and have been linked specifically to dopamine depletion in the striatum and disruption of parallel cortico-striatal circuits (Pessiglione et al., 2005). Dual-tasking in PD can exacerbate gait impairments

(Heinzel et al., 2016). Specifically, people with PD (PwP) demonstrate decreased step-width variability under dual-task conditions compared with healthy age-matched controls, leading to reduced balance reactions, and in turn, increased falls risk (Rochester et al., 2014). It has been estimated that over half of falls in PwP occur during dual-task activities (Bloem et al., 2006).

Falls are twice as common in PD as in the healthy ageing population (Chivers Seymour et al., 2019), leading to injury, loss of independence and reduced quality of life (QoL) (Allcock et al., 2009). Falls risk in PD increases with disease progression, particularly in the early to mid-stages of the condition, and the associated health-related consequences are severe (Duncan et al., 2015; Heinzel et al., 2016). Of those with PD identified as being at high falls risk, a large proportion will fall within the next six months (Duncan et al., 2015). Yet concerningly, falls prevention is often not addressed until later stages of PD, by which time falls have already occurred (Canning et al., 2014). However, the likelihood of successfully preventing falls is much higher in people with less severe disease, highlighting the pertinence of early consideration of falls prevention (Paul et al., 2016). Timely monitoring of gait and balance deterioration is a crucial aspect of falls prevention in PD (Paul et al., 2016), and a multi-factorial falls risk assessment is the gold-standard approach (Rochester et al., 2014).

A simple clinical falls prediction tool has recently been externally validated in PwP, based on falls history in the previous year, freezing of gait in the past month, and gait velocity <1.1m/s (Duncan et al., 2015). It is noteworthy that two of the three components of this tool are based on retrospective evaluation, highlighting patient

recall as the current standard of care in clinical practice (Van der Marck et al., 2014). The falls prediction tool can accurately discriminate future-fallers from non-fallers (area under-the-curve (AUC)=0.83; 95% CI=0.76 –0.89), however the authors highlight that this tool is not a comprehensive falls assessment, but rather serves as a starting point for further assessment (Duncan et al., 2015). This necessitates the development of robust outcome measures (OMs) which are quantifiable, modifiable and suitable to detect falls risk, and to inform therapeutic fall-prevention strategies (Heinzel et al., 2016).

Emerging evidence suggests that DTD in PD can be ameliorated through dual-task training (DTT) (Chomiak et al., 2017), improving motor skill retention in the short-term (Brauer and Morris, 2010) and longer-term (Strouwen et al., 2017). Early exercise intervention in particular can modify disease course and rate of progression (Frazzitta et al., 2015). This is encouraging given that currently available drug therapies for PD only treat the symptoms of the disease (Kalia and Lang, 2015). The European Physiotherapy Guidelines for PD (EPGPDs) recommend the implementation of DTT in clinical practice, particularly in early disease stages when motor symptoms are mild and there is greatest capacity for motor learning (Keus et al., 2014).

Robust dual-task OMs sufficiently sensitive to detect DTD are therefore necessary to evaluate the effects of DTT programmes (Haas et al., 2019). The Timed Up and Go (TUG) is a valid and reliable mobility assessment in PD, and the addition of a cognitive dual-task (TUG-COGNITIVE) has been shown to distinguish between fallers and non-fallers (Vance et al., 2015). The TUG has the advantage of being quick and easy to

administer, and consequently it is widely implemented in clinical practice. Despite its apparent simplicity, the combination of transferring and turning components results in a complex measure that also reflects cognitive resources (Herman et al., 2011). However, concerns have been raised that the TUG may not be sophisticated enough to effectively differentiate between people at different stages of the disease (Weiss et al., 2010). Potential limitations of the TUG will be elaborated upon in the Literature Review section of this thesis (Section 1.5). These factors may lead to a ceiling effect, requiring complex and often expensive instrumentation to overcome (Haas et al., 2019). These potential limitations of the TUG indicate a need for an alternate measure with the capacity to further increase dual-task challenge. This view is supported by a recent systematic review which highlighted the need for studies to examine the psychometric properties of alternate dual-task walking assessment tools, designed to accurately measure dual-task walking ability (Yang et al.,.2017). Moreover, research has identified a need for concurrent assessment of motor and cognitive dysfunction through assessment of dual-task mobility (Stegemoller et al., 2014).

CHAPTER 1 LITERATURE REVIEW

1.1 Overview of Dual-Task Difficulty and Falls in Parkinson's Disease

Falls in Parkinson's Disease (PD) are complex and multi-factorial in nature (Vance et al., 2015) and often occur when individuals attempt to perform multiple tasks, or dual-tasks, simultaneously (Bloem et al., 2006). The characteristic parkinsonian gait with short, shuffling steps in itself increases falls risk (Ni et al., 2018), and this risk is further exacerbated under dual-task conditions (Brauer and Morris, 2010; Rochester et al., 2014). An estimated 65% of falls in PD result in injury (Wielinski et al., 2005), often leading to prolonged hospitalisation (Paul et al., 2016). People with PD (PwP) are approximately four times more likely to incur a hip fracture than aged-matched older persons without PD (Walker et al., 2013). Consequently, falls in PD have significant economic implications; the estimated annual cost of PD in Europe is €13.9 billion, a large proportion of which is related to inpatient care (Lindgren et al., 2005).

Dual-task difficulty (DTD), a phenomenon frequently seen in people with PwP, is thought to increase falls risk (Heinzel et al., 2016). DTD in PD has been attributed to reduced automaticity of movement (Rochester et al., 2014), which refers to the ability to perform a motor skill with minimal cognitive resources directed towards the skill (Wu et al., 2015). Certain studies on DTD in PD to date have evaluated its impact on gait (Plotnik et al., 2011; Rochester et al., 2014), while others have linked the presence of DTD to increased falls risk (Allcock et al., 2009; Stegemoller et al., 2014; Vance et al., 2015; Heinzel et al., 2016). There has also been increased research in recent years on the benefits of dual-task training (DTT) in PD (Brauer and Morris, 2010; Strouwen et al., 2017). Given the expansion of the evidence-base surrounding DTD in PD and

on rehabilitation interventions to target it, it is necessary to develop valid and reliable outcome measures (OMs) to allow clinicians to effectively assess the results of DTT programmes (Haas et al., 2019).

1.2 Nature of Dual-Task Difficulty in Parkinson's Disease

Dual-tasking involves performing two attention-demanding tasks simultaneously, where each task has a different goal and one task is the primary, and the other is the secondary task (Beauchet and Berrut, 2006). To successfully perform a dual-task, an individual must have the capacity to perform the motor task automatically, and the cognitive ability to integrate different task demands (Strouwen et al., 2017). Dual-task ability becomes impaired in PD due to basal ganglia pathology, and dual-task interference (DTI) occurs when there is a deterioration in performance in one or both tasks under the dual-task condition (Chomiak et al., 2017). In other words, DTI arises when attentional control fails to compensate for motor impairment (Rochester et al., 2014).

DTI during gait can be assessed by adding a secondary attention-demanding task to a walking task and calculating dual-task cost (DTC) (Smulders et al., 2012). Rochester et al. (2014) employed this assessment method in a cohort study which aimed to investigate the nature of DTI in PD. A strength of the study is inclusion of a control group without PD, allowing comparison of DTI with respect to pathology (PD versus non-PD). Participants walked for two minutes at their preferred pace under single and dual-task conditions. The dual-task condition was the Wechsler Forward-Digit Span, a validated test of working memory; patients listened to a sequence of pre-recorded

digits played through speakers and were asked to recall as many digits as possible (Wechsler, 1997). The authors found that DTI during walking was similar for both early PD and control groups, suggesting an age-related reduction in resource capacity common to both groups. However, there was a disproportionate effect on postural stability seen only in the early PD group, who were unable to adjust step-width variability under the dual-task condition ($F=2.34$, $p=0.127$). Conversely, the control group showed a significant increase in step-width variability under the dual-task condition ($F=9.91$, $p=0.0062$), leading the authors to suggest a PD-specific dual-task co-ordination deficit. The study was robust in its inclusion of a large sample of PwP ($n=121$) and its use of a large control group ($n=189$) which reduced risk of sampling bias. However, participants were recruited within 4-months of diagnosis and were thus in early disease stages, limiting generalisability to those with more advanced disease. A further limitation of the study is the inclusion of only one cognitive dual-task, and it is therefore unclear whether the DTI seen would be similar for manual dual-tasks. Interestingly, regulation of step-width is associated particularly with the inferior parietal lobe and basal ganglia (Morris et al., 2017). This adds weight to the findings by Rochester et al. (2014) regarding the impact of dual-tasking on step-width variability. The authors suggest a need to initiate training of postural control under dual-task conditions from the early phase of PD. This highlights the need for robust outcome measures (OMs) for assessment of dual-tasking during walking which are sufficiently sensitive to detect dual-task difficulty (DTD).

1.3 Dual-Task Difficulty and Falls in Parkinson's Disease

Cognitive dual-tasking is thought to have detrimental effects on postural stability in PD, in turn increasing falls risk (Rochester et al., 2014). Vance et al. (2015) conducted

a retrospective cohort study to investigate whether adding a cognitive or manual dual-task to the Timed Up-and-Go (TUG) (TUG-COGNITIVE or TUG-MANUAL) would increase the ability of the test to identify falls risk in PwP (n=36). The TUG-COGNITIVE involved counting backwards in threes from a random starting-point, while for the TUG-MANUAL, participants were asked to complete the test while holding a glass of water in one hand. Cognitive dual-tasking was more predictive of falls than manual dual-tasking, with a sensitivity and specificity of 76.5% and 73.7% respectively, compared to 29.5% and 68.4% respectively for the TUG-MANUAL. The authors suggest that the manual dual-task may have been less challenging than the cognitive dual-task, however they justify its use in their assertion that it is a task frequently used in clinical practice. Falls history was collected retrospectively, which may have introduced recall bias. However, the authors attempted to reduce this risk by limiting the timeframe for falls recall to 6 months, and by excluding people with a history of only one fall.

While Vance et al. (2015) concluded that cognitive dual-task assessment was more predictive of falls in PwP, Heinzel et al. (2016) found that motor dual-tasking had greater predictive ability in identifying fallers than cognitive dual-tasking. In this study, walking speed during box-checking (motor task) and subtracting serial-7s exercises (cognitive task) was assessed every six months for 2.8 (±1.0 SD) years in a sample of 40 PwP. Similarly to Vance et al. (2015), Heinzel et al. (2016) assessed falls retrospectively over the previous six months, identifying this as a limitation of their study. However, they provided a clear definition as to what constituted a fall, reducing potential for recall bias. Fallers had significantly slower walking speeds while box-checking (fallers=1.00m/s, SD+/-0.30; non-fallers=1.22m/s, SD+/-0.21; p=0.031) but

there was no difference in the speed of box-checking while walking (1.08m/s, SD+/-0.27, p=0.502) compared with non-fallers (1.22m/s, SD+/-0.33, p=0.502). The authors suggest that participants prioritised successful completion of the complex motor task over maintaining their walking speed. This is in line with the 'posture-second' strategy, which proposes that PwP prioritise successful completion of the secondary task over postural stability (Bloem et al., 2006). The 'posture-second' strategy may also explain the finding of the above study by Rochester et al. (2014) regarding the deterioration in postural control under the dual-task condition. Heinzel et al. (2016) concluded that PwP with high DTC under challenging primary and secondary motor tasks were at increased risk of future falls.

The above study findings highlight DTD arising from both motor and cognitive tasks as an important problem and potential contributory factor to falls in PwP (Vance et al., 2015; Heinzel et al., 2016). The development of OMs capable of effectively identifying DTD in PwP is therefore a priority. Smulders et al. (2012) suggested a need to develop a single robust OM to predict falls risk in PwP. However, falls in PD are complex and heterogeneous in nature and a single OM is unlikely to be sufficiently sensitive or specific to detect falls risk (Vance et al., 2015). Other authors recommend use of a multi-factorial falls risk assessment (Rochester et al., 2014). The European Physiotherapy Guidelines for PD (EPGPDs) highlight inter-disciplinary falls assessment as the gold-standard approach, where person-centred goals are set by a team of health professionals together with the individual (Keus et al., 2014).

1.4 Dual-Task Training (DTT) in Parkinson's Disease

DTT for PwP has traditionally been avoided in clinical practice due to concerns regarding increased falls risk, however the EPGPDs now advise that it can be implemented with a cautious approach (Keus et al., 2014). Dual-tasking is an unavoidable part of daily life and it would seem necessary to prepare patients for such situations (Strouwen et al., 2014). Research suggests that training PwP to increase attention to the secondary task can improve dual-task performance, reduce interference from the automatic walking task and in turn improve dual-task ability (Cameron et al., 2010). Evidence is emerging on the benefits of DTT in PD (Brauer and Morris, 2010; Chomiak et al., 2017; Strouwen et al., 2017), and a recent systematic review identified highly challenging DTT as effective in improving motor function and cognitive status in PD (Ni et al., 2018).

Brauer and Morris (2010) conducted a test-retest experimental study involving participants with idiopathic PD (n=20) which aimed to determine whether practice would enable PwP to walk with larger steps while performing added tasks. Gait performance was assessed before and after a single, 20-minute training session. Tasks were designed to assess different domains of attention: motor-postural demand (carrying a tray with 4 wine-glasses); motor-manipulation (transferring coins between pockets); controlled oral word-association test (saying as many words as possible beginning with certain letters); cognitive-count (counting backwards by 3s); cognitive-auditory (participants reported whether an auditory tone was high or low in pitch) and cognitive-visuospatial (participants reported whether a spatial pattern of nine dots in a grid was the same or different from another grid). Significant increases were observed in step length ($p<0.001$) and gait speed ($p=0.01$) following training in five of the six

added tasks, indicating that PwP could be trained to walk with a larger step length under dual-task conditions. The only task condition in which step length did not improve was walking while carrying the tray with 4 wine-glasses, with the authors proposing that participants may have shortened their steps to increase postural stability in an effort to avoid dropping the glasses. The increased step length observed post-training in this study provides evidence of short-term improvements in motor skills. Further studies are necessary, however, to evaluate longer-term motor skill retention.

Strouwen et al. (2017) conducted the first single-blind randomised clinical trial (RCT) comparing the efficacy of two DTT programmes in improving gait in a large cohort of participants with mild-moderate PD (n=121). The longitudinal design is a strength of the study, allowing evaluation of long-term motor skill retention, which was not feasible in the above study by Brauer and Morris (2010). Participants were randomised to either a consecutive task-training group (CTT) in which gait and cognitive tasks were trained separately, or to an integrated dual-task training group (IDT) involving simultaneous training of gait and cognitive tasks. Both groups received training supervised by a physiotherapist twice-per-week for six weeks, and both groups underwent a 6-week control period without training prior to the intervention. Primary outcome was gait velocity during the auditory Stroop task; the words 'high' or 'low' were played via a recording in a high or low pitch, and participants were required to respond to the pitch rather than the word (Strouwen et al., 2016). Secondary outcomes were gait speed while performing a backward digit-span task, and while using a mobile phone. Both groups demonstrated improvements in dual-task gait regardless of the training method (Stroop task: $F=38.99$, $p<0.001$) and these effects transferred to untrained dual-tasks, suggesting carryover of learning. Furthermore, benefits were

retained after 12-week follow-up, indicating that carryover of learning had been consolidated. There was no difference between groups in total falls incurred, or in number of recurrent fallers, suggesting safety of both interventions. However, the study was not powered to analyse falls, which the authors identify as a limitation. This study is nonetheless highly powered; sample size was calculated based on the primary outcome of dual-task gait velocity with a power of 80%. Power should not be less than 80% and higher power reduces the chance of missing a true effect (Sakpal, 2010). Strengths of this study include the use of the intention-to-treat principle and random assignment of participants to IDT or CTT training groups by computerised block randomisation. Group allocation was completed by an independent statistician, ensuring allocation concealment (Strouwen et al., 2014) and participants were assessed by blinded testers, limiting ascertainment bias. Furthermore, the mobile phone task potentially represents a more functionally-challenging motor-task than carrying a glass of water, the task used in the above study by Vance et al. (2015).

1.5 Current Dual-Task Outcome Measures in Parkinson's Disease

The TUG is a valid and reliable assessment of functional mobility widely used in PD (Morris and Morris, 2001) with high inter-rater (ICC=0.99) (Morris and Morris, 2001) and test-retest reliability (ICC=0.80, 95% CI=0.70-0.87) (Huang et al., 2011). The TUG involves standing-up from a chair, walking 3-metres, turning around, and returning to sit down in the chair (Morris and Morris, 2001). The TUG is quick, simple to administer and easy to implement in clinical practice (Palmisano et al., 2019). Dual-task ability can be assessed by adding a cognitive dual-task to the TUG, which has been shown to differentiate between PwP with high or low falls risk (Vance et al., 2015).

However, the TUG may not be sophisticated enough to effectively identify people at different stages of PD (Weiss et al., 2010). In everyday life PwP must walk in complex situations for prolonged periods of time and the TUG may not be sufficiently challenging to reflect 'real-life' functional ambulation (Kim et al., 2015). Furthermore, when completing the TUG participants self-select direction of turning, which may mask unilateral impairments and lead to a ceiling effect (Haas et al., 2019). A ceiling effect occurs when participants achieve the highest, or close to the highest possible score on an OM, reducing the likelihood that the OM has accurately measured the intended domain (Salkind, 2010). Any ceiling effects associated with the TUG are likely to be particularly evident in mild PD; for those less significantly impaired, adding a dual-task to the TUG may not be sufficiently challenging to detect DTD. An extended version of the TUG has been proposed to increase the accuracy of gait assessment in PD, which increases the total walking distance from 6 to 14 metres (Salarian et al., 2010). However, while the extended-TUG increases walking distance, it does not necessarily increase the complexity of the task. Participants are still required to turn in only one direction, and thus the extended-TUG cannot overcome the issue of potential masking of unilateral impairments (Haas et al., 2019). Assessing backwards walking with the addition of a cognitive dual-task has been proposed as another means of identifying DTD in a chronic stroke population (Yang et al., 2016). However, backwards walking has limited functional relevance and may be too difficult for individuals with advanced PD, potentially increasing falls risk and thus giving rise to safety implications. These limitations in current methods of assessing dual-task walking ability highlight the need for an alternate, more challenging mobility measure for identification of DTD at different stages of PD.

1.6 The L-Test Outcome Measure

Similarly to the TUG, the L-Test requires participants to rise from a chair and turn around a cone, however it extends the total walking distance from six metres to 20 metres and necessitates turning in both clockwise and anticlockwise directions (Haas et al., 2019). The L-Test was initially developed with the intention of overcoming ceiling effects of the TUG for active older people and younger people with amputations (Deathe and Miller, 2005). Psychometric properties of the L-Test were subsequently further investigated in hospitalised older people (Nguyen et al., 2007) and in individuals with chronic stroke (Kim et al., 2015) and it has recently been validated for the first time in PwP (Haas et al., 2019) as described in Section 1.7. The L-Test may provide a challenging, functionally relevant assessment of how PwP manage in everyday dual-task situations (Evans et al., 2017). Furthermore, adding a secondary motor and/or cognitive task may increase its sensitivity in identifying falls risk compared to the TUG. Versions of the L-Test with secondary tasks are yet to be validated, highlighting a gap in the current literature and forming the basis of the research question within the present study.

1.7 Psychometric Properties of the L-Test in Parkinson's Disease

While the validity and reliability of the TUG in PD has been previously demonstrated (Morris and Morris, 2001; Huang et al., 2011), psychometric properties of the L-Test are less well researched. Haas et al. (2019) recently conducted the first study evaluating the psychometric properties of the L-test in PwP. The cross-sectional study involved 16 participants with mild-moderate PD and aimed to assess concurrent validity and test-retest reliability of the L-Test in relation to the TUG. During the first testing

session participants completed two timed-trials of the L-Test and TUG. The tests were repeated 7 days later to establish test-retest reliability. The L-Test showed excellent test-retest reliability with a high degree of agreement between measurements taken on each day. There was a strong correlation between the L-test and TUG on days 1 and 2 respectively ($r=0.97$, $p<0.001$; $r=0.96$, $p<0.001$). Excellent test-retest reliability was demonstrated (ICC=0.97, 95% CI=0.86-0.99) with a Minimal Detectable Change (MDC) of 5.31 seconds i.e. any improvements in time taken to complete the L-Test following training need to be above this level to reach clinical significance. The small sample size is a limitation of the study. However, the authors used a power calculation to justify the small sample size, which demonstrated that seven participants would be necessary to ensure the study was adequately powered. Moreover, several small, high quality studies combined can provide sufficient evidence for a measurement property (Mokkink et al., 2010). A further limitation of this study is that participants had mild-moderate PD of Hoehn & Yahr (H&Y) stages 1-2 and results may not be appropriate to generalise to patients in later disease stages.

1.8 Psychometric Properties of the L-Test in Other Populations

Deathe and Miller (2005) initially developed the L-Test to assess functional gait of patients post lower-extremity amputation. The L-Test was found to have excellent inter-rater and intra-rater reliability (ICC=0.96, 95% CI=0.93-0.98 and ICC=0.97, 95% CI=0.93-0.98 respectively), indicating minimal measurement error when performed in a standardised manner by different testers (inter-rater reliability), or by the same tester on different occasions (intra-rater reliability). The highest correlation was seen between the L-test and the 10-metre walk test (10MWT) ($r=0.97$, $p<0.001$), followed by the TUG ($r=0.93$, $p<0.001$), followed by the 2-minute walk test (2MWT) ($r=0.86$,

$p<0.001$). A relatively large sample (n=93) of people with unilateral amputations was included, however there is no evidence of use of a sample size calculation to justify this. Order of testing was not randomised which could potentially introduce an order or a learning effect, however the authors justify their use of a sequenced order of testing in stating that this allowed them to observe for potential compromise of cardiovascular capacity.

The L-Test was subsequently found to provide a valid and reliable assessment of walking ability in hospitalised older adults (Nguyen et al., 2007). Fifty participants were tested on two occasions, with both sessions completed on the same day. During the first session participants performed the L-Test, TUG and the Frailty and Injuries Cooperative Studies of Intervention Techniques (FICSIT-4) balance. A physical therapist and a research assistant completed the testing to assess inter-rater reliability and order of testing was randomised to reduce potential order effects. During the second session the physical therapist completed testing of the L-Test only a second time to assess intra-rater reliability. Both intra-rater and inter-rater reliability were found to be excellent (ICC=0.97, 95% CI=0.99-1.00 and ICC=1.00, CI=0.95-0.98 respectively) and there was a statistically significant positive correlation between the L-Test and the TUG ($r=0.96$, $p<0.001$). The authors propose that the more complex set-up of the L-Test provided a greater challenge to balance and mobility in their cohort of older people and may thus allow the tester to overcome possible ceiling effects associated with the TUG.

Kim et al. (2015) evaluated the psychometric properties of the L-Test in the chronic stroke population. The L-Test was assessed alongside the TUG, 10MWT and 2MWT in a sample of 33 participants. The L-Test had high inter-rater and intra-rater reliability (ICC=0.99, 95% CI=0.97-0.99 and ICC=0.99, 95% CI=0.97-0.99 respectively). There was a significant positive correlation between duration of the L-Test and TUG ($r=0.89$; $p<0.001$), and the duration of the L-Test and 10MWT ($r=0.88$, $p<0.001$). Conversely, a significant negative correlation was found between duration of the L-Test and distance walked in the 2MWT ($r=-0.91$; $p<0.001$). The authors proposed that the L-Test might be a useful means of assessing mobility in high-functioning stroke survivors, and that it may offer a more functional way of evaluating gait than the TUG.

1.9 Conclusion

DTD poses a significant problem in PD and its link to increased falls risk is of clinical concern. The evidence-base surrounding the benefits of DTT in PD is increasing, and the European Physiotherapy Guideline for Parkinson's Disease support its implementation in clinical practice. However, there is a lack of robust dual-task mobility OMs to evaluate dual-task ability in PD. The widely used TUG, even when performed with a secondary attention-demanding task, may have a ceiling effect in PwP with mild disease severity. The L-Test has been hailed as more complex and functionally relevant and may have the potential to overcome the ceiling effects associated with the TUG. Moreover, the addition of secondary tasks to the L-Test may increase sensitivity in detecting DTD. The L-Test has recently been validated in PD, however its validity with the addition of secondary dual-tasks is yet to be established. The current study therefore aims to establish the concurrent validity of the L-Test with

a manual and cognitive task, i.e. the L-test-MANUAL and L-test-COGNITIVE, and to determine its predictive ability in identifying fallers.

CHAPTER 2 METHODOLOGY

2.1 Aims and Objectives

The primary study aim was to establish the concurrent validity of the L-Test-MANUAL and L-Test-COGNITIVE with the TUG-MANUAL and TUG-COGNITIVE in participants with idiopathic PD. The secondary aim was to determine the predictive ability of the L-Test, L-Test-MANUAL and L-Test-COGNITIVE in identifying fallers.

The objectives of the study were to test the following hypotheses:

(1) That the L-Test-MANUAL and L-Test-COGNITIVE would show at least a strong correlation with the TUG-MANUAL and TUG-COGNITIVE respectively, based on previous studies demonstrating high correlations between the L-Test and TUG (Deathe and Miller, 2005; Nguyen et al., 2007; Kim et al., 2015; Haas et al., 2019).

(2) That a ceiling effect would be observed with the TUG-MANUAL and TUG-COGNITIVE when compared with the L-Test-MANUAL and L-Test-COGNITIVE.

(3) That the L-test COGNITIVE and TUG-COGNITIVE would be more predictive of falls than the L-test-STANDARD and TUG-STANDARD, and the L-test-MANUAL and TUG-MANUAL.

(4) That the L-Test-MANUAL and L-Test-COGNITIVE would be more predictive of falls than the TUG-MANUAL and TUG-COGNITIVE.

2.2 Study Design

2.2.1 Study Design

The study design was cross-sectional; testing was conducted in a single session for a defined population, i.e. PwP. The COSMIN (Consensus-based Standards for the Selection of Health Status Measurement Instruments) checklist has been recommended to guide design and/or reporting of studies on measurement properties and was used to inform the current study design (Mokkink et al., 2010).

2.2.2 Sample Size Estimation

Twenty-five participants were required for concurrent validity based on α of 0.05, power of 90% and a moderate correlation of 0.6 (Hulley et al., 2013) between the L-Test-STANDARD and TUG-STANDARD, the L-Test-MANUAL and TUG-MANUAL, and the L-Test-COGNITIVE and TUG-COGNITIVE.

2.3 Participants

2.3.1 Recruitment

Participants were recruited from Neurology Outpatient clinics and Neurological Physiotherapy Outpatient clinics in Tallaght University Hospital (TUH) by convenience sampling. A Consultant Neurologist, a PD Clinical Nurse Specialist (CNS) and a Senior Physiotherapist in Neurology were responsible for recruitment and acted as gatekeepers to the study. The gatekeepers completed a Study Inclusion Form (Appendix 1) to ensure eligibility and provided potential participants with the Patient Information Leaflet (PIL) (Appendix 2), outlining the purpose and nature of the study.

They then used the Permission to be Contacted form (Appendix 3) to gain written consent for the Principal Investigator (PI) to contact volunteers by phone regarding inclusion in the study. Participants were allowed a 1-week period to assimilate information provided and decide whether or not they wished to volunteer for the study. Following this period, they were contacted by the PI to schedule a date and time for testing. Verbal consent was gained at this point over the phone, and formal written consent obtained prior to testing (Appendix 4). Recruitment took place over a 3-month period from mid-November 2019 to early-March 2020.

2.3.2 Inclusion and Exclusion Criteria

Inclusion Criteria:

- Diagnosis of Idiopathic PD by a Consultant Neurologist.
- Disease severity of 1-3 on the H&Y scale, representing people with mild-moderate PD (Hoehn and Yahr, 1967) (Appendix 5).
- Ability to walk a minimum of 20-metres independently with or without a walking aid.

Exclusion criteria:

- Diagnosis of non-idiopathic PD.
- Mini-Mental State Examination (MMSE) score of ≤24, where a score of 24-30 indicates no cognitive impairment (Tombaugh and McIntyre, 1992) (Appendix 6).
- Presence of visual or auditory problems that may have interfered with assessment.

- Presence of any neurological (other than PD), orthopaedic or cardio-respiratory conditions that may have affected walking or safety during testing.

2.4 Ethical Considerations

2.4.1 Ethical Approval

Ethical approval was sought from the St. James' Hospital/TUH Research Ethics Committee (REC) on 25th June 2019 and granted on 9th October 2019 (Appendix 7a and 7b). An amendment to this application was sought in order to add the PD CNS as an additional gatekeeper and was subsequently granted by the aforementioned REC on 21st February 2020 (Appendix 7c).

2.4.2 Informed Consent

Written consent was obtained from the Consultant Neurologist to recruit participants, and from the Physiotherapy Manager in TUH to undertake testing in the Physiotherapy gym (Appendix 8a and 8b). Written consent was gained by the gatekeepers for the PI to contact volunteers with respect to participation in the study. The PI contacted potentially eligible volunteers by phone and gained verbal consent, and written consent was gained prior to testing. The PIL provided to participants advised that participation was voluntary and that they were free to withdraw at any time, without having to provide a reason and without any personal consequence.

2.4.3 Data Management and Storage

All data remained confidential throughout the study. The PIL explained that all personal data would be kept strictly confidential. The PI acted as both data controller and data processor and completed online General Data Protection Regulation (GDPR) training prior to undertaking the study. The PI did not have direct access to any medical records; the Consultant Neurologist, PD CNS and Senior Physiotherapist based in TUH acting as gatekeepers to the study accessed healthcare records for the purpose of recruitment. A hard copy of the study data was stored securely in a locked filing cabinet in the Physiotherapy Department in TUH and was accessible only to the PI. This was coded and inputted onto an electronic spreadsheet following recruitment, and participants were assigned a Unique Identification Number (UIN) on data-recording sheets. Only the PI retained the 'key' to re-identify coded data, which was stored separately from the original data for confidentiality reasons. Coded electronic data were stored on a password-protected computer in the Physiotherapy Department in TUH, only accessible by the PI.

2.5 Assessment

2.5.1 Cognitive Assessment

<u>Mini-Mental State Examination</u>

The MMSE (Appendix 6) is a brief screening tool for cognitive impairment which has been validated in PwP (Aarsland et al., 2004; Zadikoff et al., 2008; Kandiah et al., 2009; Dujardin et al., 2010; Harvey et al., 2010). It consists of 30 questions examining orientation to time and place, word registration and recall, attention and calculation, and language and visual construction (Folstein et al., 1975). Volunteers were evaluated

using the MMSE to ensure that they could provide an accurate medical history and understand test instructions. Volunteers were included in the study if they scored ≥24, indicating no cognitive impairment (Tombaugh and McIntyre, 1992). To ensure competency in using the MMSE the PI completed a training session with an Occupational Therapist who was skilled in its administration.

2.5.2 Outcome Measures

L-Test

The L-Test (Appendix 9) is an extended version of the TUG, in which participants are required to turn in both clockwise and anticlockwise directions. Participants were requested to stand-up from a chair, walk 3-metres to a cone, turn 90° to the right, continue walking for 7-metres to the next cone, turn 180° to the left, then return and walk back along the same path to sit down in the chair. Time taken to complete the test was recorded in seconds. The L-Test is a valid and reliable test of functional walking ability in lower-limb amputees (Deathe and Miller, 2005), hospitalised older adults (Nguyen et al., 2007) and chronic stroke (Kim et al., 2015). It has also recently been validated as a functional mobility assessment in mild-moderate PD, with excellent test-retest reliability (ICC=0.97, 95%CI=0.86-0.99) (Haas et al., 2019). The MDC for the L-Test in the same study involving 16 participants with PD was 5.31 seconds.

Timed Up-and-Go

The TUG (Appendix 9) is a valid and reliable measure of mobility in PD and widely used in clinical practice (Morris and Morris, 2001). It has excellent test-retest reliability (ICC=0.80, 95% CI=0.70-0.87) (Huang et al., 2011) and inter-rater

reliability in PwP (ICC=0.99) (Morris and Morris, 2001). Participants were requested to stand-up from a chair, walk 3-metres to a cone, turn around, and return to sit down in the chair. The L-Test requires participants to turn in both directions, whereas with the TUG participants self-select direction of turning. The time taken to complete the TUG was recorded in seconds. The TUG has been identified as predictive of falls in PwP with cut-off scores 13.5 seconds (Shumway-Cook et al., 2000) and 11.5 seconds (Nocera et al., 2013).

Dual-Tasking Assessment

Participants were requested to complete the L-Test and TUG with two concurrent secondary tasks. For the L-Test-MANUAL and TUG-MANUAL, participants completed each test as described above, while carrying a glass of water in one hand. Previous studies have used carrying a glass of water as the secondary motor task (Vance et al., 2015; Yang et al., 2016). For the L-Test-COGNITIVE and TUG-COGNITIVE, participants counted backwards in threes from a random starting point between 20 and 200, selected using a random numbers generator (Randomness and Integrity Services Ltd., 2010). To calculate DTC, walking speed under the dual-task condition was expressed as a percentage of walking speed under the single-task condition: (single-task/dual-task) X 100, where a maximum score of 100% indicated no decrease in performance under the dual-task condition (Paul et al., 2005). Vance et al. (2015) found that adding a cognitive task to the TUG was more predictive of falls than the standard TUG or TUG with a manual task, with a likelihood ratio of 2.9 (95% CI=1.3-6.5). Cut-off scores for discriminating fallers from non-fallers were 12 seconds, 14.7 seconds and 13.2 seconds for the TUG, TUG-cognitive and TUG-manual respectively (Vance et al, 2015).

2.5.3 Classification of Fallers and Non-Fallers

Falls were assessed retrospectively by asking participants whether they had fallen in the last 6 months (Vance et al., 2015). A fall was defined as unintentionally coming to rest on the ground or other lower level, without external force or loss of consciousness (Gibson., 1987). Participants were then classified into 'faller' or 'non-faller' groups. Participants reporting at least one fall in the previous 6 months were defined as fallers, while those reporting no falls were defined as non-fallers (Vance et al., 2015). Various authors have classified participants as 'fallers' or 'non-fallers' retrospectively, based on self-reported falls history (Nocera et al., 2013; Vance et al., 2015; Palmisano et al., 2019).

2.5.4 Testing Procedure

Testing took place in the Physiotherapy Gym in TUH, with an allocated timeframe of 1-hour for each participant; 15-minutes for completion of the MMSE and documentation of demographic data, and 45-minutes for outcome measurement. Participants were tested in a self-reported 'on' medication state (Brauer and Morris, 2010; Strouwen et al., 2016; Zirek et al., 2018) and within a 3-hour window post-PD medication intake to reduce effects of motor fluctuation (Evans et al., 2017). All testing sessions were conducted in the afternoon.

The order of completion of each of the L-Test and TUG single-task, manual dual-task and cognitive dual-task conditions was randomised for each participant (Brauer and Morris, 2010). Randomisation of testing was achieved by creating cards with pre-determined permutations of test order. Participants were asked to choose a card from

an envelope to avoid subject bias (Goh et al., 2017). Other studies have used a standardised assessment order (Zirek et al., 2018), however this could potentially introduce fatigue effects or practice bias. Each test was demonstrated by the PI prior to testing and standardised instructions were provided. Participants were required to sit with their hips to the back of the seat on a stable chair with armrests with a seat height of 43cm and were allowed to use the armrests during the transition to standing if required. Participants were instructed to walk at a comfortable speed and tests were timed by the PI with a stopwatch. Time taken to complete the tests was recorded to the nearest second and was started from when the PI said 'go' and stopped when the participants back touched the back of the chair.

Participants were allowed a single practice-trial for the single-task L-Test and TUG. They then completed two timed-trials for each of the OMs, the average of which was used for data analysis. A maximum rest period of 1-minute was allowed between trials (Goh et al., 2017) and a 2-minute rest period after each separate OM to minimise fatigue and learning effects i.e. between the L-Test and TUG (Haas et al., 2019).

2.6 Statistical Methods

2.6.1 Data Collection

Data collection took place in the Physiotherapy Gym in TUH, between December 2019 and March 2020**.** The MMSE was completed at the start of each testing session and participants were excluded from the study if their MMSE was <24. A data collection form (Appendix 10) was developed by the PI to record baseline information, i.e. age, gender, H&Y stage, disease duration, falls history in the previous six-months, time

since last dose of anti-parkinsonian medication, comorbidities and use or non-use of a walking-aid. Participants were separated into 'faller' and 'non-faller' categories. Participants then completed six walking tests, the order of which was randomised as described above: L-Test-STANDARD, L-Test-MANUAL and L-Test COGNITIVE, and the TUG-STANDARD, TUG-MANUAL and TUG-COGNITIVE.

2.6.2 Statistical Analysis

Statistical analyses were carried out using the Statistical Package for the Social Sciences (SPSS) (Version 22.0, IBM Corp. SPSS Statistics for Windows. Armond, NY, USA). Descriptive statistics including means and standard deviations were used for parametric data, and medians and inter-quartile ranges for non-parametric data. Baseline variables were compared using independent t-tests for normally distributed continuous variables, or the Mann-Whitney U test for non-parametric data. The Pearson Chi-square test was used to compare categorical variables. Data were tested for normality using the Shapiro Wilks test, recommended for sample sizes of <50 (Sahngun Nahm, 2016), where a significance level of $p \geq 0.05$ indicated normality.

Mean differences for fallers and non-fallers were tested for significance using independent t-tests for normally distributed continuous variables, or the Mann-Whitney U test for non-parametric data. The boxplots for each of the L-Test and TUG conditions were inspected for clustering of scores at faster or slower test speeds which might indicate a ceiling or floor effect. The L-Test and TUG are measured in total time taken to complete the test, and therefore slower test speeds indicate poorer performance. A clustering of faster test speeds was taken to indicate a ceiling effect,

whereas a clustering of slower test speeds would have indicated a floor effect. The 25th percentile was thus used as the cut-off for a ceiling effect, and the 75th percentile as the cut-off for a floor effect.

Spearman's Rank Order Correlation Coefficients (rho) for non-parametric data were calculated to determine the relationship between the L-Test-MANUAL and TUG-MANUAL, and the L-Test-COGNITIVE and TUG-COGNITIVE. Correlations were classified as follows; 0-0.20=negligible, 0.21-0.4=weak, 0.41-0.60=moderate, 0.61-0.80=strong, 0.81-1.00=very strong (Prion and Haerling, 2014). Each of the independent variables (i.e. the L-Test and TUG conditions and baseline variables) were analysed using univariate regression to identify factors contributing to risk of falling. The dependent variables were the faller versus non-faller groups. Receiver operating characteristic (ROC) curve analyses with 95% CIs were used to describe model discrimination for each of the L-Test and TUG conditions. The area under the curve (AUC) was reported and cut-off scores for identifying fallers versus non-fallers were determined by visual observation of the ROC plot and using Youden's index (sensitivity+specificity-1) (Yang et al., 2016). Cut-off scores were reported to maximise both sensitivity and specificity, compromising between avoiding false negatives and false positives (Leddy et al., 2011). Sensitivity referred to how often the L-Test and TUG detected falls risk for a participant in the faller group, whereas specificity indicated how often the participant was not at risk of falling and was categorised as a non-faller (Vance et al., 2015). Statistical tests are displayed on SPSS output sheets (Appendix 11).

CHAPTER 3 RESULTS

3.1 Screening and Eligibility

Recruitment took place between November 2019 and March 2020. Sixty-six patients were screened for inclusion by the study recruiters during Neurology and Neurological Physiotherapy out-patient appointments at TUH. Thirty-two patients met the eligibility criteria and completed the Permission to be Contacted Form indicating consent to be contacted over the phone by the PI. Thirty-four patients were excluded as they did not meet the eligibility criteria. Five patients withdrew from the study prior to testing. Two patients were excluded on the day of testing; one patient's data were used as a pilot for the study and was not included in the final analysis; the other was found to have an MMSE of 22/30 and therefore did not meet study eligibility criteria. Twenty-five participants consented to testing and were included in the final analysis. Figure 3.1 outlines patient flow through the study.

3.2 Participant Demographics

3.2.1 All Participants

Twenty-five PwP participated in the study (76% male). Participant ages ranged from 45-84 years (mean 65.64, SD± 9.40). Disease duration ranged from 0.5-17 years (mean 7.18, SD± 4.54). The median MMSE score was 29 (IQR=3), indicating no cognitive impairment. Number of comorbidities ranged from 0-5 (median 1.0, IQR 3). Participant disease severity ranged from 1-3 on the H&Y scale, with 52% (n=13) in stage one, 40% (n=10) in stage two, and 8% (n=2) in stage 3 (Figure 3.2). All participants were taking anti-parkinsonian medication, were assessed within a three-hour window of medication intake and were in a self-reported 'on' phase.

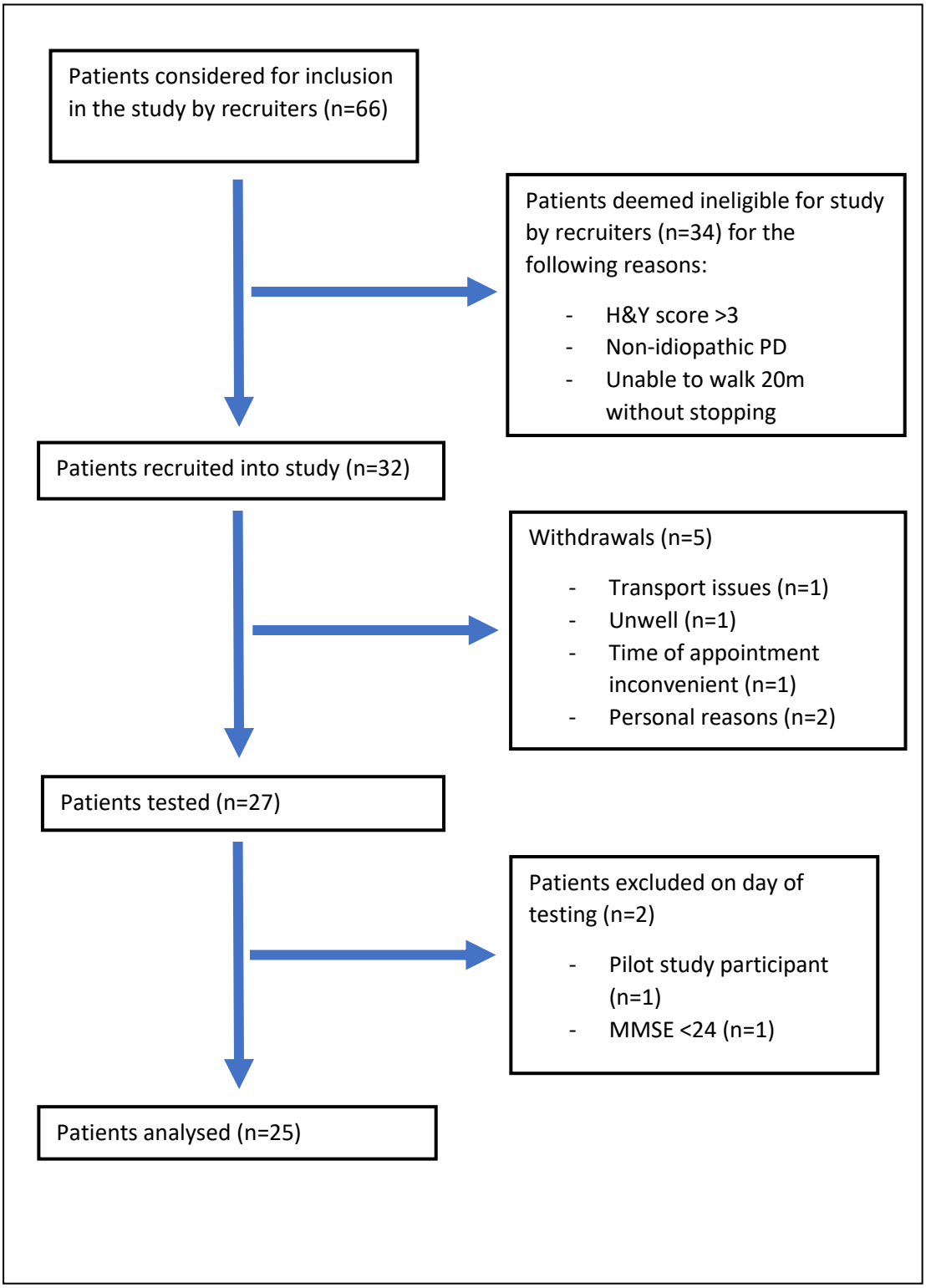

Figure 3.1 Participant Flow Chart

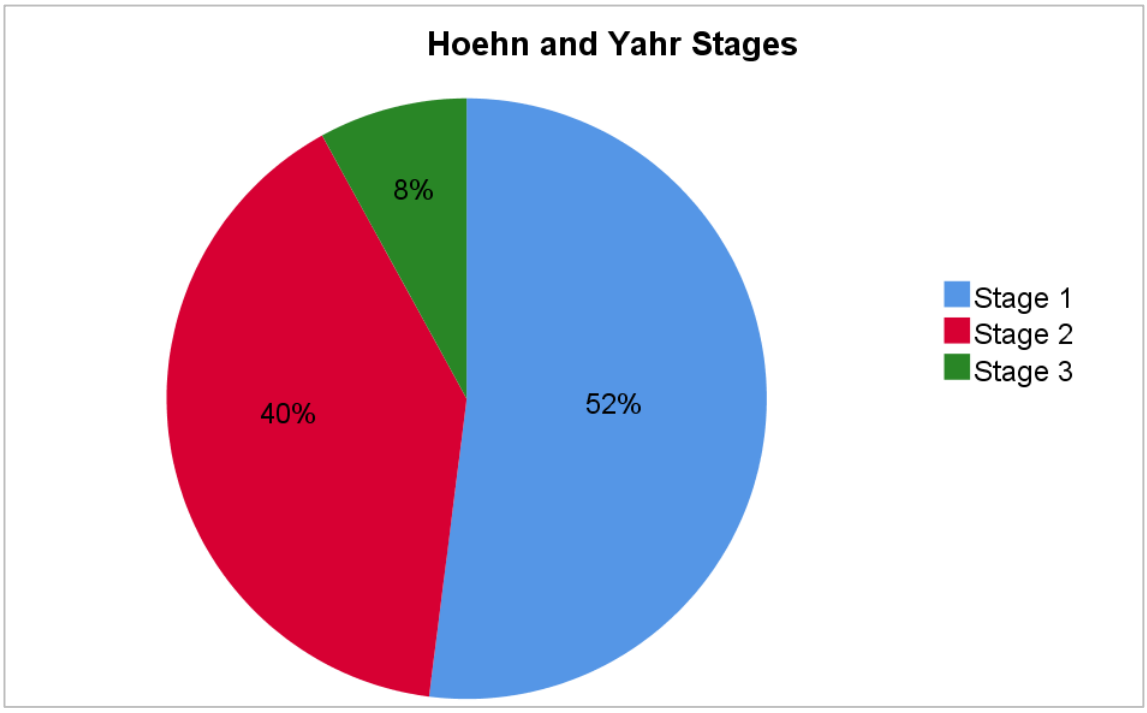

Figure 3.2 Participant Hoehn and Yahr Stages

All participants were independently mobile indoors and outdoors. The majority of participants did not use a walking aid (92%, n=23). Of those who used a walking aid (8%, n=2), one used a walking stick while the other used a four-wheeled rollator. Eighteen participants (72%) reported no falls in the previous six months. Seven participants (28%) reported at least one fall in the previous six months; of these two (8%) reported one fall, while five (20%) reported two or more falls.

3.2.2 Faller versus Non-Faller Groups

Participants were divided into faller and non-faller groups. The number of falls in the faller group ranged from 1-4 (median 2, IQR 2). There was no significant difference between fallers and non-fallers for age (p=0.73), disease duration (p=0.15), number of comorbidities (p=0.92) or MMSE score (p= 0.08). The Pearson Chi-square test for categorical variables showed no significant difference in gender (p=0.74) or type of

walking aid (p=0.22) for fallers and non-fallers, however there was a significant difference in H&Y stage (p=0.005). Demographic information for fallers and non-fallers is presented in Table 3.1.

Participant Demographics		**Fallers (n=7)**	**Non-fallers (n=18)**
		Mean (+/-SD)	**Mean (+/-SD)**
Age (y)		64.57 (+/-12.38)	66.06 (+/-8.37)
Disease duration (y)		9.28 (+/-5.76)	6.36 (+/-3.84)
Gender (% male)		71.4%	28.6%
		Mean (SD)	**Median (IQR)**
MMSE		27.30 (+/-2.21)	29 (1)
		Mean (SD)	**Median (IQR)**
No. of comorbidities		1.29 (+/-1.11)	1 (3)
	Stage	**Number (%)**	**Number (%)**
H&Y	**Stage-1**	0 (0%)	13 (72.2%)
	Stage-2	6 (85.7%)	4 (22.2%)
	Stage-3	1 (14.3%)	1 (5.5%)
Walking aid	**No walking-aid**	6 (85.7%)	17 (94.4%)
	Walking stick	1 (14.3%)	0 (0%)
	4-wheeled rollator	0 (0%)	1 (5.6%)

(y)=years; (n)=number of participants; SD=standard deviation; IQR=interquartile range; MMSE=Mini-Mental State Examination; H&Y=Hoehn and Yahr

Table 3.1 Participant Demographics: Fallers versus Non-Fallers

3.3 Normality Testing

The L-Test and TUG single-task and dual-task conditions were tested for normality using the Shapiro-Wilks test, as were the L-Test and TUG dual-task cost (DTC) scores. The TUG-MANUAL and TUG-COGNITIVE were normally distributed in the faller

group. All the other L-Test and TUG conditions were non-normally distributed in both faller and non-faller groups. For the DTC scores, all the conditions were normally distributed, except the L-Test-MANUAL DTC and TUG-COGNITIVE DTC in the faller group. This was supported on visual inspection of the corresponding histograms and Q-Q plots, which indicated a skewed distribution. The L-Test and TUG single-task and dual-task conditions were therefore treated as non-parametric data for analysis. For the DTC scores, the L-Test-COGNITIVE DTC and TUG-MANUAL DTC were treated as parametric data for analysis, and the L-Test-MANUAL DTC and TUG-COGNITIVE DTC were treated as non-parametric data. Table 3.2 displays normality scores for fallers and non-fallers.

Test	**Fallers p-value**	**Non-fallers p-value**
L-Test-STANDARD	0.014	0.00
L-Test-MANUAL	0.01	0.00
L-Test-COGNITIVE	0.05	0.00
TUG-STANDARD	0.03	0.004
TUG-MANUAL	0.06*	0.00
TUG-COGNITIVE	0.14*	0.00
L-Test-MANUAL DTC	0.47*	0.04
L-Test-COGNITIVE DTC	0.60*	0.08*
TUG-MANUAL DTC	0.89*	0.91*
TUG-COGNITIVE DTC	0.88*	0.04

DTC=dual-task cost *Normal distribution statistical significance p≥0.05

Table 3.2 Normality Scores: Fallers versus Non-Fallers

3.4 Correlations between L-Test and Timed Up-and-Go Single and Dual-Task conditions

Correlations between the L-Test and TUG conditions were assessed using Spearman's Rank Order Correlation Coefficients for non-parametric data. The three L-Test conditions correlated very highly with the TUG conditions (Table 3.6). The highest correlations were observed between the L-Test and TUG single-task and manual dual-task conditions. Scatterplots demonstrate a linear relationship for each of the L-Test and TUG conditions (Figures 3.9-3.11). The scatterplots also identify three distinct outliers for each of tests. The Spearman's rho was repeated following removal of the outliers, which did not affect the strength of the correlation.

	Correlation Coefficient for corresponding L-Test conditions (Spearman's rho)	**95% CI**	**p-value**
TUG-STANDARD	0.94	0.86-0.97	<0.001*
TUG-MANUAL	0.94	0.87-0.97	<0.001*
TUG-COGNITIVE	0.92	0.84-0.97	<0.001*

CI=confidence interval *Correlation significant at the 0.001 level (2-tailed)

Table 3.3 Correlations of L-Test and TUG Data

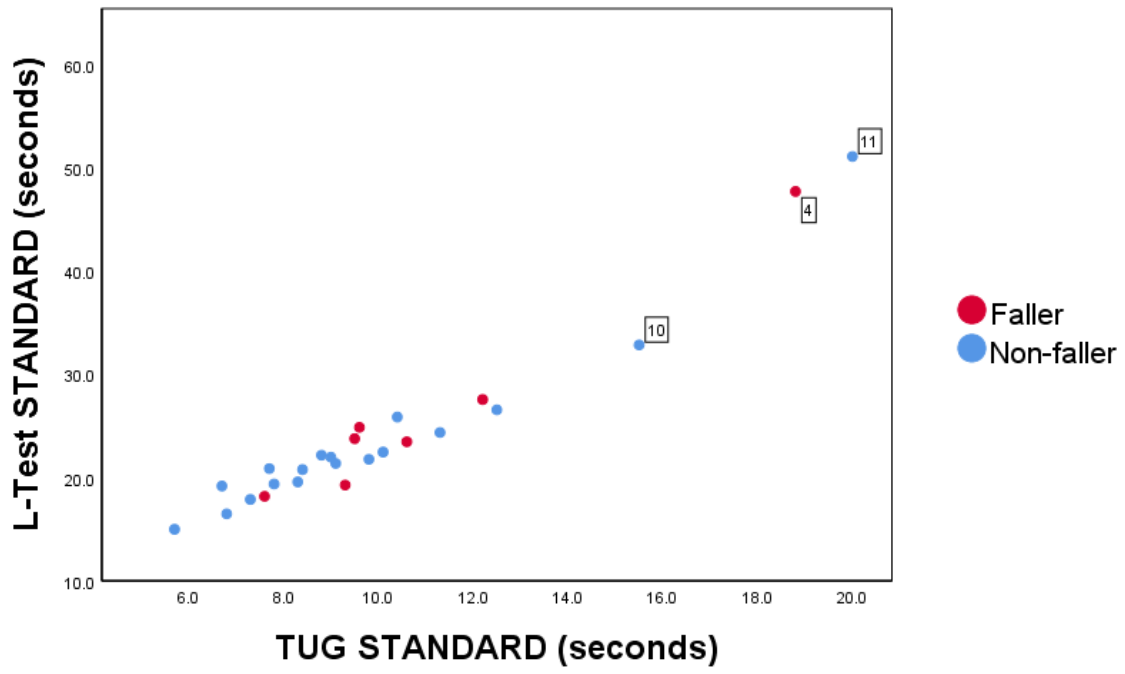

Figure 3.3 Correlation between L-Test-STANDARD and TUG-STANDARD

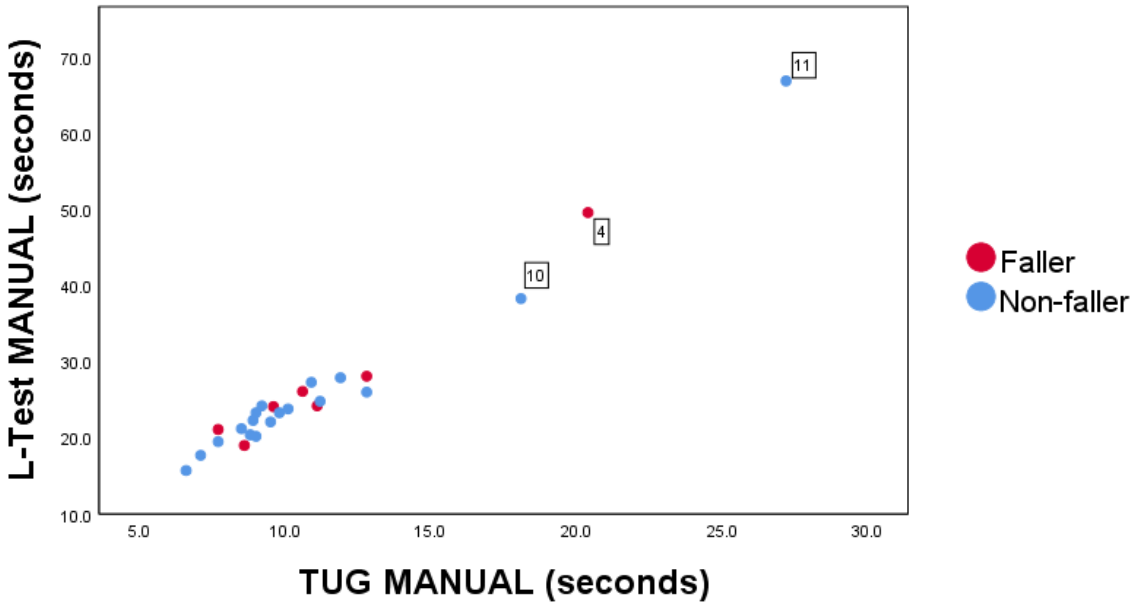

Figure 3.4 Correlation between L-Test-MANUAL and TUG-MANUAL

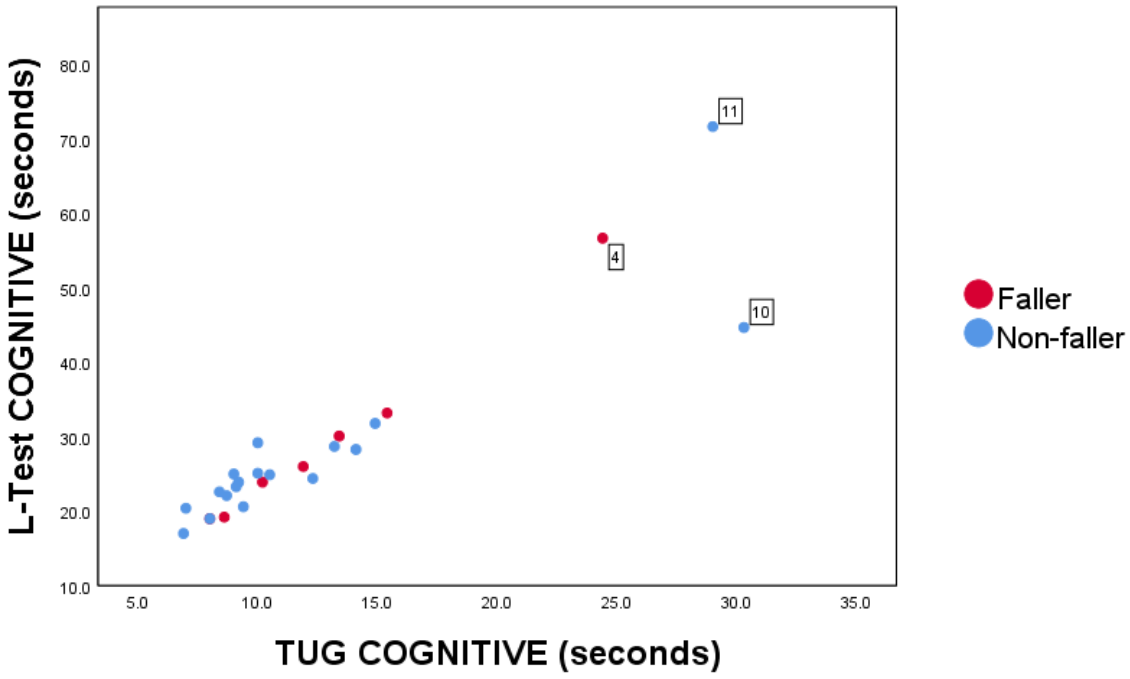

Figure 3.5 Correlation between L-Test-COGNITIVE and TUG-COGNITIVE

3.5 Comparisons between Faller and Non-Fallers

3.5.1 L-Test and TUG Single and Dual-Task Conditions

The Mann Whitney U test was used to compare differences between fallers and non-fallers for the L-Test and TUG conditions. Scores for each of the L-Test and TUG conditions were not significantly different between fallers and non-fallers ($p \leq 0.05$). Table 3.3 displays group differences for each of the test conditions. Normally distributed data are presented as means and standard deviations, and non-normally distributed data as medians and interquartile ranges.

Test	Faller (s) Median (IQR)	Non-faller (s) Median (IQR)	p-value
L-Test-STANDARD (s)	23.80 (8.3)	21.60 (5.4)	0.33
L-Test-MANUAL (s)	24.20 (7.0)	23.30 (6.0)	0.42
L-Test-COGNITIVE (s)	26.00 (14.0)	24.65 (7.1)	0.66
TUG-STANDARD (s)	9.60 (2.9)	8.90 (3.0)	0.24
	Mean (SD)		
TUG-MANUAL (s)	11.54 (4.24)	9.35 (2.6)	0.53
TUG-COGNITIVE (s)	13.13 (5.61)	9.70 (4.8)	0.46

(s)=seconds; SD=standard deviation; IQR=Interquartile range *Statistical significance p≤0.05

Table 3.4 Group differences in L-Test and TUG Scores

3.5.2 Dual-Task Cost

To calculate DTC, walking speed under the dual-task condition was expressed as a percentage of walking speed under the single-task condition: (single-task/dual-task) X 100, where a maximum score of 100% indicated no decrease in performance under the dual-task condition (Paul et al., 2005). There were no statistically significant differences in DTC for fallers and non-fallers (p≤0.05). Table 3.5 displays group differences in DTC scores. DTC is presented as means and standard deviations to allow comparison between groups.

Test	Faller DTC (%) Mean (SD)	Non-faller DTC (%) Mean (SD)	p-value
L-Test-MANUAL	96.28 (6.14)	92.16 (7.08)	0.14
L-Test-COGNITIVE	91.25 (11.11)	85.94 (10.34)	0.41
TUG-MANUAL	97.11 (7.08)	90.82 (7.32)	0.16
TUG-COGNITIVE	87.74 (13.21)	84.81 (13.10)	0.80

DTC=dual-task cost; SD=standard deviation *Statistical significance p≤0.05

Table 3.5 Group differences in L-Test and TUG Dual-task Cost Scores

3.5.3 Outliers

Figures 3.3 to 3.8 display group differences for each L-Test and TUG condition. The boxplots clearly identify outliers with slower test speeds in both faller and non-faller groups. Statistical techniques can be sensitive to outliers, and outliers were therefore analysed using the 5% Trimmed Mean value. The Trimmed Mean and Mean values were similar and thus deemed unlikely to skew the data.

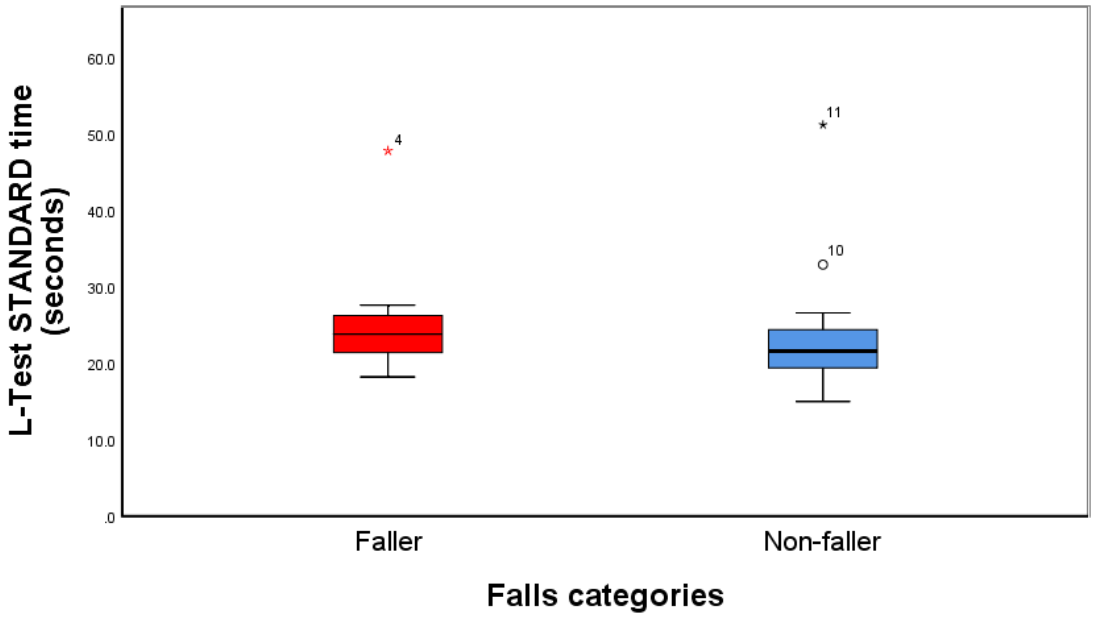

Figure 3.6 Group differences in L-Test-STANDARD scores

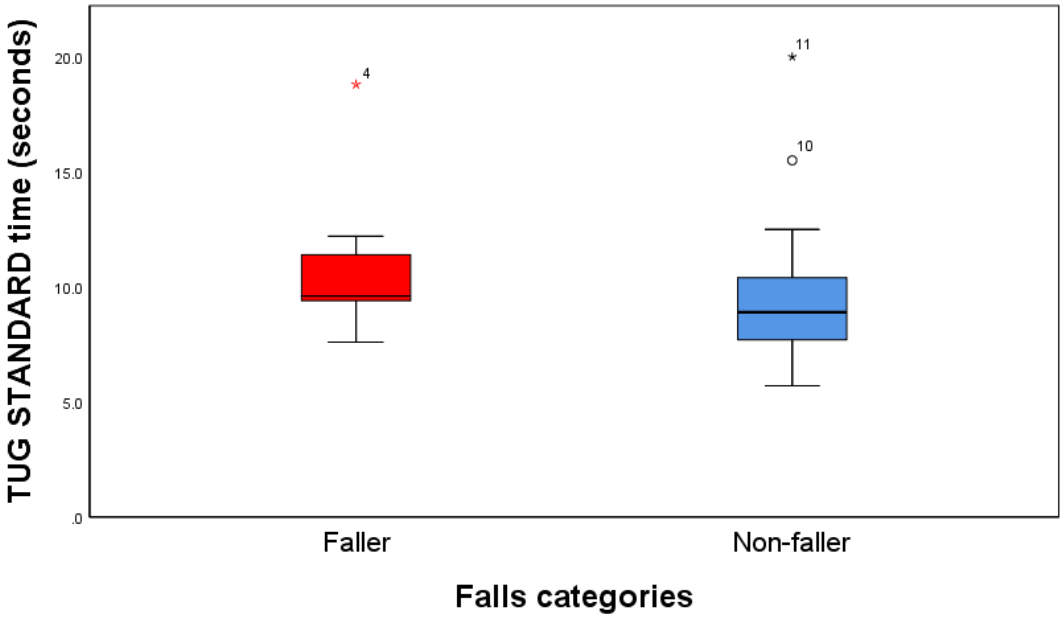

Figure 3.7 Group differences in TUG-STANDARD scores

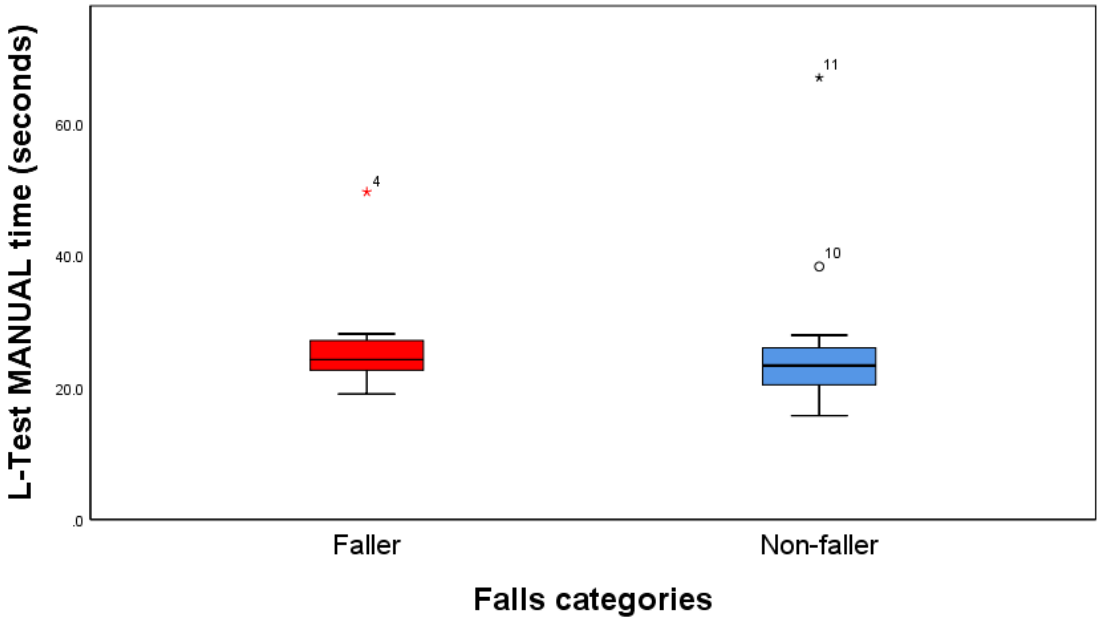

Figure 3.8 Group differences in L-Test-MANUAL scores

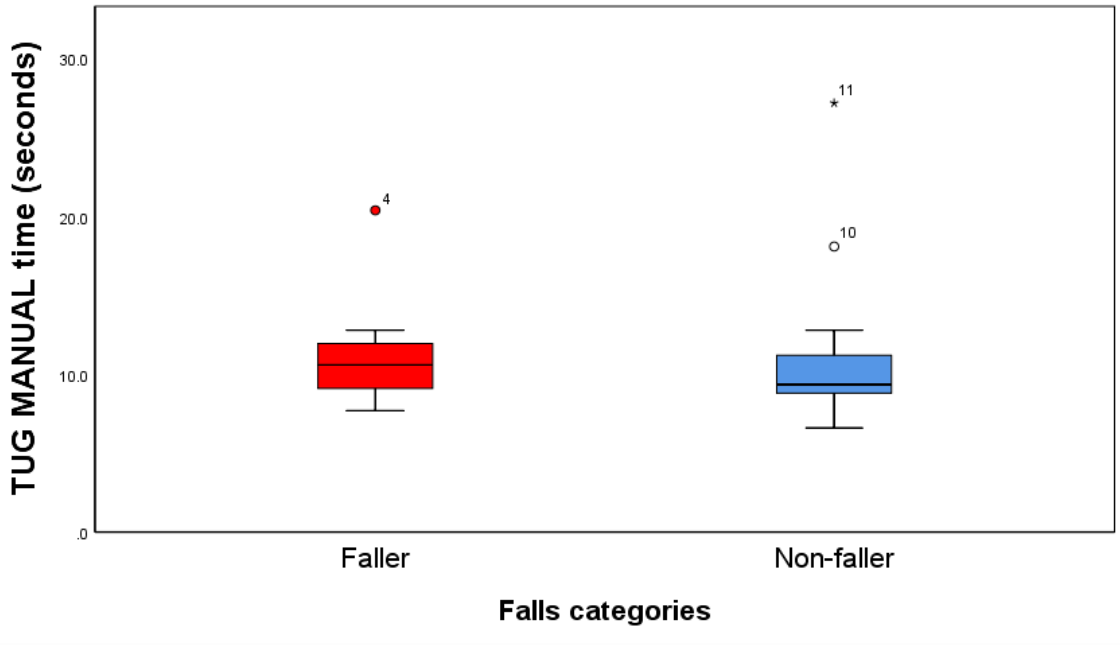

Figure 3.9 Group differences in TUG-MANUAL scores

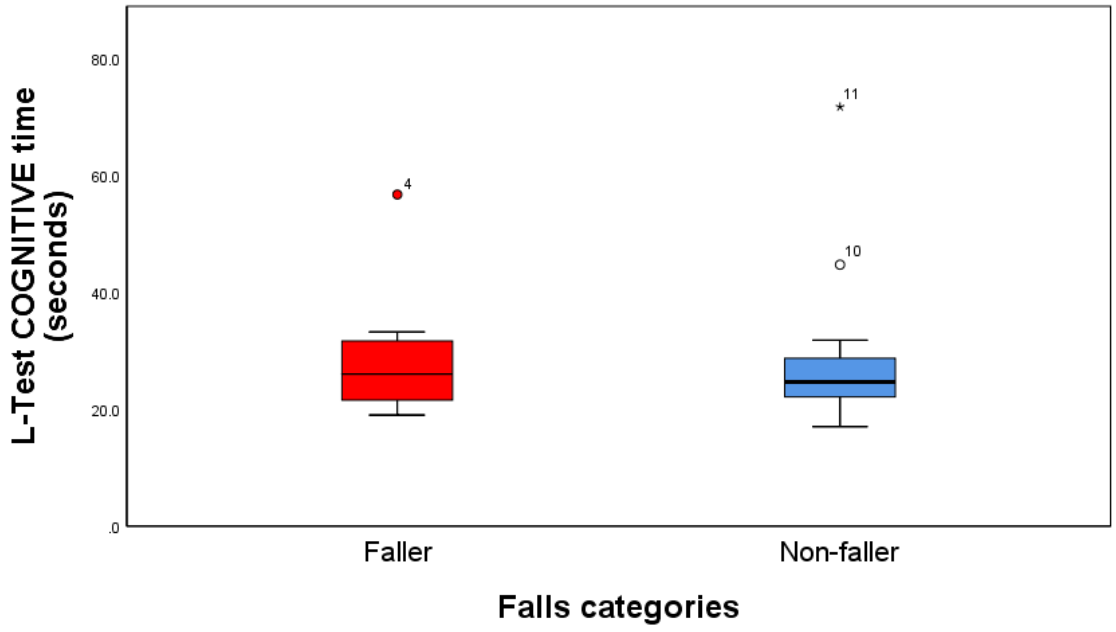

Figure 3.10 Group differences in L-Test-COGNITIVE scores

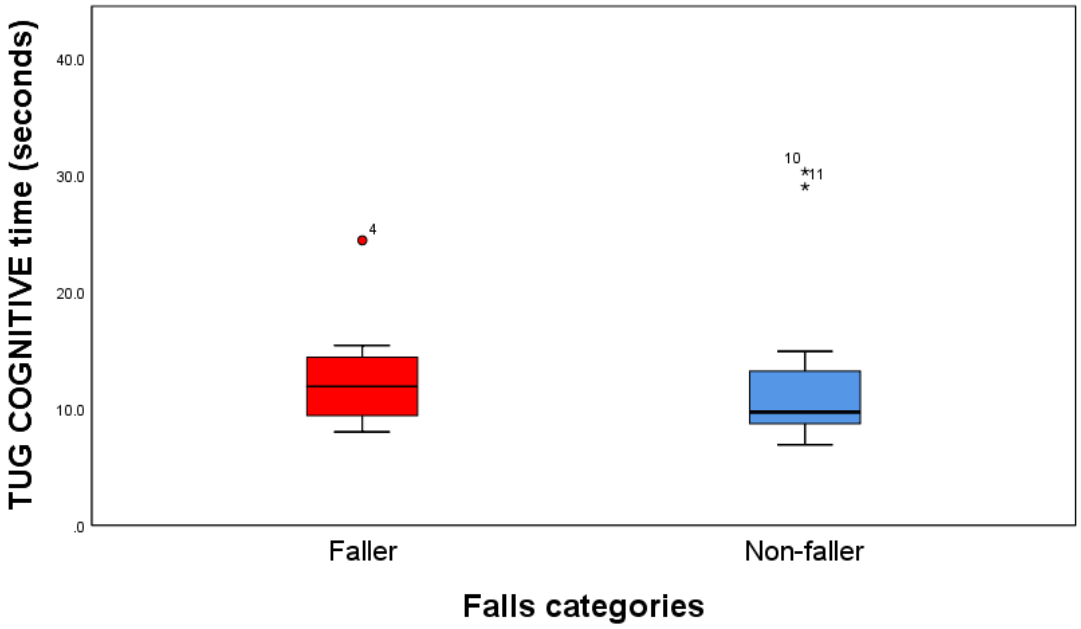

Figure 3.11 Group differences in TUG-COGNITIVE scores

3.5.4 Floor and Ceiling Effects

On inspection of the boxplots for the L-Test and TUG conditions there was no clustering of scores at faster or slower test speeds which might indicate a potential ceiling or floor effect (Figures 3.5 to 3.8). A floor or ceiling effect is said to exist when the incidence of minimum (floor) and maximum (ceiling) scores in an outcome measure exceeds 15% of the total sample (Hayley and Fragala-Pinkham, 2006). Table 3.5 demonstrates 25th and 75th percentile scores for each of the L-Test and TUG conditions and numbers of participants falling below or above these ranges. The number of participants scoring below the 25th percentile, and number of participants scoring above the 75th percentile is similar across groups and thus there is no indication of a ceiling effect or floor effect respectively. All participants scoring below the 25th percentile were in H&Y stages 1-2, indicating mild disease severity. All participants but one scoring above the 75th percentile was in H&Y stages 2-3.

Test	25th percentile Time (s)	Participants scoring <25th percentile (Ceiling effect) n (%)	75th percentile Time (s)	Participants scoring >75th percentile (Floor effect) n (%)
L-Test-STANDARD	19.35	6 (24%)	25.40	6 (24%)
L-Test-MANUAL	20.75	5 (20%)	26.70	6 (24%)
L-Test-COGNITIVE	21.35	6 (24%)	29.65	6 (24%)
TUG-STANDARD	7.75	4 (16%)	10.95	6 (24%)
TUG-MANUAL	8.70	6 (24%)	11.55	6 (24%)
TUG-COGNITIVE	8.65	6 (24%)	13.75	6 (24%)

(s)=seconds; (n)=number of participants

Table 3.6 Floor and Ceiling Effects

3.6 Predictors of Falls Outcome

3.6.1 L-Test and TUG Single and Dual-Task Conditions

Univariate regression analysis was completed to assess the ability of the L-Test and TUG conditions to predict falls. None of the L-Test or TUG conditions reached statistical significance, indicating that the tests were not able to distinguish between fallers and non-fallers (Table 3.7).

Test	Exp(B)	95% CI	p-value
L-Test-STANDARD (s)	1.04	0.94-1.15	0.42
L-Test-MANUAL (s)	1.01	0.94-1.09	0.73
L-Test-COGNITIVE (s)	1.01	0.94-1.08	0.74
TUG-STANDARD (s)	1.11	0.87-1.42	0.39
TUG-MANUAL (s)	1.03	0.85-1.24	0.75
TUG-COGNITIVE (s)	1.02	0.89-1.17	0.74

(s)=seconds; CI=confidence interval *Statistical significance level p≤0.05

Table 3.7 Univariate Regression of L-Test and TUG Data

3.6.2 Baseline Variables

Univariate regression analysis was used to assess whether any of the baseline variables were predictive of falls. The baseline (independent) variables of age, gender, MMSE, H&Y stage, disease duration and number of comorbidities were analysed for predictive value against falls (dependent variable). None of the independent variables reached statistical significance, indicating that the variables were unable to differentiate between fallers and non-fallers (Table 3.8).

Baseline variables		Exp(B)	95% CI	p-value
Age		0.98	0.89-1.08	0.72
Gender		0.71	0.10-5.18	0.74
MMSE		0.64	0.39-1.05	0.08
H&Y	**Stage 1**	0.00		1.00
	Stage 2	1.50		0.79
Disease duration		1.16	0.94-1.42	0.16
No. of comorbidities		0.86	0.47-1.58	0.63

CI=confidence interval; H&Y=Hoehn and Yahr *Statistical significance level p≤0.05

Table 3.8 Univariate Regression Independent Variables

3.7 Receiver Operating Curve Analysis: Faller versus Non-Faller

Table 3.9 displays AUC, sensitivity and specificity values and cut-off times for each of the L-Test and TUG conditions. ROC analyses were performed for each of the L-Test and TUG conditions to determine their ability to distinguish fallers from non-fallers. The AUC values ranged from 0.56 (95% CI: 0.28-0.84) to 0.66 (95% CI: 0.43-0.88). AUC values for the L-Test-STANDARD and TUG STANDARD approached the conventional value of good fit of 0.7 (Nocera et al., 2013). However, none of the AUC values reached statistical significance level ($p \leq 0.05$). Therefore, none of the walking tests under either single or dual-task condition could significantly discriminate fallers from non-fallers.

Test	AUC (95% CI)	Sensitivity (%)	Specificity (%)	Cut-off score (s)
L-Test-STANDARD (s)	0.635 (0.38-0.89)	71.4	72.2	≤23.0
L-Test-MANUAL (s)	0.607 (0.35-0.86)	71.4	61.1	≤23.9
L-Test-COGNITIVE (s)	0.563 (0.28-0.84)	57.1	66.7	≤25.5
TUG-STANDARD (s)	0.659 (0.43-0.88)	85.7	61.1	≤9.2
TUG-MANUAL (s)	0.587 (0.33-0.84)	71.4	55.6	≤9.5
TUG-COGNITIVE (s)	0.599 (0.35-0.85)	71.4	61.1	≤10.1

(s)=seconds; AUC=area under the curve; CI=confidence interval

Table 3.9 ROC Analysis: Faller versus Non-Faller

3.8 Summary of Results

- Baseline characteristics for fallers and non-fallers were similar except for H&Y stage; the majority of fallers were in H&Y stage 2 (85.7%), whereas the majority of non-fallers were in H&Y stage 1 (72.2%).
- The L-Test single and dual-task conditions correlated very strongly with the corresponding TUG conditions.
- There was no significant difference in L-Test and TUG times between the faller and non-faller group.
- There was no significant difference in L-Test and TUG DTC scores between the faller and non-faller group.
- There was no evidence of a ceiling or floor effect for any of the L-Test or TUG conditions.
- Neither the L-Test nor the TUG were able to detect falls under single or dual-task conditions.

CHAPTER 4 DISCUSSION

This is the first known study to evaluate the validity of the L-Test with the addition of secondary dual-tasks in PwP. The results demonstrated a very strong positive correlation between each of the L-Test single and dual-task conditions and the corresponding TUG conditions, thus supporting the use of the dual-task L-Test in clinical practice. These findings support those of Haas et al. (2019), who similarly found a strong correlation between the single-task L-Test and the TUG in a cohort of PwP. The current study is also the first to establish cut-off values for falls prediction for the L-Test single and dual-task conditions. However, in contrast to findings of previous authors with respect to the TUG (Nocera et al., 2013; Vance et al., 2015; Heinzel et al., 2016), none of the L-Test conditions were able to significantly distinguish fallers from non-fallers.

4.1 Participant Demographics

4.1.1 All Participants

Participants were predominantly in H&Y stage 1 (52%, n=13), which may preclude generalisability to later disease stages. Participant mobility levels were reflective of the overall low disease severity of the group; all participants were independently mobile indoors and outdoors and the majority did not use a walking aid (92%). Eligibility criteria necessitated the ability to walk a minimum of 20m without stopping. Nguyen et al. (2007) identified 20-metres as the mobility cut-off above which hospitalised older adults were more likely to have a sustainable home discharge, which reflects the cohort of community-dwelling PwP in the present study. The broad age range of participants in the study (45-84 years) was expected considering that

prevalence of PD increases with age (Von Campenhausen et al., 2005). The mean disease duration of 7.18 years (SD±4.54) is reflective of previous studies (Allcock et al., 2009; Stegemoller et al., 2014; Da Silva et al., 2017; Haas et al., 2019). There was an overall greater representation of males (72%) compared to females, which is reflective of the wider PD population as the incidence of the condition is approximately 1.5 times higher in males than in females (Taylor et al., 2007).

4.1.2 Fallers versus Non-Fallers

A relatively low proportion of participants were fallers (28%, n=7), which may limit interpretation of the results. However, this is comparable to previous studies by Smulders et al. (2012) and Heinzel et al. (2016) where fallers accounted for 35% of the total group. Sample sizes in these studies were 263 and 40 respectively, and thus were significantly larger than that of the current study, however neither study provides evidence of use of a sample size calculation, which is recommended for studies of high quality (Mokkink et al., 2010). Fallers in the current study were predominantly male (71.4%), which is unsurprising given the overall greater representation of males in the study and is likely compounded by the relatively small sample size. There was no difference between fallers and non-fallers with respect to type of walking aid used, however only 8% (n=2) of all participants used a walking aid, which may have influenced this finding. There were no differences between fallers and non-fallers in age, disease duration, number of comorbidities or MMSE score. H&Y stage was the only baseline characteristic which differed significantly between fallers and non-fallers, with the majority of fallers in H&Y stage 2 (85.7%, n=6). This result was somewhat expected given that incidence of falls increases with increasing PD severity (Hoskovcova et al., 2015). However, a previous study involving a large sample of 332

PwP found no significant differences in H&Y stage between fallers and non-fallers (p=0.724) (Smulders et al., 2012). The robustness of that study was enhanced by use of prospective falls evaluation using the 'falls telephone', found to be reliable in PD (sensitivity=100%, specificity=78%) (Van der Marck et al., 2011).

4.2 Correlations between L-Test and TUG Single and Dual-Task Conditions

The validity of the single-task L-test was recently evaluated for the first time in PwP (Haas et al., 2019). The authors conducted testing over two test sessions, 7-days apart, demonstrating a positive significant correlation between the single-task L-test and TUG (r=0.97, p<0.001; r=0.96, p,0.001). The results of the current study support these findings, demonstrating a very high positive correlation between the single-task L-Test and single-task TUG (Table 3.6). As hypothesised, very strong positive correlations were also found between the L-Test and TUG manual dual-task conditions and cognitive dual-task conditions (Table 3.6). Furthermore, a power calculation ensured that the sample would be sufficiently powered to address the primary aim, i.e. to detect significant differences in correlations between the L-Test and TUG conditions ($p \leq 0.05$). Previous studies have similarly demonstrated high correlations between the L-Test and the TUG in other patient populations, including patients post lower-extremity amputation (r=0.93, p=0.001), hospitalised older adults (r=0.96, p=0.001) and chronic stroke patients (r=0.89, p=0.001).

The high correlation shown in the current study between each of the L-Test and TUG conditions was expected given that the L-Test is essentially an extension of the TUG (Nguyen et al., 2007). Both tests have similar characteristics; participants must

perform a sit-to-stand, initiate gait, walk in a straight line, turn in one or two directions (TUG and L-Test respectively), and finally perform a stand-to-sit transition. The design of both tests is complex, comprising several sub-components. The L-Test in particular, given its increased distance and requirement to perform bi-directional turns, is likely to be sufficiently challenging for individuals in later disease stages as a stand-alone assessment, even before the addition of secondary dual-tasks. Palmisano et al. (2019) demonstrated the complexity of the 'sit-to-walk' sub-component of the L-Test and TUG. The authors evaluated the 'sit-to-walk' task in faller (n=9) and non-faller (n=15) PwP and in control participants (n=20). Peak velocity of trunk momentum in the anterior-posterior direction successfully discriminated fallers from non-fallers (0.66m/s, sensitivity=89%, specificity=93%; 0.81m/s, sensitivity=82%, specificity=100% in off and on-medication states respectively), and offer this as confirmation of the difficulties encountered by PwP in merging consecutive motor tasks. However, the authors do not provide information on disease severity, making it difficult to determine whether results are applicable to the current study. Nonetheless, use of a control group of age-matched healthy participants strengthens the findings, and supports the assertion of the current study on the complexity of the L-Test and TUG as baseline assessments.

4.3 Floor and Ceiling Effects

There was no evidence of a floor or ceiling effect for any of the L-Test or TUG single-task or dual-task conditions within the study (Table 3.5). It was expected that a greater ceiling effect would be observed with the TUG-MANUAL and TUG-COGNITIVE compared to the L-Test-MANUAL and L-Test-COGNITIVE for those in milder disease stages. This was based on the expectation that the TUG would not pose a

sufficient challenge to those with milder disease, and that the L-Test would increase the difficulty of the assessment and thus provide a more accurate picture of DTD. The small sample size within the study and larger representation of non-fallers than fallers is likely to have contributed to the lack of floor or ceiling effects.

4.4 Differences between Fallers and Non-Fallers

4.4.1 L-Test and TUG

There were no significant differences in faller and non-faller scores for each of the three L-Test or TUG conditions (single-task, dual-task-manual and dual-task-cognitive). This result contrasts with previous research which demonstrated significantly slower TUG scores in fallers compared to non-fallers (Smulders et al., 2012; Vance et al., 2015). It is noteworthy that mean scores in the current study for the single-task L-Test and TUG in both faller and non-faller groups were faster than those previously documented for PwP of similar disease severity (Stegemoller et al., 2015; Haas et al., 2019). Participants in a recent study involving PwP demonstrated mean scores for the single-task L-Test of 35.46s and 29.66s, and for the single-task TUG of 15.33s and 12.4s, measured across two test occasions (Haas et al., 2019). In contrast, mean scores for each of these tests in the current study were faster for both faller and non-faller groups (Table 3.3). Certain demographic differences between the two studies may account for this. Participants in the Haas et al. (2019) study had a greater mean age (75 years, SD+/-6.7) than those in the present study (65.64 years, SD+/- 9.40). Furthermore, in the current study all participants were tested within a three-hour window of taking anti-PD medication and in a self-reported ‘on’ medication phase; this does not appear to have been implemented by Haas et al. (2019) and may have resulted

in participants being tested in an 'off' medication period. This could have had a negative impact on functional ability and may have resulted in slower than normal walking speeds. There are also factors within the study by Haas et al. (2019) which preclude direct comparison with the current study; information on distribution of participants across different H&Y stages is insufficient and there is lack of clarity as to whether participants used a walking aid to mobilise. Stegemoller et al. (2015) similarly demonstrated slower walking speeds in the TUG than those in the current study. They conducted a cross-sectional study involving 6624 PwP. The median score for the single-task TUG (11s) was higher than those in the current study for the single-task TUG in both faller and non-faller groups (9.6s and 8.9s respectively). The large sample size strengthens study findings, however, there are factors which limit direct comparison between the current study and that of Stegemoller et al. (2015). With respect to the latter study, no information was collected on disease severity, participants were enrolled without exclusion criteria and participants completed only one trial of the TUG. These factors, given the fluctuations in functional level seen in PD, may limit interpretation of the results.

4.4.2 Dual-Task Cost (DTC)

A recent meta-analysis of dual-task ability in PD concluded that performing dual-tasks while walking can have significant and meaningful negative consequences on gait (Raffegeau et al., 2019). This is of clinical relevance as DTD may affect performance of ADLs such as walking while talking or negotiating obstacles while mentally considering everyday tasks (Fuller et al., 2013). In the present study, DTC was calculated to determine whether there was a deterioration in performance of the L-Test and TUG under dual-task conditions (Chomiak et al., 2017). No significant differences

were found in DTC between fallers and non-fallers for the L-Test-MANUAL, L-Test-COGNITIVE, TUG-MANUAL or TUG-COGNITIVE (p=0.14, 0.27, 0.06 and 1.00 respectively). Only the difference between TUG-MANUAL DTC for fallers and non-fallers approached statistical significance (Table 3.4). Based on previous research, it was expected that the L-Test-COGNITIVE and TUG-COGNITIVE would result in a significant deterioration in speed in both faller and non-faller groups (Vance et al., 2015; Goh et al., 2017). However, another study found that while recurrent fallers with PD had significantly slower gait speed than non-recurrent fallers (5.3% difference, 95% CI=0.2-10.6%; p=0.041,), they did not have higher DTC than patients without recurrent falls (F=0.20, p=0.657) (Smulders et al., 2012).

PwP may have sufficient cognitive reserve to attend to gait in the single-task condition, but in the dual-task condition reduced cognitive reserve can result in deterioration in task performance (Fuller et al., 2013). Although there was no significant difference in DTC between fallers and non-fallers in the current study, the non-faller group nonetheless demonstrated a DTC of approximately 15% for both the L-Test-COGNITIVE and TUG-COGNITIVE. representing a clinically meaningful decline in performance (Table 3.4). This assertion is supported by a previous study which suggested the presence of dual-task interference (DTI) as an explanation for the 10% decrease in walking speed seen under the dual-task condition (Strouwen et al., 2016).

There are factors within this study which may have impacted the ability of the walking tasks to detect DTI. The secondary tasks were chosen based on those used in previous research (Vance et al., 2015). However, overly simple walking tasks may preclude

detection of DTI (Smulders et al., 2012). It is possible that the secondary tasks within the present study were not sufficiently challenging to reach the threshold where attentional control was unable to compensate for motor impairment, particularly given that most participants had mild disease severity (Rochester et al., 2014). Furthermore, the specificity and type of secondary task has been shown to influence DTI (Brauer and Morris, 2010). Two studies evaluated dual-task ability using the auditory Stroop task (Smulders et al., 2012; Strouwen et al., 2017). Use of this task in detection of DTI may be questionable, as it has been suggested that the auditory Stroop can produce a cueing effect on gait, which could potentially confound improvements in dual-task performance (Baker et al., 2008). Other studies involved more complex secondary tasks, i.e. carrying a tray, generating words, or reacting to auditory or visual stimuli (Raffegeau et al., 2019). Future studies evaluating secondary motor and cognitive tasks of varying complexity are necessary to further investigate the influence of type of task on DTI.

4.5 Predictive Ability of the L-Test and Timed Up-and-Go Single and Dual-Task Conditions in Identifying Fallers

This study hypothesised that the L-Test and TUG cognitive dual-task conditions would be more predictive of falls than the single and manual dual-task conditions. This was based on results from a previous study which demonstrated the predictive ability of the TUG-cognitive in identifying fallers in PwP (AUC=0.82, sensitivity=76.5%, specificity=73.7%, cut-off=14.7s) (Vance et al., 2015). Contrary to the hypothesis, neither the L-Test nor TUG single or dual-task conditions within the current study were able to predict fallers (Table 3.7). However, certain differences in eligibility criteria between the two studies may have influenced results. Vance et al. (2015) included PwP

in H&Y stages 2-4, and fallers had more advanced disease, with 94% in H&Y stages 3-4. Conversely, participants in the current study had mild disease severity (Fig.3.2). This is important as participants in later H&Y stages would have greater mobility impairments, potentially placing them at increased likelihood of falls (Keus et al., 2014). Another study concluded that motor rather than cognitive dual-tasking was predictive of falls in PD and was discussed in the Literature Review section of this thesis (Heinzel et al., 2016). Mean H&Y score was 2.6 (SD+/-0.7) and 2.3 (SD+/-0.7) for faller and non-fallers respectively, indicating moderate disease severity, and thus findings are not directly comparable to the present study. Importantly, participants in the Heinzel et al. (2016) study were evaluated off anti-parkinsonian medication, which may have influenced results as participants are likely to have increased motor difficulty in the off-medication state (Keus et al., 2014).

Smulders et al. (2012) also evaluated predictive ability of dual-task over single-task walking in identifying fallers in PD. There was no association between future falls and dual-task performance during gait ($F=0.175$, $p=0.676$). Strengths of their study include use of a large sample size (n=263) and prospective recording of falls over a one-year period. Participants completed two separate walks along a 10-metre trajectory under single-task and dual-task conditions. The dual-task was the auditory Stroop task, which has been used as the secondary task in a previous study (Strouwen et al., 2017) and was described in the Literature Review section of this thesis. However, the simplicity of the walking task in the Smulders et al. (2012) study may have limited detection of DTI. Given that participants had mild-moderate disease severity, the task of walking in a straight, 10-metre line is unlikely to have posed a sufficient challenge to participants' mobility to successfully identify DTI. In contrast and as previously outlined in section

4.2 of this discussion, the design of the L-Test and TUG is inherently complex. The heterogeneity of results of the current study and of the others discussed renders it difficult to draw conclusions on the value of assessment of dual-task mobility in falls prediction. It would seem that predictive value of dual-task conditions for identifying falls risk may be more suitable for PwP with more severe disease, as shown in the study by Vance et al. (2015).

4.6 Determination of Cut-Off Scores and Sensitivity and Specificity Values

This is the first known study to establish cut-off scores for the L-Test in PwP. Results indicated that the single-task L-Test and TUG were the most sensitive and specific predictors of falls risk (71.4% and 72.2%, and 85.7% and 61.1% respectively). Sensitivity referred to how often the L-Test and TUG detected falls risk for a participant in the faller group, whereas specificity indicated how often the participant was not at risk of falling and was categorised as a non-faller (Vance et al., 2015). The AUC values for the single-task L-Test and TUG both approach the conventional value of good fit of 0.7 (Table 3.9) (Nocera et al., 2013). The manual dual-task and cognitive dual-tasks for both the L-Test and TUG had lower prognostic accuracy than the single-task L-Test and TUG for identifying fallers, with AUC values greater than chance (Table 3.9). The cut-off scores established within this study for the single-task TUG (9.2s) is notably lower than those determined in previous studies; Nocera et al. (2013) demonstrated a cut-off of 11.5s, while Shumway-Cook et al. (2000) established a cut-off of 13.5s. For the TUG with a cognitive dual-task, Vance et al. (2015) found that a cut-off of 14.7s optimised the discriminative performance of the test, with sensitivity of 76.5% and specificity of 73.7% (Vance et al., 2015). This is again substantially higher than the TUG-COGNITIVE cut-off (10.1s) established in the present study.

A recent systematic review found that the ability of dual-task walking assessments to differentiate between fallers and non-fallers varied, and that sensitivity tended to be lower than specificity (Yang et al., 2017). The findings of the current study are largely reflective of this. The study demonstrated a relatively high sensitivity and specificity for falls prediction for the single-task L-Test and TUG, however this alone is not sufficient to identify falls risk. While dual-task mobility assessments may indicate increased susceptibility to falling, they cannot be taken as a stand-alone indicator of falls risk. Results of this study therefore support the recommendation of previous authors that dual-task mobility assessments should only be used as part of a multifactorial falls assessment (Vance et al., 2015; Rochester et al., 2014). There are factors within this study which have already been discussed which may have contributed to the low cut-off scores and variations in sensitivity and specificity values; participants had predominantly mild disease and the majority were non-fallers, thus reducing generalisability to a wider PD population. Future studies of a larger scale are required to provide more reliable and accurate cut-off and sensitivity and specificity values for the single-task and dual-task L-Test.

4.7 Clinical Implications

This study supports the use of the L-Test with concurrent dual-tasks in people with mild-moderate PD, as demonstrated by the very strong significant correlations between the L-Test and TUG manual and cognitive dual-task conditions (rho=0.94, CI=0.87-0.97p<0.001 and rho=0.92, CI=0.84-0.97, p<0.001 respectively). Furthermore, results of this study reflect those of Haas et al. (2019), demonstrating a positive significant correlation between the L-Test and TUG single-task conditions (rho=0.94, CI=0.86-0.97 p<0.001). However, this study has been unable to demonstrate superiority of

either test. The TUG requires less space, potentially making it easier to implement in clinical practice. Future large-scale studies are required to investigate potential value of the dual-task L-Test in patients with mild disease severity, as outlined in Section 4.9.

Contrary to the hypothesis, there was no indication of ceiling effects for any of the L-Test or TUG conditions in this population of community-dwelling PwP of mild-moderate disease severity. In terms of predictive ability for identifying fallers, none of the L-Test or TUG conditions could distinguish between fallers and non-fallers, and the study cannot comment on superiority of one test over the other for this purpose. Sensitivity and specificity values and cut-off scores for fallers were established for each of the L-Test and TUG conditions. However, only those for the single-task L-Test and TUG approached acceptable sensitivity and specificity. Study findings are in agreement with those of previous authors in recommending that dual-task mobility assessments should only be used as part of a multi-factorial falls risk assessment.

4.8 Study Limitations

- Results can only be generalised to community-dwelling individuals with mild-moderate PD. The study aimed to include a range of PwP who would be representative of the general PD population, however it was necessary to set inclusion and exclusion criteria to ensure appropriate study design (Mokkink et al., 2010). Only patients in H&Y stages 1-3 were included to ensure that participants would have sufficient mobility levels to complete the walking tasks, which may have precluded generalisability of results to individuals with more advanced disease.

- The study was cross-sectional and therefore cannot account for external factors which may have impacted on results on the day of testing.
- Falls history was collected retrospectively, which may have limited accuracy of fall rates. Prospective recording of falls is preferable in evaluating falls risk as it provides a more accurate picture of incidence and frequency of falls (Lamb et al., 2005; Allcock et al., 2009). However, the cross-sectional nature and limited timeframe of this study meant that prospective collection of falls information was not possible.
- There was a significantly greater representation of non-fallers compared to fallers within this study, which may limit interpretation of results. The sample size calculation was based on primary aim of establishing concurrent validity and the study is therefore likely to be inadequately powered to address the secondary aim of determining predictive ability of the L-Test in identifying fallers.
- Tests were measured with a stop-watch, using a single-duration measure of time; total time taken to complete the tests was recorded, rather than timing specific sub-components of the test (i.e. sit-to-stand, or time taken for turning). This may not accurately reflect subtle differences in how individuals complete the task (Stegemoller et al., 2015).
- Although efforts were made to reduce learning and fatigue effects, such effects cannot be ruled out as participants were exposed to the testing procedure repeatedly during data collection.
- The study did not account for non-motor factors which may have impacted falls, such as fear of falling or self-efficacy in relation to ADLs.

4.9 Recommendations for Future Research

- Future larger-scale studies are required to evaluate inter-rater and test-retest reliability of the L-Test dual-task conditions in PwP.
- Longitudinal, prospective studies involving greater number of fallers are necessary to establish predictive ability of the single and dual-task L-Test in identifying fallers.
- Studies evaluating predictive ability of dual-task outcome measures in identifying fallers may benefit from investigating PwP in different categories of disease severity separately, i.e. patients with moderate-severe disease severity should be evaluated separately to those with mild disease severity. Furthermore, attention should be paid to the increased falls risk associated with certain PD subtypes, such as the postural-instability and gait-difficulty predominant subtype (PIGD) (Kotagal, 2016).
- Studies are required to evaluate the relationship between the single and dual-task L-Test single and a validated PD QoL measure, such as the PDQ-39 (Stegemoller et al., 2014).
- Future studies should investigate gait parameters using the single and dual-task L-Test in people with mild-moderate PD. Incorporation of instrumented assessments to detect gait abnormalities may increase predictive ability for identifying falls given the disproportionate effect of dual-tasking on postural stability (Rochester et al., 2014).
- Earlier identification of falls risk in PwP is necessary to allow timely implementation of falls prevention programmes (Nocera et al., 2013). Future studies on the L-Test involving PwP of mild disease severity should focus on

prediction of those who have not fallen yet may be as risk of falls, through evaluating occurrence of near-falls (Lindholm et al., 2015).

- Future studies using retrospective falls evaluation would benefit from taking additional measures to reduce risk of recall bias, such as using a 3-month timeframe for recall of falls history (Nocera et al., 2013) and classifying participants as either ‘recurrent fallers’ (>1 fall) or ‘non-recurrent fallers’ (no falls or 1 fall) (Smulders et al., 2012). This method of classification has been found to result in high sensitivity values (Hyndman and Ashburn, 2004).

CONCLUSION

Reduced automaticity of movement in PD manifests in DTD, which in turn is associated with increased risk of falls. This has important implications for clinical practice, as the detection and prevention of falls is a priority. This primary aim of this study was to establish the concurrent validity of the L-Test manual and cognitive dual-task conditions in participants with idiopathic PD. It was additionally hypothesised that there would be greater evidence of a ceiling effect with the TUG than L-Test dual-task conditions. Finally, it was expected that the cognitive dual-task conditions for both tests would be more predictive of falls than the single and manual dual-task conditions, and that overall, the L-Test would have greater predictive ability in identifying fallers than the TUG.

Results indicated that the L-Test dual-task conditions correlated very strongly with those of the TUG, thus supporting the first hypothesis. Additionally, the single-task L-Test showed a very strong correlation with the single-task TUG. This was anticipated, given the similarities in design of the two instruments. The second objective of this study related to the predictive ability of the L-Test in identifying fallers. The L-Test, although similar to the TUG, involves an increased walking distance and necessitates bi-directional turning, and it was therefore expected that the greater complexity of the L-Test would pose an increased challenge to participants, and would thus demonstrate greater ability to distinguish between fallers and non-fallers. Furthermore, it was anticipated that the TUG single and dual-task conditions would show ceiling effects for this cohort of mild-moderate PD patients which would be less evident for the L-Test. Contrary to these hypotheses, this study showed no evidence of a ceiling effect

for any of the L-Test or TUG conditions, and none of the tests had the ability to distinguish between fallers and non-fallers.

Certain limitations of this study have been acknowledged which may have influenced the study findings. Participants had predominantly mild disease severity and a relatively small proportion were classified as fallers. Furthermore, the sample size calculation was based on establishing concurrent validity, and in this respect the study is likely to be underpowered to distinguish between fallers and non-fallers. Retrospective evaluation of falls history may have reduced accuracy of falls recall, despite efforts made within the study design to reduce this possibility.

This study established that adding secondary dual-tasks to the L-Test provides a valid assessment of dual-task mobility in people with mild-moderate PD. While the study has been unable to establish predictive ability for identifying falls, findings are in line with those of previous research in suggesting that dual-task mobility assessments should only be completed as part of a multi-factorial falls assessment.

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APPENDICES

Appendix 1

Tallaght University Hospital
Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

RCSI

Study Inclusion Form

Study Title: The Concurrent Validity of the Dual-Task L-Test in Parkinson's Disease and its Predictive Ability in Identifying Falls

To be completed by the NEUROLOGIST/PHYSIOTHERAPIST/CLINICAL NURSE SPECIALIST prior to participant inclusion in the study:

Please tick to indicate that the following eligibility criteria are met:

Diagnosis of Idiopathic Parkinson's Disease	
Able to walk 20 metres unaided (with or without a walking aid)	
No visual or auditory problems which may interfere with assessment	
No other neurological, orthopaedic or cardio-respiratory conditions that may affect walking or safety during testing	

Please indicate Hoehn & Yahr level by ticking the corresponding box:

1	Only Unilateral involvement, usually with minimal or no functional disability	
2	Bilateral or midline involvement without impairment of balance	
3	Bilateral disease: mild to moderate disability with impaired postural reflexes; physically independent	

4	Severely disabling disease; still able to walk or stand unassisted	
5	Confinement to bed or wheelchair unless aided	

List type and dosage of antiparkinsonian medication:

_____

Neurologist/Physiotherapist/Clinical Nurse Specialist name (BLOCK CAPITALS):	
Neurologist/Physiotherapist/Clinical Nurse Specialist Signature:	
Date:	

Appendix 2

Tallaght University Hospital
Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

RCSI

Patient Information Leaflet

Study Title: The Concurrent Validity of the Dual-Task L-Test in Parkinson's Disease and its Predictive Ability in Identifying Falls

Principal Investigator's name:	**Claire Griffin**
Principal Investigator's title:	**Chartered Physiotherapist / MSc Student, RCSI**
Principal Investigator's contact number:	**083 116 0555**
Academic Supervisor's name:	**Dr. Helen French**
Academic Supervisor's title:	**Senior Lecturer in Physiotherapy, RCSI**
Consultant Co-investigator's name:	**Dr. Richard Walsh**
Consultant Co-investigator's title: **Neurologist**	**Consultant**
Consultant Co-investigator's contact number:	**01 414 4061**
Consultant Co-investigator's email: **Richard.Walsh@tuh.ie**	
Physiotherapist Co-investigator's name:	**Anne Belton**
Physiotherapist Co-investigator's title: **Physiotherapist**	**Chartered**
Clinical Nurse Specialist Co-investigator's name :	**Nicola Kavanagh**
Clinical Nurse Specialist Co-investigator's title :	**Parkinson's Disease Clinical Nurse Specialist**

Data Controller's Identity:	Claire Griffin
Data Controller's Email:	clairegriffin@rcsi.ie
Research Ethics Committee:	St. James' Hospital/Tallaght University Hospital Joint Research Ethics Committee

You are being invited to take part in a research study to be carried out in Tallaght University Hospital by Claire Griffin, MSc student at the Royal College of Surgeons in St. Stephen's Green. Claire is being supervised for this study by Dr. Helen French, Senior Lecturer in Physiotherapy.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

PART 1 – THE STUDY

Why is this study being done?

People with Parkinson's Disease can have difficulty doing two things at once, especially when they are walking (e.g. walking while talking to someone beside them, or walking while being on a mobile phone). This is called dual-tasking. This can cause them to walk more slowly and can lead to a risk of falling.

Physiotherapists use walking tests to assess whether or not a person with Parkinson's Disease has difficulty doing dual tasks. This is usually done by asking the person to walk along a set walking course. They are then asked to walk along the same course while doing another task at the same time; e.g. carrying a glass of water or counting backwards from a certain number.

This study will involve a walking test which has been recently shown to be useful in Parkinson's Disease, called the 'L-test'. Another mobility test which is often used by physiotherapists is called the 'Timed Up and Go'.

This study is taking place for two reasons:

- Firstly, to see whether doing the 'L-test' with a second task at the same time is as good at detecting difficulty with dual tasks as the 'Timed Up and Go'.
- Secondly, to see whether the 'L-test' alone, and the 'L-test' with a second task can identify people who might be at risk of falling.

Why am I being asked to take part?

You are being asked to take part because you have been diagnosed with Idiopathic Parkinson's Disease by your Consultant Neurologist. We are looking for people who can walk without help from another person for a distance of at least 20 metres. This can be with or without a walking aid such as a stick or a frame. We are also looking for people without significant visual difficulty or deafness. This is to make sure they will be able to see the walking course used in the study, and to make sure they can hear instructions being given to them.

Do I have to take part? What happens if I say no? Can I opt out?

You don't have to take part in this study. If you decide not to take part, it won't affect your future medical care at Tallaght University Hospital. You can also change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future. If you do wish to opt out, please contact Claire Griffin, the Principal Investigator on 083 116 0555. She will be able to organise this for you.

How will the study be carried out?

We will be recruiting for the study between September and October 2019 and 25 volunteers are needed. You will be asked to attend only one testing session, which will take place in the Physiotherapy Gym in Tallaght University Hospital. Taking part in the study will take approximately one hour of your time.

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

If you agree to take part, you will be asked to attend the Physiotherapy Gym in Tallaght University Hospital on one occasion only. Testing will take no longer than one hour. When you arrive, you will meet Claire Griffin, the Principal Investigator, who will do the testing.

The first part of testing will take approximately 15 minutes. You will be asked to complete a brief cognitive assessment. This will test your ability

to do different mental tasks. You will also be asked whether or not you have had any falls in the last year.

The second part of testing will take a maximum of 45 minutes. You will be asked to complete a series of walking tests. Each walking test will be repeated twice, to allow the Principal Investigator to calculate the average score.

- The first test (the Timed Up and Go) involves standing-up from a chair, walking three metres, turning around a cone, and returning to sit in the chair.
- The second test (the L-test) involves standing-up from a chair, walking three metres, turning 90° to the right, walking another 7 metres, turning 180°, and walking back to the chair along the same pathway.

You will then be asked to complete the above tests with a second manual task, and also with a second cognitive task, performed at the same time as the walking tests. For the manual task you will be asked to carry a glass of water, while for the cognitive task you will be asked to count backwards from a certain number.

The tests will be demonstrated and explained to you by the Principal Investigator on the day of testing. She will make sure that you fully understand the procedure before starting the test. You will be allowed adequate time to rest and recover between each test and before going home.

Are there any benefits to me or others if I take part in the study?

It is important that Physiotherapists use effective and easy-to-use tests to help detect difficulties that people with Parkinson's Disease may have with walking. This study aims to identify a new way of testing walking and dual-tasking ability in Parkinson's Disease. This will be of benefit to people with Parkinson's Disease generally, who are attending Physiotherapy.

The study may also be of benefit to you personally in the following ways.

- It will indicate whether and to what extent you have difficulty doing dual tasks while walking.
- It will also indicate whether you may be at risk of falling

If we identify that you have difficulty with dual tasks or feel that you may be at risk of falls, we will share this information with your Physiotherapist. If difficulties are identified and you are not currently under the care of a Physiotherapist, you will be offered referral to Physiotherapy, if you so wish.

Are there any risks to me or others if I take part in the study?

The tests involve walking in straight lines and turning around cones. As with any walking tests, there is a small risk of falling. However, given that you can walk independently, this is highly unlikely. You will also be closely supervised by the Principal Investigator at all times during testing. As there is a possible risk that you may become tired or fatigued during the walking tests, you will be allowed time to rest between each test and before going home.

Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?

The Principal Investigator will discuss the results of the tests with you, and any difficulties identified will be highlighted to you, as mentioned above.

The results of the study will be presented in a thesis as part of an MSc in Neurology and Gerontology in RCSI. The results may also be published in journals related to rehabilitation in Parkinson's Disease.

PART 2 – DATA PROTECTION

Is the study confidential?

Yes - all information that we find out about you during this study will remain confidential throughout the study and afterwards, when the study's findings are published. Only the Principal Investigator will have access to this information.

Paper records will be kept in a locked filing cabinet in the Physiotherapy Dept in Tallaght University Hospital and all electronic information (e.g. walking test results) will be stored in an encrypted directory on RCSI's secure network without any identifying details, such as your name. All study paperwork will have a Unique Identification Number (UIN) on it, rather than your name. There will be a code key linking your name and UIN, which will be encrypted and kept on the computer servers in the Physiotherapy Department in Tallaght University Hospital and in RCSI School of Physiotherapy. This information will be stored only for the duration of the trial.

Your Consultant Neurologist Dr. Walsh will be involved in recruitment for the study and will receive a summary of your assessments after the study. If you are currently receiving treatment from a Physiotherapist, they may also receive a summary of your assessments.

We will collect and process the following personal data in connection with this study:

What information about me will be used in the study? Will my medical records be accessed?

- Personal details such as your name, date of birth, phone number and email address
- Sensitive personal data collected will include: stage of Parkinson's disease, scores from the cognitive assessment, whether or not you have had any falls, past medical history, and what Parkinson's Disease medication you are on.

What is the legal basis to use my personal data?

The legal basis for collecting and using personal data is your consent and falls under Article 6(1)(f) Legitimate Interests & Article 9(2)(j) Scientific Research purposes.

Who will my personal data be disclosed to?

Only your Consultant Neurologist Dr. Walsh, PD Clinical Nurse Specialist Nicola Kavanagh and Physiotherapist Anne Belton will have access to your medical records. They may share some of this information with the Principal Investigator for the purpose of this study. Only information relevant to the study will be shared. Testing will be completed by the Principal Investigator only. Your Consultant Neurologist and your Physiotherapist will receive a brief summary of the assessment findings.

Will my data be transferred abroad?

No. Encrypted electronic data will be stored on RCSI's secure network at 123 St. Stephen's Green, Dublin. Your assessment and clinical data will be stored in a locked filing cabinet in the Physiotherapy Gym in Tallaght University Hospital.

Will my data be kept secure and confidential?

Study information will be stored electronically in an encrypted directory on RCSI's secure network without any identifying details, such as your name. An encrypted UIN code key will be stored separately on this network.

What rights do I have in relation to my data?

You have the following rights, in certain circumstances, in relation to your personal data:

- The right to access to your personal data
- The right to restrict the use of your personal data
- The right to correct inaccuracies in your personal data

- The right to have your personal data deleted
- The right to object to automated processing of your personal data
- The right to receive your personal data, which you provided to us, in a structured, commonly used and machine-readable format or to require us to transmit that data to another controller.

In order to exercise any of these rights or to withdraw your consent, please contact Claire Griffin (clairegriffin@rcsi.ie).

PART 3 – COSTS, FUNDING & APPROVAL

Will it cost me anything to take part?

You will incur the cost of hospital parking or public transport to the hospital for the single testing session. There will be no other costs on your part. There will be indemnity cover in place for both the Principal Investigator and the co-investigators at Tallaght University Hospital.

Who is funding the study?

There is no funding in place for this study. The study is being completed as part of an MSc in Neurology and Gerontology in RCSI School of Physiotherapy. The Principal Investigator responsible for the study is a Chartered Physiotherapist and will not receive any payment for recruiting patients to the study. The Co-investigators (Dr. Walsh, Consultant Neurologist, Nicola Kavanagh, PD Clinical Nurse Specialist and Anne Belton, Chartered Physiotherapist) are employed by Tallaght University Hospital and will not receive any additional payment for recruiting patients. The results of the study will not under any circumstances be used or disclosed for commercial purposes.

Has the study been approved by a Research Ethics Committee?

Yes. The study has been approved by the Tallaght University Hospital / St. James' Hospital Joint Research Ethics Committee. They can be contacted by email at ResearchEthics@tuh.ie, or by phone, on 01-414 2199.

PART 4 – FUTURE RESEARCH

Will my personal data be used in future studies?

When providing your consent to participate in this study, you may wish to give consent to the use of your data in the current study only. However, we will also ask for your permission to store and electronically process your data for possible future research by the research team related to the current study, without further consent being required. This will, however, only happen if the research is approved by a Research Ethics Committee.

You will be asked to give explicit consent for such future use and are under no obligation to say yes.

PART 5 – FUTHER INFORMATION

Where can I get further information?

If you have any further questions about the study, now or at any time in the future, please contact:

Claire Griffin MISCP, MSc Student Neurology and Gerontology, Royal College of Surgeons in Ireland, 123 St. Stephen's Green, Dublin 2.

Email: clairegriffin@rcsi.ie

Tel: 083 116 0555

Appendix 3

Tallaght University Hospital
Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

RCSI

PERMISSION TO BE CONTACTED FORM

Study Title: The Concurrent Validity of the Dual-Task L-Test in Parkinson's Disease and its Predictive Ability in Identifying Falls

Dear Sir/Madam,

You have been invited to participate in the above research study that is being conducted in Tallaght University Hospital by Claire Griffin, a Chartered Physiotherapist. Claire is carrying out the research as part of a Masters in Neurology and Gerontology through the Royal College of Surgeons in Ireland.

Claire would like to contact you by telephone to discuss potential participation in the study. If you are happy for her to do so, please indicate this by signing below.

'I agree to be contacted by Claire at the following phone number _____ regarding inclusion in the above study'

PRINT NAME: _____

SIGNED: _____

DATE: _____

Appendix 4

Tallaght University Hospital
Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

RCSI

Consent Form

Study Title: The Concurrent Validity of the Dual-Task L-Test in Parkinson's Disease and its Predictive Ability in Identifying Falls

To be completed by the PARTICIPANT:

For each statement below, please tick either Yes or No in the box provided

Statement:	**Yes**	**No**
I have read and understood the Patient Information Leaflet		
I have had the opportunity to discuss the study, ask questions about the study and I have received satisfactory answers to all my questions		
I have received sufficient information about the study		
I understand that I am free to withdraw from the study at any time, without giving a reason, and that this will not affect my future medical care		
I agree to allow the investigators to use my personal data as part of this study, as outlined in the Patient Information Leaflet		
I agree to allow the investigators to access my medical records as part of this study		
I agree to be contacted by the investigators as part of this study		
I consent to take part in this research study, having been fully informed of the benefits and purpose of the study and of potential risks involved		
I give my explicit consent to have my data processed as part of this research study		
I give my explicit consent to have my data processed and stored electronically for possible use in future research by the research team related to the current study, without further consent being required		

Participant's Name (BLOCK CAPITALS):	
Participant's Signature:	
Date	

To be completed by the RESEARCHER:

Statement:	**Yes**	**No**
I have fully explained the purpose and nature (including benefit and risks) of this study to the participant in a way that he / she could understand. I have invited him / her to ask questions on any aspect of the study.	Yes	No
I confirm that I have given a copy of the Patient Information Leaflet and Consent Form to the participant.	Yes	No

Researcher's name (BLOCK CAPITALS):	
Researcher's Title & Qualifications:	
Researcher's Signature:	
Date:	

Appendix 5

Tallaght University Hospital
Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

RCSI

Hoehn and Yahr Clinical Rating Scale for Parkinson's Disease

1	Only Unilateral involvement, usually with minimal or no functional disability
2	Bilateral or midline involvement without impairment of balance
3	Bilateral disease: mild to moderate disability with impaired postural reflexes; physically independent
4	Severely disabling disease; still able to walk or stand unassisted
5	Confinement to bed or wheelchair unless aided

Reference: Hoehn, M., Yahr, M. (1967). Parkinsonism: onset, progression and mortality. Neurology, 17(5). 427-442.

Appendix 6

Mini-Mental State Examination (MMSE)

Patient's Name: _____ Date: _____

***Instructions:* Ask the questions in the order listed. Score one point for each correct response within each question or activity.**

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day of the week? Month?"
5		"Where are we now: State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible. Number of trials: _____
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, ...) Stop after five answers. Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.) 
30		TOTAL

(Adapted from Rovner & Folstein, 1987)

Appendix 7a

APPLICATION FORM

For the Ethical Review of Health-Related Research Studies, which are not Clinical Trials of Medicinal Products For Human Use as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM

IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

THIS APPLICATION FORM HAS BEEN ADAPTED FROM THE STANDARD APPLICATION FORM TO COMPLY WITH THE DATA PROTECTION ACT (2018) AND THE DATA PROTECTION ACT (HEALTH RESEARCH) REGULATIONS 2018: APPLICATIONS SUBMITTED ON OR AFTER 8TH AUGUST 2018 WILL ONLY BE ACCEPTED USING THIS VERSION OF THE FORM

REVISIONS ARE HIGHLIGHTED IN YELLOW

Title of Study: The Concurrent Validity of the Dual-Task L-test in Parkinson's Disease and its Predictive Ability in Identifying Falls

Application Version No: 1

Application Date: 25/06/19

For Official Use Only – Date Stamp of Receipt by REC:

TABLE OF CONTENTS /OPTIONAL	MANDATORY

SECTION A: GENERAL INFORMATION MANDATORY*

SECTION B: STUDY DESCRIPTORS MANDATORY*

SECTION C: STUDY PARTICIPANTS MANDATORY*

SECTION D: RESEARCH PROCEDURES MANDATORY*

SECTION E: DATA PROTECTION MANDATORY*

SECTION F: HUMAN BIOLOGICAL MATERIAL (OPTIONAL)

SECTION G: RADIATION (OPTIONAL)

SECTION H: MEDICAL DEVICES (OPTIONAL)

SECTION I: MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS (OPTIONAL)

SECTION J: INDEMNITY AND INSURANCE MANDATORY*

SECTION K: COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS MANDATORY*

SECTION L: ADDITIONAL ETHICAL ISSUES (OPTIONAL)

This Application Form is divided into Sections.

*Sections A, B, C, D, E, J and K are **Mandatory.**

(Sections F, G, H, I and L are optional. Please delete Sections F, G, H, I and L if these sections do not apply to the application being submitted for review.)

IMPORTANT NOTE: Please refer to **Section I** within the form before any attempt to complete the Standard Application Form. **Section I** is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

PLEASE ENSURE TO REFER TO THE ACCOMPANYING GUIDANCE MANUAL

WHEN COMPLETING THIS APPLICATION FORM.

SECTION A: GENERAL INFORMATION

SECTION A IS MANDATORY

A1. WHAT IS THE TITLE OF THE RESEARCH STUDY?

The Concurrent Validity of the Dual-Task L-test in Parkinson's Disease and its Predictive Ability in Identifying Falls

A2. Is this a single site or multi-site study? Single Site

For single site studies: Answer questions A3 (a) and (b) and delete questions A3 (c), (d) and (e)

A3(a). Where will this single site study will take place?

Tallaght University Hospital (TUH)

A3(b). Who is the principal investigator with overall responsibility for the conduct of this single site study?

Title: Ms.
Name: Claire Griffin
Qualifications: BSc (HONS) Physiotherapy
Position: Senior Physiotherapist
Dept: Physiotherapy
Organisation: Peamount Healthcare
Address: Peamount Road, Newcastle, Co. Dublin
TEL: 01 6010300
E-MAIL: cgriffin@peamount.ie

A4. WHO ARE THE CO-INVESTIGATORS FOR THIS STUDY?
NAME OF SITE (IF APPLICABLE): TUH
Title: Dr. Name: Richard Walsh
QUALIFICATIONS: MD MRCPI
POSITION: Consultant Neurologist
Dept : Neurology
ORGANISATION: TUH
Address: Tallaght, Dublin 24, D24 NR0A
TEL: 01 4144061
E-MAIL: Richard.Walsh@tuh.ie
ROLE IN RESEARCH E.G. STATISTICAL / DATA / LABORATORY ANALYSIS: Participant recruitment and consent

A4. WHO ARE THE CO-INVESTIGATORS FOR THIS STUDY?
NAME OF SITE (IF APPLICABLE): TUH

Title: Ms. Name: Anne Belton
QUALIFICATIONS: BSc (Hons) Physiotherapy, MSc Neurology and Gerontology
POSITION: Senior Physiotherapist
Dept : Physiotherapy
ORGANISATION: TUH
Address: Tallaght, Dublin 24, D24 NR0A
TEL: 01 4143055
E-MAIL: anne.belton@tuh.ie
ROLE IN RESEARCH E.G. STATISTICAL / DATA / LABORATORY ANALYSIS: Participant recruitment and consent

A5. Who is the lead contact person i.e. the person to receive correspondence in relation to this application or be contacted with queries about this application.

Name: Claire Griffin
POSITION: Senior Physiotherapist
ORGANISATION: Peamount Healthcare
Address for Correspondence: Physiotherapy Dept., Peamount Healthcare, Peamount Road, Newbridge, Co. Dublin
TEL (WORK): 01 6010300
TEL (MOB.): 083 1160555
E-MAIL: clairegri@gmail.com

A6(A). IS THIS STUDY BEING UNDERTAKEN AS PART OF AN ACADEMIC QUALIFICATION? Yes

If No, delete A6(b) and (c).

A6(b) IF YES, complete the following:
Student Name(s): Claire Griffin
Academic Course: MSc Neurology and Gerontology
Academic Institution: Royal College of Surgeons Ireland

A6(c) Academic Supervisor(s):
Title: Dr. **Name:** Helen French
Qualifications: PhD, MSc, B. Physio Stat Dip
Position: Senior Lecturer in Physiotherapy
Dept: Physiotherapy
Organisation: Royal College of Surgeons Ireland (RCSI)
Address: RCSI, 123 Stephen's Green, Dublin 2
TEL: 01 4022258
E-MAIL: hfrench@rcsi.ie

A7. Has an application been submitted to any other research ethics committee in relation to this study? No

If yes, provide further details.

Site:	Name of Research Ethics Committee:	Status / Outcome of the Application:
Answer	Answer	In Progress / Approved / Not Approved

SECTION B: STUDY DESCRIPTORS

SECTION B IS MANDATORY

B1. What is the anticipated start date of this study?

September 2019

B2. What is the anticipated duration of this study? State the anticipated duration in months or, if more than 12 months, in years.

The study duration will be 6-months, from September 2019 to March 2020.

B3. Provide a brief lay (plain English) description of the study. The description should be in the format of an abstract using the following headings: study background, research aim(s), study design, study setting, participants (including selection and recruitment), data collection and processing, data analysis). Ensure the language used in your answer is at a level suitable for use in a research participant information leaflet. This section should not exceed 500 words.

Study Background: People with Parkinson's Disease (PD) often have difficulty with carrying out dual tasks, which can also lead to falls. Evidence is currently emerging on the benefits of dual task (DT) training in PD, and valid and reliable assessment measures are required to identify DT difficulty. The Timed Up and Go (TUG) is a valid and reliable measure of mobility in PD, and in clinical practice a secondary cognitive task is often added to the TUG to identify DT difficulty (TUG-cognitive). However, the TUG and TUG-cognitive may have limitations in certain cases. The L-test is an extended version of the TUG and has recently been identified as valid and reliable in people with PD (Haas et al, 2009).

However, versions with secondary motor and cognitive tasks are yet to be validated, highlight a gap in the current literature and the basis for this research question.

Research Aims:

(1) To establish the concurrent validity of the L-test-MANUAL and L-test-COGNITIVE with TUG-MANUAL and TUG-COGNITIVE
(2) To determine the predictive ability of the L-test, L-test-MANUAL and L-test-COGNITIVE in identifying falls

Study Design: Cross-sectional

Study Setting: Tallaght University Hospital

Participants (including selection and recruitment): 25 participants with idiopathic PD (Hoehn & Yahr stages 1-3) will be recruited directly from Neurology Clinic and Physiotherapy Neurology Outpatient Clinics in TUH, by means of convenience sampling. Participants will additionally be classified into 'faller' or 'non-faller' groups, with falls assessed retrospectively by asking participants if they have had a fall in the last year.

Data Collection and Processing: Participant will complete 6 tests: The L-test, L-test-MANUAL and L-test-COGNITIVE, and the TUG, TUG-MANUAL and TUG-COGNITIVE. Order of testing will be randomised, i.e. the L-test and its motor and cognitive versions will be completed in a random order, and the TUG and its motor and cognitive versions also in a random order. All test procedures will be completed on the same day, instructions will be standardised, and tests will be demonstrated by the research prior to testing. Participants will be instructed to walk at a comfortable gait speed and a 5-minute rest period will be provided between each test. Dual-task cost (DTC) will then be calculated using an automaticity index: (single task/dual task) x 100. A maximum score of 100% will indicate no decrease in performance under the DT condition.

Data Analysis: Data will be analysed using the Statistical Package for the Social Sciences (SPSS) (IBM Corp. SPSS Statistics for Windows, Version 22.0. Armonk, NY, USA). Pearson's correlation coefficients (r) will be calculated to determine the relationship between the L-test-MANUAL and L-test-COGNITIVE and the TUG-MANUAL and TUG-COGNITIVE. Mean difference for fallers and non-fallers will be tested for significance using independent t-tests or the Mann Whitney *U* test, for continuous variables with parametric or non-parametric distributions respectively. Variables will additionally be analysed using logistic regression to identify potential factors contributing to risk of falling.

B4. Provide brief information on the study background. Ensure the rationale for undertaking the research is clear. This section should not exceed 500 words and five references.

Reduced automaticity of movement is a key problem in Parkinson's Disease (PD), where automaticity is defined as 'the ability to perform a skilled movement without conscious attention or executive control' (Cameron et al, 2010). This leads to difficulty in carrying out dual tasks (DTs), which has been also recognised as a risk factor for falls (Heinzel et al, 2016). Evidence continues to emerge on the benefits of DT training in PD, the assessment of which is dependent on the availability of valid and reliable outcome measures for this purpose (Haas et al, 2019). The Timed Up and Go (TUG) is a valid and reliable mobility assessment widely used in PD, and the addition of a cognitive task to the TUG (TUG-cognitive) has been shown to identify participants with high or low falls risk (Vance et al, 2015). However, potential limitations of the TUG have been identified. Firstly, it may not be sophisticated enough to effectively differentiate between people at different stages of the disease process (Weiss et al, 2010). In addition, participants self-select direction of turning, which could potentially mask unilateral impairments, particularly in early disease stages (Haas et al, 2019). The L-test is a modified, extended version of the TUG which has recently been identified as valid and reliable in people with mild-to-moderate PD (Haas et al, 2019), however, versions with secondary motor and/or cognitive task are yet to be validated. This highlights a gap in knowledge within current literature and forms the basis of the research question within the present study.

B5. List the study aim(s) and objective(s).

(1) To establish the concurrent validity of the L-test-MANUAL and L-test-COGNITIVE with the Timed Up and Go-MANUAL and Timed Up and Go-COGNITIVE
(2) To determine the predictive ability of the L-test, L-test-MANUAL and L-test COGNITIVE in identifying falls

B6. List the study outcomes (s).

- Mini-Mental State Examination (MMSE)
- L-test
- L-test-MANUAL
- L-test-COGNITIVE
- Timed Up and Go

- Timed Up and Go-MANUAL
- Timed Up and Go-COGNITIVE

B7. Provide information on the study design and the rationale for that design.

Study design is cross-sectional in that tests will be conducted in one single session for a defined population, i.e. people with Parkinson's Disease (PD). A cross-sectional design was chosen as the primary aim of the study is to establish concurrent validity, which requires assessment on only one occasion.

B8. For experimental studies, provide information on the study intervention(s).

Answer

B8. List where the study will take place i.e. where:

- **the participants will be recruited;**
- **the participants will undertake the research;**
- **the data will be collected;**
- **the data will be stored;**
- **the data will be analysed.**

Participants will be recruited and will undergo testing in TUH. Data will also be collected, stored and analysed in TUH.

B8. Who is the target population for the study?

The target population is Parkinson's Disease patients under the care of the Neurology Clinic in TUH, with Hoehn & Yahr levels 1-3.

B10 (a) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).

The proposed sample size is 25. This was obtained from a power calculation which showed that 25 participants would be necessary to demonstrate a power of 90% with a correlation of r=0.60 and alpha of 0.05 (Hulley et al, 2013).

B10 (b) Where sample size calculation is impossible (e.g. it is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.

Answer

B11 How many research participants are to be recruited in total?

25

B12 (a) How many research participants are to be recruited in each study group (where applicable)? Please complete the following table (where applicable).

Name of Study Group:	**Name of Study Group:**	**Name of Study Group:**	**Name of Study Group:**	**Name of Study Group:**
Answer	Answer	Answer	Answer	Answer
Number of Participants in this Study Group:	**Number of Participants in this Study Group:**	**Number of Participants in this Study Group:**	**Number of Participants in this Study Group:**	**Number of Participants in this Study Group:**
Answer	Answer	Answer	Answer	Answer

B12 (b) Please provide details on the method of randomisation (where applicable).

Randomisation will not be employed within this study.

B13 How many research participants are to be recruited at each study site (where applicable)? Please complete the following table.

Site:	Number of Research Participants at this site:
TUH	25

B7. List the data set that will be created and tools used to collect the data.

Baseline data collected will include the following: age, Mini Mental State Examination (MMSE) score, Hoehn & Yahr stage of PD, use or non-use of a walking-aid, classification as a 'faller' or 'non-faller'. Outcome measures will include the L-test, L-test-MANUAL and L-test-COGNITIVE; and the TUG, TUG-MANUAL and TUG-COGNITIVE.

A data collection form will be used to collect all the above baseline and outcome measure data.

B9 Provide information on the statistical approach to be used in the analysis of your results (if appropriate) / source of any statistical advice.

Descriptive statistics will be used to describe the baseline assessments and demographics. Pearson's correlation coefficients (r) will be calculated to determine the relationship between the L-test-MANUAL and L-test-COGNITIVE, and the TUG-MANUAL and TUG-COGNITIVE. Correlations will be considered negligible if between 0 and 0.20, weak if 0.21-0.4, moderate if 0.41-0.60, strong if 0.61-0.80 and very strong if 0.81-1.00 (Prion et al, 2014). Mean differences for fallers and non-fallers will be tested for significance using independent t-tests for continuous variables with parametric distributions, or the Mann-Whitney U test for continuous variables with non-parametric distributions. Variables will be analysed using logistic regression to identify potential factors contributing to risk of falling; independent variables identified as significantly associated with falls will undergo multiple logistic regression analyses to determine best explanatory independent variables. To investigate the discriminative value of the L-test, L-test-MANUAL and L-test-COGNITIVE, 2x2 tables will be used to calculate sensitivity and specificity and associated positive and negative likelihood ratios. Receiver operating characteristic curve

analyses with 95% confidence intervals will also be used to describe model discrimination for the three types of L-test.

Statistical advice will be sought from the academic supervisor and a statistician in RCSI as necessary.

SECTION C: STUDY PARTICIPANTS

SECTION C IS MANDATORY

C1: SELECTION AND RECRUITMENT

C1.1. What are the inclusion criteria? Justify where necessary.

(1) Diagnosis of idiopathic Parkinson's Disease by a Consultant Neurologist
(2) Disease severity of 1-3 on the Hoehn & Yahr scale (those with Hoehn & Yahr level 4 will be excluded on the basis that they are likely to have difficulty completing the dual tasks, and as they are likely to require increased levels of supervision).
(3) In the 'on' phase of the medication cycle (to minimise fluctuation of symptoms)
(4) Able to walk 20m independently with or without a walking aid (distance necessary for the L-test, which is longer than the TUG)

C1.2. What are the exclusion criteria? Justify where necessary.

(1) Non-idiopathic PD
(2) Mini-Mental State Examination score ≥24 (to ensure participants have sufficient cognitive capacity to complete dual-tasks)
(3) Presence of visual or auditory problems that may interfere with assessment
(4) Presence of any other neurological (other than PD), orthopaedic or cardio-respiratory conditions that may affect walking or safety during testing

C1.3. How will potential research participants be identified <u>by or to</u> the researchers? Ensure that you specify any source(s) that will be used e.g. databases, healthcare records.

Participants will be identified to the researcher by a Consultant Neurologist and by a Senior Physiotherapist in TUH who will act as gatekeepers to the study:

(1) The Consultant Neurologist will identify suitable participants in Neurology clinic at TUH

(2) The Physiotherapist will additionally identify appropriate patients from Physiotherapy Outpatient Clinics at TUH.

C1.4. Who will identify potential research participants?

The Consultant Neurologist and Physiotherapist will identify research participants, and both will act as gatekeepers for recruiting participants into the study.

Under the Health Research Regulations 2018,

- Health professionals **providing care to a patient** may access **that patient's** healthcare record in order to identify if the patient is suitable for inclusion in health research without the patient's explicit consent;

- Health professionals or other persons **not connected with the care of a patient** may not access that patient's healthcare record in order to identify if the patient is suitable for inclusion in health research without the patient's explicit consent.

C1.5. What sampling method(s) will be used?

- **Simple random sampling** No
- **Stratified sampling** No
- **Systematic sampling** No
- **Convenience sampling** Yes
- **Cluster sampling** No

C1.6. How will the research participants be recruited?

Potential participants will be recruited by a Consultant Neurologist working in the Neurology Clinic, TUH and by a Senior Physiotherapist. Both will act as gatekeepers for the study. They will provide potential participants with a Patient Information Leaflet (PIL) and Consent Form, outlining the purpose and nature of the study. At this point they will also gain permission from participants for the Principal Investigator (PI) to contact them by telephone regarding inclusion in the study. Participants will be allowed a timeframe of 1-week to assimilate information provided and decide whether or not they wish to volunteer for the study. They will then by contacted by the PI to schedule a date and time for testing. Verbal consent will be gained at this point over the phone, and formal written consent will be obtained prior to testing.

C1.7. Who will recruit the research participants?

A Consultant Neurologist and a Senior Physiotherapist based in TUH.

C1.8 Will any participants recruited to this research study be simultaneously involved in any other research project? Not

C2: CONSENT

C2.1 (a) Will informed consent be obtained? Yes

Under the Data Protection Act (Health Research Regulations) 2018, explicit consent **is required** to process personal data for research purposes except if a consent declaration has been made by the Health Research Consent Declaration Committee.

C2.1 (c) If yes, please outline the consent process in full. (How will consent be obtained, when, by whom and from whom etc.)

The Consultant Neurologist and Senior Physiotherapist involved in recruitment will initially provide potential participants with an information pack containing the PIL and the study Consent Form. They will also gain consent for the PI to contact them. The PI will then contact participants by phone following a cooling-off period of 1-week to determine consent. If consent is obtained, a date and time for testing will be arranged. Verbal consent will be acknowledged initially over the phone, and formal written consent will be obtained at baseline prior to commencing testing.

C2.2 (a) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study? Yes

C2.3 (a) Will there be a time interval between giving information and seeking consent? Yes

C2.3 (b) If yes, please elaborate.

The PIL states that participation in the study is entirely voluntary and that potential participants are under no obligation to participate. It also

stipulates that consent can be withdrawn at any time, without any adverse consequences to their care. A cooling-off period of 1-week will be allowed between provision of the PIL and phone call to participants to arrange a data and time for testing. This is to allow participants adequate time for assimilation of information and to make an informed decision regarding participation in the study.

C2.3 (c) If no, please justify and explain why an instantaneous decision is reasonable having regard to the rights of the prospective research participants and the risks of the study.

Answer

C3: CAPACITY – ADULT PARTICIPANTS (AGED 18 OR OVER)

C3.1 (a) Will all adult research participants have the capacity to give informed consent? YES

If answer is Yes, please delete remaining questions in Section C3

C4: CAPACITY – CHILD PARTICIPANTS (AGED 17 OR UNDER)

C4.1 (a) Will any research participants be under the age of 18 i.e. Children? No

If answer is No, please delete remaining questions in Section C4

C4: CHECKLIST

C5.1 Please confirm if persons from any of the following groups will participate in this study. This is a quick checklist to assist research ethics committee members and to identify whether study participants include persons from vulnerable groups and to establish what special arrangements, if any, have been made to deal with issues of consent. It is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity. Please refer to the HSE's National Consent Policy, particularly Part 3, Section 5.

Committees are particularly interested to know if persons in any of these groups are being targeted for inclusion, as per the inclusion criteria.

(a) Healthy Volunteers No

(b) Patients Yes

- **Unconscious patients** No
- **Current psychiatric in-patients** No
- **Patients in an emergency medical setting** No

(c) Relatives / Carers of patients No

(d) Persons in dependent or unequal relationships No

- **Students** No
- **Employees / staff members** No
- **Persons in residential care** No
- **Persons highly dependent on medical care** No

(e) Intellectually impaired persons No

(f) Persons with a life-limiting condition No
(Please refer to guidance manual for definition)

(g) Persons with an acquired brain injury No

C5.2 If yes to any of the above, please comment on the vulnerability of the research participants, and outline the special arrangements in recognition of this vulnerability (if any).

Participants recruited into the study will be under the care of a Consultant Neurologist and under review in the Neurology Clinic in TUH. No special arrangements will be necessary as all participants will independently mobile and living in the community. Should any concerns regarding participants' health or safety arise during the study, they will be reported to the Consultant Neurologist who is responsible for their care, under standard Duty of Care procedure.

C5.3 Please comment on whether women of child-bearing potential, breastfeeding mothers, or pregnant women will be included or excluded in this research study.

Answer

SECTION D: RESEARCH PROCEDURES

SECTION D IS MANDATORY

D1 (A) What activities, procedures or interventions (if any) are research participants asked to undergo or engage in for the purposes of this research study?

- Participants will be asked to complete a series of mobility and dual-tasking assessments:

(1) L-test
(2) L-test-MANUAL (involves the participant carrying a glass of water)
(3) L-test-COGNITIVE (involves the participant counting backwards in 3s from random numbers between 20 and 200)
(4) Timed Up and Go (TUG)
(5) TUG-manual (involves the participant carrying a glass of water)
(6) TUG-COGNITIVE (involves the participant counting backwards in 3s from random numbers between 20 and 200)

- Each of these tests will be repeated twice

D1 (B) WHAT OTHER ACTIVITIES (IF ANY) ARE TAKING PLACE FOR THE PURPOSES OF THIS RESEARCH STUDY E.G. CHART REVIEW, SAMPLE ANALYSIS ETC?

- Demographic data will be collected prior to testing. This will include age, sex, history of falls in the last year, Hoehn and Yahr stage, type of walking aid used (if any), and time since last dose of antiparkinsonian medications
- Participants will be required to complete the Mini-Mental State Examination Score (MMSE)

D2. Please provide details below of any potential harm that may result from any of the activities, procedures, interventions or other activities listed above.

Participants will undergo mobility and secondary dual-tasking assessments, which are routine components of Physiotherapy intervention. As with any routine Physiotherapy intervention, there is a small risk of falls, however an environmental risk-assessment will be conducted prior to completion of testing to reduce this risk, as per usual care. Another minor risk is that participants may be fatigued as a result

of completing the tests. To reduce this risk, participants will be allowed adequate rest-periods between tests and will be allowed sufficient time to recover on completion of testing, before leaving the test facility.

In the unlikely event of an adverse incident, the PI will complete an Incident Report Form, as per hospital protocol. The incident will also be reported to the Research Ethics Committee in TUH.

D3. What is the potential benefit that may occur as a result of this study?

The study will determine the concurrent validity of the dual task L-test against the dual task TUG. The purpose of both of these tests is to evaluate dual-tasking difficulty/ability in PD.

The primary benefit of the study for participants will be in helping to identify whether they have difficulties with completing a secondary task while walking. Considering that dual task impairment while walking has been identified as a relevant risk factor for falls (Heinzel et al, 2016), the study may also highlight those participants particularly at risk of falling.

D4 (A) WILL THE STUDY INVOLVE THE WITHHOLDING OF TREATMENT?

NO

D4 (B) WILL THERE BE ANY HARMS THAT COULD RESULT FROM WITHHOLDING TREATMENT? N/A

D5 (A) HOW WILL THE HEALTH OF PARTICIPANTS BE MONITORED DURING THE STUDY, AND WHO WILL BE RESPONSIBLE FOR THIS?

The study will include people with PD who are independently mobile and living in the community and therefore no significant risks to health are anticipated.

However, the PI will monitor participant health during testing, as per usual care. The PI will ensure that participants do not become too fatigued during the study and adequate rest periods will be allowed to minimise this. All participants included in the study will be under the care of a Consultant Neurologist.

D5 (B) HOW WILL THE HEALTH OF PARTICIPANTS BE MONITORED AFTER THE STUDY, AND WHO WILL BE RESPONSIBLE FOR THIS?

On completion of testing participants will be allowed adequate rest periods to ensure full recovery from any fatigue effects. The PI will question participants subjectively to ensure that they have recovered prior to leaving the testing facility. All participants included in the study will be under the care of a Consultant Neurologist, who will subsequently review their condition periodically as per usual care.

D6 (A) WILL THE INTERVENTIONS PROVIDED DURING THE STUDY BE AVAILABLE IF NEEDED AFTER THE TERMINATION OF THE STUDY? NON-APPLICABLE

D7. PLEASE COMMENT ON HOW INDIVIDUAL RESULTS WILL BE MANAGED.

- Results may be discussed with individual participants following assessment to improve their awareness of any difficulties identified. Patient confidentiality will be maintained at all times.
- Results will be sent to the Consultant Neurologist as per routine clinical practice
- In the case of identification of mobility and/or dual-tasking difficulty, the following steps will be taken:
    - Participants not known to the Neurological Physiotherapy Service in TUH will be referred accordingly
    - In the case of participants already known to the Neurological Physiotherapy Service, results will be communicated with the Physiotherapist overseeing their treatment
    - In the case of any other concerns regarding results, findings will be discussed with the Consultant Neurologist

D8. PLEASE COMMENT ON HOW AGGREGATED STUDY RESULTS WILL BE MADE AVAILABLE.

- Study results will be submitted as part of an MSc thesis in RCSI
- They may be disseminated within a poster presentation
- They may also be submitted for publication in peer-reviewed journals, within the field of neurological rehabilitation

D9. WILL THE RESEARCH PARTICIPANT'S GENERAL PRACTITIONER BE INFORMED THAT THE RESEARCH PARTICIPANT IS TAKING PART IN THE STUDY (IF APPROPRIATE)? NON-APPLICABLE

D10. WILL THE RESEARCH PARTICIPANT'S HOSPITAL CONSULTANT BE INFORMED THAT THE RESEARCH PARTICIPANT IS TAKING PART IN THE STUDY (IF APPROPRIATE)? YES

SECTION E: DATA PROTECTION

SECTION E IS MANDATORY

E1: DATA PROCESSING – CONSENT

E1.1 (A). WILL **EXPLICIT** CONSENT BE SOUGHT FOR THE PROCESSING OF DATA?

Yes

Under the Data Protection Act (Health Research Regulations) 2018, explicit consent **is required** to process personal data for research purposes except if a consent declaration has been made by the Health Research Consent Declaration Committee.

- Identifiable and pseudonymised data (e.g. linked by code) is classified as personal data by GDPR and **is subject to this requirement**.
- Fully (irrevocably) anonymised data is not classified as personal data and is not subject to this requirement. However, consent **is required** to process personal data to make the data fully (irrevocably) anonymised and **is subject to this requirement**.

An **explicit** consent statement should:

- specifically refer to the particular data set that is to be processed;
- specifically refer to the precise purpose of processing (including any automated decision-making);
- identify any risks and/or implications that might arise for the data subject as a result of the data processing;
- provide any other relevant and specific information that might influence the decision of a data subject to give or not give their consent.

E2: DATA PROCESSING – PERSONNEL

E2.1. WHO WILL CONTROL (I.E. DETERMINE THE PURPOSE FOR WHICH AND THE WAY IN WHICH THE DATA WILL BE PROCESSED) AND BE RESPONSIBLE FOR THE DATA (I.E. THE DATA CONTROLLERS)?

THE PI WILL ACT AS DATA CONTROLLER.

E2.2. WHO WILL HOLD OR PROCESS THE DATA (I.E. THE DATA PROCESSORS)?

INCLUDE ANYONE WHO WILL COLLECT, STORE OR ANALYSE THE DATA. AN INDIVIDUAL CAN BE BOTH A DATA CONTROLLER AND PROCESSOR SIMULTANEOUSLY (AND MAY NEED TO BE LISTED IN E2.1 AND E2.2).

The PI and academic supervisor will also act as data processors

E2.3. WHAT TRAINING IN DATA PROTECTION LAW AND PRACTICE HAVE THE DATA CONTROLLER(S) AND DATA PROCESSOR(S) COMPLETED?

Under the Data Protection Act (Health Research Regulations) 2018, data controllers must ensure that anyone involved in carrying out research project has completed training in data protection law and practice.

The PI will be responsible for both data controlling and data processing and has completed online GDPR training. The academic supervisor has also completed GDPR training

E2.4 (A). IS IT INTENDED TO SHARE ANY OF THE COLLECTED DATA (INCLUDING PSEUDONYMISED DATA) WITH ANYONE ELSE (I.E. ANYONE NOT LISTED IN E2.1 AND E2.2)? Yes

E2.4 (B). IF YES, WITH WHOM WILL THE DATA BE SHARED AND WHAT IS THE PURPOSE OF SUCH SHARING?

Data will be shared under the following conditions:

- With the Consultant Neurologist responsible for the patient's care, as standard clinical practice
- If testing identifies difficulty with mobility and/or dual tasking, the Neurologist and Physiotherapist (if appropriate) will be informed accordingly

E2.5. IF THE DATA IS PSEUDONYMISED (CODED), WHO WILL RETAIN THE 'KEY' TO RE-IDENTIFY THE DATA?

The PI will retain the 'key' which will be stored in a locked filing cabinet in the Physiotherapy Department in TUH. This will be stored separately from the original data for confidentiality reasons – only the PI will be able to identify the data.

E3: DATA PROCESSING – CONTENT

E3.1 WHAT SPECIFIC DATA WILL BE COLLECTED?

INCLUDE ALL VARIABLES THAT WILL BE COLLECTED PARTICULARLY DEMOGRAPHIC DETAILS. IF APPROPRIATE, ATTACH A CASE REPORT FORM OR OTHER DOCUMENT(S) DETAILING THE VARIABLES THAT WILL BE COLLECTED (E.G. QUESTIONNAIRE).

- Demographic details will be collected for participants, including age, sex, history of falls in the last year, Hoehn and Yahr stage, type of walking aid used (if any), time since last dose of antiparkinsonian medications, and MMSE score
- Results from the Outcome Measures will also be collected, i.e. L-test, L-test-MANUAL, L-test-COGNITIVE, and TUG, TUG-MANUAL and TUG-COGNITIVE.

E3.2 WHAT MEASURES WILL BE TAKEN TO LIMIT THE DATA COLLECTED TO WHAT IS NECESSARY TO ACHIEVE THE AIM OF THE RESEARCH ONLY?

Under the Data Protection Act 2018, COLLECTED DATA MUST BE 'ADEQUATE, RELEVANT AND NOT EXCESSIVE IN RELATION TO THE PURPOSES FOR WHICH THEY ARE PROCESSED' (DATA MINIMISATION).

ONLY THE ABOVE VARIABLES OUTLINED IN E3.1 WILL BE COLLECTED. NO ADDITIONAL DATA WILL BE COLLECTED.

E3.3 WHAT WILL BE THE LEVEL OF IDENTIFICATION OF THE COLLECTED DATA?

- **FULLY IDENTIFIABLE (E.G. NAME, DATE OF BIRTH, ADDRESS)?** No
- **PSEUDONYMISED (E.G. CODED)?** Yes
- **FULLY (IRREVOCABLY) ANONYMISED?** No

E3.4 (A) WILL THE COLLECTED DATA UNDERGO FURTHER PROCESSING AFTER COLLECTION? Yes

E3.4 (B) IF YES, WHAT TYPE OF PROCESSING WILL BE UNDERTAKEN?

- **PSEUDONYMISATION (CODING DATA SHOULD BE CLASSIFIED AS PSEUDONYMISATION)?** Yes
- **FULL (IRREVOCABLE) ANONYMISATION?** No
- **OTHER?** No

E3.4 (C) IF OTHER, PLEASE ELABORATE.

Answer

E4: DATA PROCESSING – METHOD

E4.1 WHO WILL COLLECT THE DATA?

The Principal Investigator will collect the data.

E4.2 WHERE WILL THE DATA BE COLLECTED?

In the Physiotherapy Gym in Tallaght University Hospital.

E4.3 (A) WHAT MEDIA OF DATA WILL BE COLLECTED?

- **WRITTEN (PAPER)?** Yes
- **WRITTEN (ELECTRONIC)?** No
- **AUDIO RECORDINGS?** No
- **PHOTOGRAPHS?** No
- **VIDEO RECORDINGS?** No
- **OTHER?** No

E4.3 (B) IF OTHER, PLEASE ELABORATE.

Answer

E4.4 (A) WILL ANY OF THE DATA COLLECTED CONSIST OF AUDIO RECORDINGS / VIDEO RECORDINGS? NO

E4.4 (B) IF YES, WILL PARTICIPANTS BE GIVEN THE OPPORTUNITY TO REVIEW AND AMEND TRANSCRIPTS OF THE TAPES?

Answer

E4.5 (A) WILL ANY OF THE DATA COLLECTED CONSIST OF PHOTOGRAPHS / VIDEO RECORDINGS? NO

E4.5 (B) IF YES, PLEASE ELABORATE.

Answer

E5: ACCESS TO HEALTHCARE RECORDS

E5.1 (A) DOES THE STUDY INVOLVE ACCESS TO HEALTHCARE RECORDS (HARD COPY / ELECTRONIC)? YES

If NO, please delete the remaining questions in Section E5.

E5.1 (B) IF YES, PLEASE ELABORATE.

Only Dr. Walsh (Consultant Neurologist), and Anne Belton (Senior Chartered Physiotherapist in TUH) will have access to participant healthcare records. The Principal Investigator will collect all relevant data on the day of testing and will not have access to healthcare records.

E5.2 WHO OR WHAT LEGAL ENTITY IS THE DATA CONTROLLER IN RESPECT OF THE HEALTHCARE RECORDS?

The data controller (i.e. the Principal Investigator) is a Senior Chartered Physiotherapist in Peamount Healthcare, who is completing this study as part of an MSc in Neurology and Gerontology in RCSI. The Consultant Neurologist has granted permission to the Data Controller to access patients from the Neurology Clinic in TUH for inclusion in the study and will be involved in participant recruitment. Anne Belton, Senior Physiotherapist in TUH will also be involved in participant recruitment. Both are Co-investigators in this study. The Principal Investigator will not recruit participants directly and will not have access to healthcare records.

E5.3 WHO WILL ACCESS THESE HEALTHCARE RECORDS?

Only the Co-investigators (Consultant Neurologist Dr. Walsh and Senior Physiotherapist in TUH Anne Belton) will access healthcare records.

E5.4 WILL EXPLICIT CONSENT BE SOUGHT FROM PATIENTS FOR RESEARCH TEAM MEMBERS TO ACCESS THEIR HEALTHCARE RECORDS? YES

If YES, please delete the remaining question in Section E5.

Under the Data Protection Act (Health Research Regulations) 2018, explicit consent **is required** to access healthcare records for research purposes except if a consent declaration has been made by the Health Research Consent Declaration Committee.

E6: DATA PROCESSING – STORAGE

E6.1 WHERE WILL THE COLLECTED DATA BE STORED?

A hard copy of the data will be stored in a locked filing cabinet in the Physiotherapy Department in TUH. Only the Principal Investigator will have access to this. All electronic data will be coded and stored on a computer in the Physiotherapy Department, which will be password protected and only accessible by the Principal Investigator.

E6.2 (A) WILL DATA THAT IS COLLECTED LEAVE THE SITE(S) OF STORAGE AT ANY STAGE?

YES

E6.2 (B) IF YES, PLEASE ELABORATE.

The hard copy of the data will remain in TUH, as outlined above. The hard data will be inputted into an Excel spreadsheet, anonymised and uploaded onto the SPSS statistical software package. This anonymised electronic data will be encrypted and then be sent to a unique project folder on the V-drive in RCSI, via a HEA large file sender. Only anonymised electronic data will leave TUH, and it will be sent electronically to RCSI only and no other sites.

E7: DATA PROCESSING – ANALYSIS

E7.1 WHO WILL ANALYSE THE DATA?

The Principal Investigator will analyse the data.

E7.2 WHERE WILL THE DATA BE ANALYSED?

Data will be analysed in the Physiotherapy Department in TUH. SPSS files from the electronic anonymised data will be analysed in RCSI.

E8: DATA PROCESSING – DISPOSAL

E8.1 (A) AFTER DATA ANALYSIS HAS TAKEN PLACE, WILL DATA BE DESTROYED, ARCHIVED OR ANONYMISED?

- **DESTROYED?** No
- **ARCHIVED?** No
- **ANONYMISED?** Yes

Data will initially be stored to allow dissemination of data, and held for up to 5 years, or until the study has been published. After this point it will

be destroyed. Data will be stored in a secure folder on the V drive in RCSI and will only be accessible to the Principal Investigator.

E8.1 (B) IF DESTROYED, HOW, WHEN AND BY WHOM WILL IT BE DESTROYED?

Data will be destroyed by the Principal Investigator within a maximum period of 5 years. This is to allow for dissemination of data and potential publication. Data will be shredded using on-site HSE shredding facility for the case of paper records, while electronic records will be permanently deleted.

E8.1 (C) IF ARCHIVED, FOR HOW LONG, FOR WHAT PURPOSE, AND WHERE WILL IT BE ARCHIVED?

Answer

E8.1 (D) IF ANONYMISED, HOW, WHEN AND BY WHOM WILL IT BE ANONYMISED?

Hard data will be inputted into an Excel spreadsheet and anonymised by the Principal Investigator. This will take place directly following participant recruitment. This anonymised electronic data will then be sent in an encrypted file to a unique project folder on the V-drive in RCSI, via a HEA large file sender. Only anonymised electronic data will leave TUH, and it will be sent to RCSI only and no other sites.

E9: DATA PROCESSING – RISK ASSESSMENT & MANAGEMENT

E9.1 WHAT MEASURES (INCLUDING TECHNICAL AND ORGANISATIONAL) WILL BE IN PLACE TO ENSURE THE PROTECTION AND SECURITY OF THE COLLECTED DATA?

INCLUDE ANY SPECIFIC MEASURES THAT MAINTAIN THE CONFIDENTIALITY OF THE COLLECTED DATA.

(1) Participants will be issued a Unique Identification Number. This will be stored separately to the hard and electronic data.
(2) Any details identifying participants will be removed, i.e. name, address, date of birth.
(3) Use of codes will be meaningful only to the Principal Investigator.

(4) All electronic data will be stored on a password-protected computer in the Physiotherapy Department (accessible only to the Principal Investigator)
(5) Data will not be stored on any form of portable device.
(6) All hard data will be stored in a locked cabinet in the Physiotherapy Department in TUH.
(7) Use of codes will be meaningful only to the Principal Investigator. Only the Principal Investigator will have access to the 'key' for the codes.
(8) Anti-virus and firewall software will be in place to prevent any unauthorised attempts to access data.
(9) There will be no remote access to electronic data.
(10) Only the Wifi network in TUH will be accessed. There will be no access to unsecure Wifi networks.

E9.2 What controls will be in place to prevent unauthorised consultation, alteration, disclosure or erasure of the collected data?

- Hard and electronic data will be accessible only to the Principal Investigator. Hard data will be stored in a private, locked filing cabinet to which only the Primary Researcher will have access. Electronic Data will only be saved in a password-protected file, on the Primary Researcher's private computer account in the Physiotherapy Department.
- Only the Primary Researcher will be involved in data collection and analysis.
- Security from firewalls and anti-virus software will be in place.
- There will be a back-up system for data.
- Log-in audits will be performed.

E9.3 What controls will be in place to log whether and by whom the collected data has been consulted, altered, disclosed or erased?

Answer

E9.4 (A) IS THERE ANY ASPECT OF THE PROPOSED RESEARCH THAT INDICATES A HIGH RISK (either in terms of likelihood or severity) to the rights and freedoms of the data subject (e.g. a data breach)? No

E9.4 (B) IF YES, COMPLETE THE FOLLOWING DATA PROTECTION IMPACT ASSESSMENT.

RISK IDENTIFIED	**CONSEQUENCE**	**RISK LEVEL** (LOW / MEDIUM / HIGH)	**RISK MANAGEMENT**

EXAMPLE: DATA COLLECTION SITE (OPD CLINIC) DISTANT FROM DATA STORAGE SITE (RESEARCH OFFICE) – 10 MINUTE WALK BUT WITHIN THE HOSPITAL GROUNDS	EXAMPLE: LOSS OF DATA IN TRANSIT	EXAMPLE: MEDIUM RISK	EXAMPLES: - DATA CARRIED IN BAG SEALED PRIOR TO DEPARTURE FROM COLLECTION SITE AND ONLY UNSEALED UPON ARRIVAL AT STORAGE SITE - DATA IS BROUGHT DIRECTLY FROM COLLECTION SITE TO STORAGE SITE

E9.5 DESCRIBE HOW DATA SUBJECTS WILL BE INFORMED OF WHAT DATA WILL BE COLLECTED (AND WHY) AND HOW THEY CAN EXERCISE THEIR DATA SUBJECT RIGHTS (I.E. TRANSPARENCY).

Data will only be processed as necessary.

A Patient Information Leaflet will be provided to the patient highlighting the aims of the study and the purposed of data being collected. Their rights as a participant will be explained, in terms of access to personal data, restriction of data usage, correction of inaccuracies, and portability. They will also be informed of their right to request that their data be deleted, and to object to data profiling and processing.

E9.6 DESCRIBE THE MEASURES THAT WILL BE IN PLACE TO ENSURE COMPLIANCE WITH DATA SUBJECT RIGHTS.

- Transparency with information provided to patient on the study purpose and type and how data will be collected, stored and deleted.
- Security of data collection and storage at all times.
- Personal data will be anonymised and encrypted.
- An appropriate processing system.
- Only personal data necessary for processing will be collected.
- The Principal Investigator will act as both data controller and processor.
- The code of conduct will be followed at all times,

- GDPR security measures will be in place, including back-up of data, and a data protection impact assessment will be carried out. The Principal Investigator will liaise with the Data Protection Officer in RCSI regarding this.

SECTION F: HUMAN BIOLOGICAL MATERIAL

F1: BODILY TISSUE / BODILY FLUID SAMPLES - GENERAL

F1 Does this study involve human biological material? NO

If the answer is No, please delete Section F

SECTION G: RADIATION

G1: RADIATION – GENERAL

G1.1 (a) Does this study/trial involve exposure to radiation? NO

If answer is No, please delete remaining questions in Section G

SECTION H: MEDICAL DEVICES

H1 (A) IS THE FOCUS OF THIS STUDY/TRIAL TO INVESTIGATE/EVALUATE A MEDICAL DEVICE? NO

If answer is No, please delete remaining questions in Section H.

SECTION I: MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS

I1: NON-INTERVENTIONAL TRIALS OF MEDICINAL PRODUCTS

I1.1 (a) Does this study involve a medicinal product? No

If the answer is No, please delete remaining questions in subsection I1

I2: COSMETICS

I2.1 (a) Does this study involve a cosmetic? No

If the answer is No, please delete remaining questions in subsection I2

I3: FOOD AND FOOD SUPPLEMENTS

I3.1 (a) Does this study involve food or food supplements? N

If the answer is No, please delete remaining questions in subsection I3

SECTION J: INDEMNITY AND INSURANCE

SECTION J IS MANDATORY

J1 PLEASE CONFIRM AND PROVIDE EVIDENCE THAT APPROPRIATE INSURANCE/INDEMNITY IS IN PLACE FOR THIS RESEARCH STUDY AT EACH SITE.

The study is being carried out in TUH, which is covered by the Clinical Indemnity Scheme.

J2 PLEASE CONFIRM AND PROVIDE EVIDENCE THAT APPROPRIATE INSURANCE/INDEMNITY IS IN PLACE FOR THIS RESEARCH STUDY FOR EACH INVESTIGATOR.

The Primary Study Supervisor, Helen French, is covered by the RCSI Indemnity Scheme. The co-investigators are covered by the Clinical Indemnity Scheme at TUH.

J3.1 Please give the name and address of the organisation / or individual legally responsible for this research study?

Tallaght University Hospital

J3.2 Where an organisation is legally responsible, please specify if this organisation is:

A pharmaceutical company NO

A medical device company NO

A university NO

A registered charity NO

Other NO **If yes, please specify:** Answer

J3.3 PLEASE CONFIRM AND PROVIDE EVIDENCE OF ANY SPECIFIC ADDITIONAL INSURANCE / INDEMNITY ARRANGEMENTS WHICH HAVE BEEN PUT IN PLACE, IF ANY, BY THIS ORGANISATION / OR INDIVIDUAL FOR THIS RESEARCH STUDY?

This research study is being conducted in part fulfilment of the requirements of a Masters in Neurology and Gerontology from the Royal College of Surgeons in Ireland. The researcher, a registered student at RCSI is also covered by the indemnity provided by RCSI.

SECTION K: COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS

SECTION K IS MANDATORY

K1: COST AND RESOURCE IMPLICATIONS

K1.1 PLEASE PROVIDE DETAILS OF ALL COST / RESOURCE IMPLICATIONS RELATED TO THIS STUDY (E.G. STAFF TIME, OFFICE USE, TELEPHONE / PRINTING COSTS ETC.)

Cost implications to the study involve printing and photocopying costs only, which will be covered by the Principal Investigator.

Staff time is the biggest resource issue within the study; adequate time will be allocated to the Principal Investigator by her Line Manager in Peamount Healthcare to travel to TUH for data collection. Arrangements will be made with the Senior Physiotherapist in TUH (acting as gatekeeper) to book an area of the gym for testing.

K2: FUNDING

K2.1 (a) Is funding in place to conduct this study?

NO

K2.1 (b) If no, has funding been sought to conduct this study? From where? Please elaborate.

Funding has not been sought to conduct this study; this is unnecessary as it is part of a taught MSc programme.

K2.1 (c) If yes, please state the source of funding (industry, grant or other), the name of the funder, the amount of funding and duration of funding.

Source of funding (industry, grant or other):
Answer
Name of Funder:
Answer
Amount of Funding:
Answer
Duration of Funding
Answer

K2.1(d) Please provide additional details in relation to management of funds.

Answer

K2.1(e) Is the study funded by a 'for profit' organisation? NO

K2.2 (a) Do any conflicts of interest exist in relation to funding or potential funding? NO

K2.2 (b) If yes, please elaborate.

Answer

K3: PAYMENTS TO INVESTIGATORS

K3.1 (a) Will any payments (monetary or otherwise) be made to investigators? NO

K3.1 (b) If yes, please provide details of payments (including amount).

Answer

K4: PAYMENTS TO PARTICIPANTS

K4.1 (a) Will any payments / reimbursements (monetary or otherwise) be made to participants? NO

K4.1 (b) If yes, please provide details of payments / reimbursements (including amount).

Answer

SECTION L: ADDITIONAL ETHICAL ISSUES

L1 (a) Does this project raise any additional ethical issues? NO

If answer is No, please delete remaining questions in Section L.

L1 (b) If yes, please identify any particular additional ethical issues that this project raises and discuss how you have addressed them.

Answer

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.

Appendix 7b

Tallaght University Hospital | Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

SJH/TUH Research Ethics Committee Secretariat
email: researchethics@tuh.ie

Ms Claire Griffin,
Peamount Hospital,
Peamount Road,
Newcastle,
Co. Dublin

09th October 2019

REF: The Concurrent Validity of the Dual-Task L-Test in Parkinson's disease and it's Predictive Ability in Identifying Falls

REC: 2019-10 Chairman's Action (6)
(Please quote reference on all correspondence)

Date of Valid Submission to REC: 25.06.2019
Date of Ethical Review: 08.10.2019
Research and Innovation Application Number: N/A

Dear Ms Griffin,

The REC is in receipt of your recent request to TUH/SJH Research Ethics Committee in which you queried ethical approval for the above named study.

The Chairman, Prof. Richard Dean, on behalf of the Research Ethics Committee, has reviewed your correspondence has given full approval for this study to take place. Please register your participation in this study in TUH with the HR department and inform REC once complete. On the PIL please add Dr Walsh's contact details and add the name of the JREC – St James's Hospital/Tallaght University Hospital Joint Research Ethics Committee.

Applicants must submit an annual report for ongoing projects and an end of project report upon completion of the study. It is the responsibility of the researcher/research team to ensure all aspects of the study are executed in compliance with the General Data Protection regulation (GDPR), Health Research Regulations and the Data Protection Act 2018. ***Additionally, please note for documents submitted for GDPR purposes that the REC and the Chair are not confirming that you're documents are GDPR compliant, they are approving the document from an ethical perspective.***

Yours sincerely,

Sadhbh O'Neill

REC Officer – Dr Sadhbh O'Neill
SJH/TUH Research Ethics Committee

Appendix 7c

SJH/TUH Research Ethics Committee Secretariat
email: researchethics@tuh.ie

JREC Reference: 2020-02 List 5 – Amendment (30)

Ms Claire Griffin,
Peamount Healthcare,
Peamount Road,
Newcastle,
Co. Dublin

09th March 2020

REF: The Concurrent Validity of the Dual-Task L-Test in Parkinson's Disease and its Predictive Ability in Identifying Falls

REC: 2020-02 List 5 – Amendment (30)
(Please quote reference on all correspondence)

Date of Valid Submission to REC: 31.01.2020
Date of Ethical Review: 21.02.2020

Dear Ms Griffin,

The Chairman, Prof. Richard Deane, on behalf of the Research Ethics Committee, has reviewed the amendment you submitted to the SJH/TUH JREC for the above named study and has given **FULL** approval for this amendment to proceed.

The following documents were reviewed:

- Amendment Request Form, dated 30.01.2020
- Standard Application Form, V2, dated 28.01.2020
- Patient Information Leaflet, V2, dated 28.01.2020
- Consent Form, V2, dated 28.01.2020

Please note that ethical approval for this study is only active under the following conditions:

1. *Applicants must submit an annual report for ongoing projects.*
2. *Applicants must submit an end of study declaration/end of study report upon completion of the study.*
3. *All adverse events must be reported to the JREC.*
4. *All changes (minor and substantial) to documentation/study must be submitted to the JREC using the amendment request form and the changes must be tracked/highlighted clearly. Approval from the JREC is required before implementation of the changes.*

It is the responsibility of the researcher/research team to ensure all aspects of the study are executed in compliance with the General Data Protection regulation (GDPR), Health Research Regulations and the Data Protection Act 20l8.

Yours sincerely,

Sadhbh O'Neill

REC Officer – Dr Sadhbh O'Neill

Appendix 8a

Tallaght University Hospital
Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

Dr. R. Walsh
Consultant Neurologist
Tallaght University Hospital
Tallaght
Dublin 24
D24 NROA
01 414 4061

17th November 2019

Re: MSc project entitled **'The Concurrent Validity of the Dual-Task L-Test in Parkinson's Disease and its Predictive Ability in Identifying Falls'**

Dear Sir/Madam,

I hereby grant consent to Physiotherapist Claire Griffin to recruit patients for testing from my Neurology Outpatient Clinics as part of her MSc research project.

Yours sincerely,

Dr Richard Walsh MB, MD, FRCPI
Consultant Neurologist MCRN 124542

Appendix 8b

Tallaght University Hospital
Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

Physiotherapy Department

17th November 2019

Re: MSc project entitled **'The Concurrent Validity of the Dual-Task L-Test in Parkinson's Disease and its Predictive Ability in Identifying Falls'**

Dear Sir/Madam,

I hereby grant permission to Physiotherapist Claire Griffin to complete testing for her MSc research project in the Physiotherapy Gym in TUH.

Yours sincerely,

Elaine Barker

Physiotherapist Manager-in-Charge III
Tallaght University Hospital
Tallaght
Dublin 24
D24 NROA
+353 1 414 2756
Elaine.Barker@tuh.ie

Appendix 9

Tallaght University Hospital
Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

RCSI

Outcome Measures (Timed Up & Go and L-test)

General Instructions:

- Participants wear their usual footwear and use their usual walking aid (if applicable)
- Recording time: the stopwatch will be starts when the Principal Investigator say the word 'go', and stops when the participant's back touches the back of the chair
- Test procedure is demonstrated by the Principal Investigator once prior to testing
- Participants are allowed one trial of each test before being timed

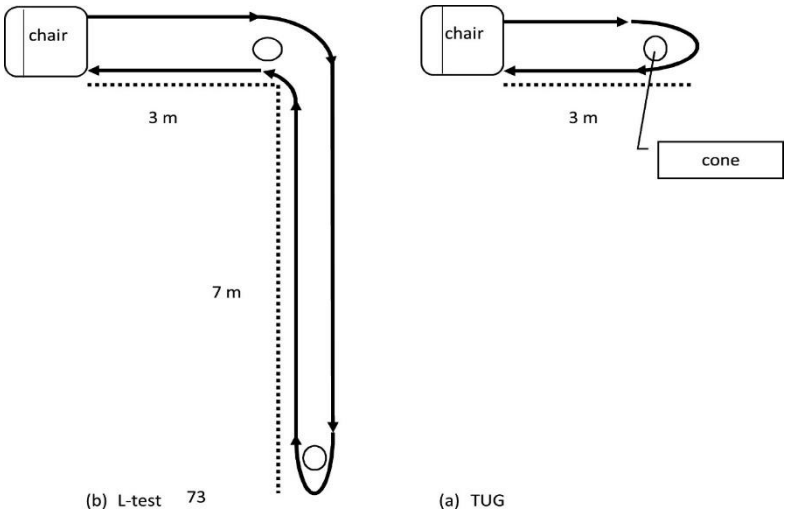


Fig.1. Haas et al (2019)

Timed Up & Go (a):

Directions:

- Participant stands up from a standard chair, with or without use of arms
- Walks for 3-metres and turns around a cone, before returning to the chair to sit down
- Instruction to participants: "On the word 'go', stand up, walk at a comfortable and safe pace to the cone, turn around, walk back to the chair and sit down"

L-test (b):

Directions:

- Participant stands up from a standard chair, with or without use of arms
- Walks for 3-metres to a cone and turns 90° to the right
- Continues walking for 7-metres to the next cone and turns 180° to the left around the cone, then returns to the chair along the same path
- Instruction to participants: "On the word 'go', stand up, walk at a comfortable and safe pace to the cone and turn right. Walk to the next cone and turn 180° around it to the left, then walk back to the chair and sit down"

Reference: Haas, B., Clarke, E., Elver, L., Gowman, E., Mortimer, E., Byrd, E. (2019). The reliability and validity of the L-test in people with Parkinson's Disease. Physiotherapy, 105, 84-89.

Appendix 10

Tallaght University Hospital
Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

Data Collection Form

Participant UIN: _____ Date of testing: _____

Time of testing: _____

Screening Information	
MMSE Score	/30
Eligible to continue study	Yes ☐ No ☐

Demographic Information	
Age + date of birth	
Gender	Male ☐ Female ☐
Hoehn & Yahr Stage	1 2 3 4 5
No. of years since PD diagnosis	
PMH/Co-morbidities	
No. of falls in last 6 months + details/mechanism	
Currently taking anti-parkinsonian medication	Yes ☐ Details: _____ No ☐
Time since last dose of anti-parkinsonian medication (should be within 3-hours)	
Use of a walking aid	Yes ☐ Type: _____ No ☐

Participant UIN: _____ Date of testing: _____

Time of testing: _____

Outcome Measurement				
Outcome Measure	**Time taken (s)**	**Freezing**	**Average (s)**	**DTC (%)**
TUG-STANDARD	Trial 1 _____ Trial 2 _____	Yes ☐ No ☐ No. of episodes: _____ Duration: _____ Trigger:_____		
TUG-MANUAL	Trial 1 _____ Trial 2 _____	Yes ☐ No ☐ No. of episodes: _____ Duration: _____ Trigger: _____		
TUG-COGNITIVE	Trial 1 _____ Trial 2 _____	Yes ☐ No ☐ No. of episodes: _____ Duration: _____ Trigger: _____		
L-test-STANDARD	Trial 1 _____ Trial 2 _____	Yes ☐ No ☐ No. of episodes: _____ Duration: _____ Trigger: _____		
L-test-MANUAL	Trial 1 _____ Trial 2 _____	Yes ☐ No ☐ No. of episodes: _____ Duration: _____ Trigger: _____		
L-test-COGNITIVE	Trial 1 _____ Trial 2 _____	Yes ☐ No ☐ No. of episodes: _____ Duration: _____ Trigger: _____		

Appendix 11

```
FREQUENCIES VARIABLES=SEX H_and_Y ANTIPD_MEDS WALK_AID Falls_yes_no
  /STATISTICS=MINIMUM MAXIMUM
  /ORDER=ANALYSIS.
```

Frequencies

Statistics

		SEX	H and Y	ANTI-PD_MEDS	WALK_AID	Falls categorised yes or no
N	Valid	25	25	25	25	25
	Missing	0	0	0	0	0
Minimum		1				
Maximum		2				

Frequency Table

SEX

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	19	76.0	76.0	76.0
	2	6	24.0	24.0	100.0
	Total	25	100.0	100.0	

H and Y

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	13	52.0	52.0	52.0
	2	10	40.0	40.0	92.0
	3	2	8.0	8.0	100.0

	Total	25	100.0	100.0	

ANTI-PD_MEDS

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	25	100.0	100.0	100.0

WALK_AID

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1	23	92.0	92.0	92.0
	2	1	4.0	4.0	96.0
	4	1	4.0	4.0	100.0
	Total	25	100.0	100.0	

Falls categorised yes or no

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	18	72.0	72.0	72.0
	Yes	7	28.0	28.0	100.0
	Total	25	100.0	100.0	

```
DESCRIPTIVES VARIABLES=AGE MMSE YEARS_SINCE_DIAG COMORBIDITIES FALLS
  /STATISTICS=MEAN STDDEV MIN MAX KURTOSIS SKEWNESS.
```

Descriptives

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation	Skewness
	Statistic	Statistic	Statistic	Statistic	Statistic	Statistic
AGE	25	45	84	65.64	9.402	-.546
MMSE	25	24	30	28.40	1.871	-1.096
YEARS_SINCE_DIAG	25	.5	17.0	7.180	4.5366	.594
COMORBIDITIES	25	0	5	1.52	1.558	.966
FALLS	25	0	4	.60	1.118	1.867
Valid N (listwise)	25					

Descriptive Statistics

	Skewness	Kurtosis	
	Std. Error	Statistic	Std. Error
AGE	.464	.287	.902
MMSE	.464	-.024	.902
YEARS_SINCE_DIAG	.464	-.472	.902
COMORBIDITIES	.464	.120	.902
FALLS	.464	2.776	.902
Valid N (listwise)			

```
EXAMINE VARIABLES=FALLS BY Falls_faller_nonfaller
  /PLOT BOXPLOT HISTOGRAM NPPLOT
  /COMPARE GROUPS
  /STATISTICS DESCRIPTIVES EXTREME
  /CINTERVAL 95
  /MISSING LISTWISE
  /NOTOTAL.
```

Explore

Falls yes no

Case Processing Summary

		Cases					
		Valid		Missing		Total	
	Falls yes no	N	Percent	N	Percent	N	Percent
FALLS	0	18	100.0%	0	0.0%	18	100.0%
	1	7	100.0%	0	0.0%	7	100.0%

Descriptives

	Falls yes no			Statistic	Std. Error
FALLS	0	Mean		.00	.000
		95% Confidence Interval for Mean	Lower Bound	.00	
			Upper Bound	.00	
		5% Trimmed Mean		.00	
		Median		.00	
		Variance		.000	
		Std. Deviation		.000	
		Minimum		0	
		Maximum		0	
		Range		0	
		Interquartile Range		0	
		Skewness		.	.
		Kurtosis		.	.
	1	Mean		2.14	.404
		95% Confidence Interval for Mean	Lower Bound	1.15	
			Upper Bound	3.13	
		5% Trimmed Mean		2.10	

	Median	2.00	
	Variance	1.143	
	Std. Deviation	1.069	
	Minimum	1	
	Maximum	4	
	Range	3	
	Interquartile Range	2	
	Skewness	.772	.794
	Kurtosis	.263	1.587

Extreme Values[c]

	Falls yes no			Case Number	Value
FALLS	0	Highest	1	2	0
			2	3	0
			3	5	0
			4	7	0
			5	8	0[a]
		Lowest	1	25	0
			2	24	0
			3	23	0
			4	22	0
			5	21	0[b]
	1	Highest	1	13	4
			2	14	3
			3	6	2[d]
		Lowest	1	4	1
			2	1	1
			3	18	2[e]

a. Only a partial list of cases with the value 0 are shown in the table of upper extremes.

b. Only a partial list of cases with the value 0 are shown in the table of lower extremes.

c. The requested number of extreme values exceeds the number of data points. A smaller number of extremes is displayed.

d. Only a partial list of cases with the value 2 are shown in the table of upper extremes.

e. Only a partial list of cases with the value 2 are shown in the table of lower extremes.

Tests of Normality

		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Falls yes no	Statistic	df	Sig.	Statistic	df	Sig.
FALLS	0	.	18	.	.	18	.
	1	.267	7	.140	.894	7	.294

a. Lilliefors Significance Correction

```
EXAMINE VARIABLES=AGE MMSE YEARS_SINCE_DIAG COMORBIDITIES
 /PLOT BOXPLOT HISTOGRAM NPPLOT
 /COMPARE GROUPS
 /STATISTICS DESCRIPTIVES EXTREME
 /CINTERVAL 95
 /MISSING PAIRWISE
 /NOTOTAL.
```

Explore

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
AGE	25	100.0%	0	0.0%	25	100.0%
MMSE	25	100.0%	0	0.0%	25	100.0%
YEARS_SINCE_DIAG	25	100.0%	0	0.0%	25	100.0%
COMORBIDITIES	25	100.0%	0	0.0%	25	100.0%

Descriptives

			Statistic	Std. Error
AGE	Mean		65.64	1.880
	95% Confidence Interval for Mean	Lower Bound	61.76	
		Upper Bound	69.52	
	5% Trimmed Mean		65.81	
	Median		68.00	
	Variance		88.407	
	Std. Deviation		9.402	
	Minimum		45	
	Maximum		84	
	Range		39	
	Interquartile Range		13	
	Skewness		-.546	.464
	Kurtosis		.287	.902
MMSE	Mean		28.40	.374
	95% Confidence Interval for Mean	Lower Bound	27.63	
		Upper Bound	29.17	

	5% Trimmed Mean		28.54	
	Median		29.00	
	Variance		3.500	
	Std. Deviation		1.871	
	Minimum		24	
	Maximum		30	
	Range		6	
	Interquartile Range		3	
	Skewness		-1.096	.464
	Kurtosis		-.024	.902
YEARS_SINCE_DIAG	Mean		7.180	.9073
	95% Confidence Interval for Mean	Lower Bound	5.307	
		Upper Bound	9.053	
	5% Trimmed Mean		7.017	
	Median		6.000	
	Variance		20.581	
	Std. Deviation		4.5366	
	Minimum		.5	
	Maximum		17.0	
	Range		16.5	
	Interquartile Range		6.5	
	Skewness		.594	.464
	Kurtosis		-.472	.902
COMORBIDITIES	Mean		1.52	.312
	95% Confidence Interval for Mean	Lower Bound	.88	
		Upper Bound	2.16	
	5% Trimmed Mean		1.41	
	Median		1.00	

	Variance	2.427	
	Std. Deviation	1.558	
	Minimum	0	
	Maximum	5	
	Range	5	
	Interquartile Range	3	
	Skewness	.966	.464
	Kurtosis	.120	.902

Extreme Values

			Case Number	Value
AGE	Highest	1	4	84
		2	24	79
		3	2	74
		4	9	74
		5	7	72[a]
	Lowest	1	23	45
		2	18	46
		3	6	53
		4	17	56
		5	8	56
MMSE	Highest	1	5	30
		2	7	30
		3	10	30
		4	11	30
		5	15	30[b]
	Lowest	1	16	24
		2	8	25

		3	4	25
		4	20	26
		5	9	26
YEARS_SINCE_DIAG	Highest	1	18	17.0
		2	2	15.0
		3	1	14.0
		4	16	13.0
		5	20	13.0
	Lowest	1	23	.5
		2	22	1.5
		3	10	1.5
		4	14	2.0
		5	11	3.0[c]
COMORBIDITIES	Highest	1	2	5
		2	10	5
		3	11	4
		4	4	3
		5	19	3[d]
	Lowest	1	25	0
		2	18	0
		3	17	0
		4	15	0
		5	9	0[e]

a. Only a partial list of cases with the value 72 are shown in the table of upper extremes.

b. Only a partial list of cases with the value 30 are shown in the table of upper extremes.

c. Only a partial list of cases with the value 3.0 are shown in the table of lower extremes.

d. Only a partial list of cases with the value 3 are shown in the table of upper extremes.

e. Only a partial list of cases with the value 0 are shown in the table of lower extremes.

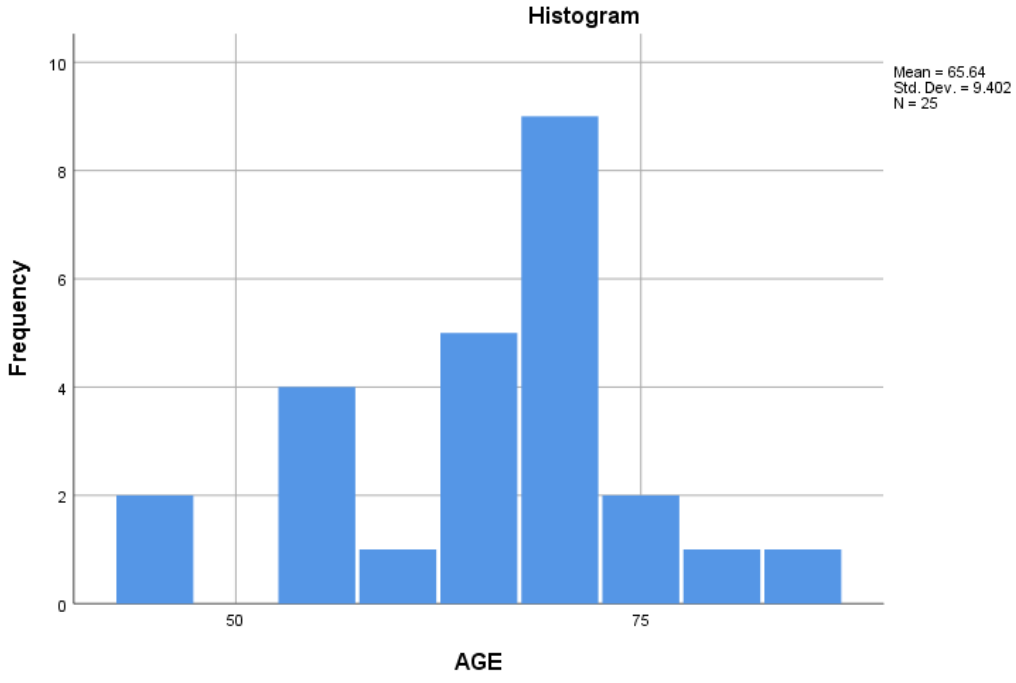
Tests of Normality

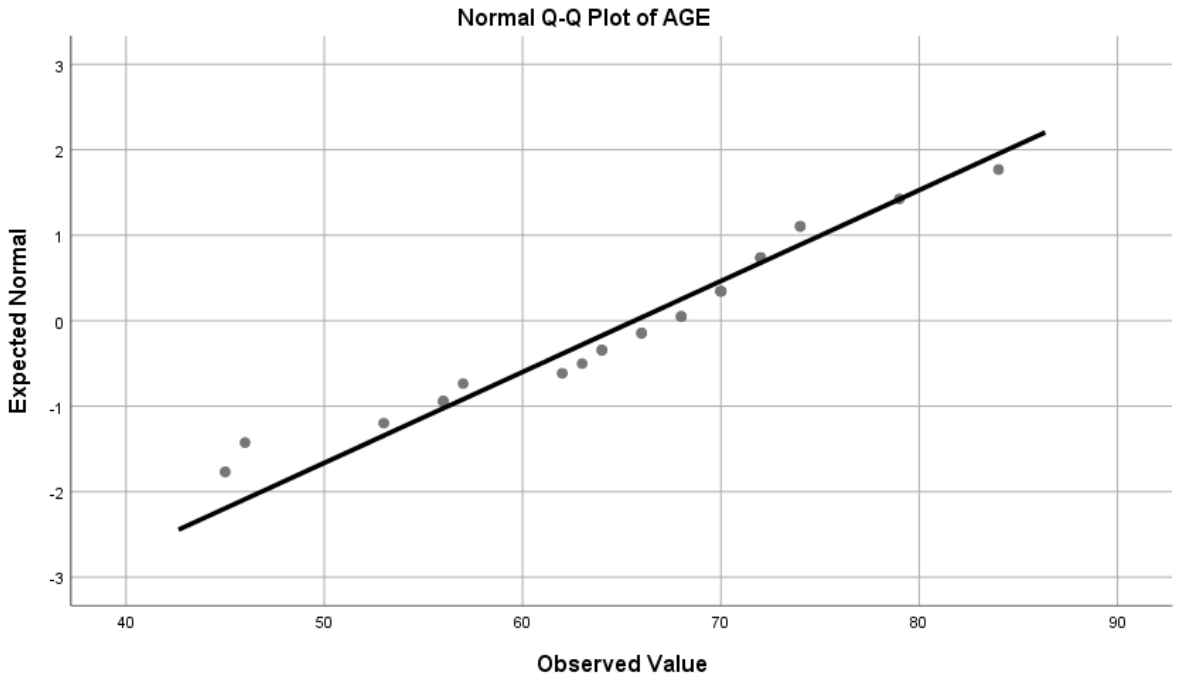
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
AGE	.119	25	.200*	.955	25	.327
MMSE	.306	25	.000	.802	25	.000
YEARS_SINCE_DIAG	.163	25	.087	.941	25	.159
COMORBIDITIES	.231	25	.001	.853	25	.002

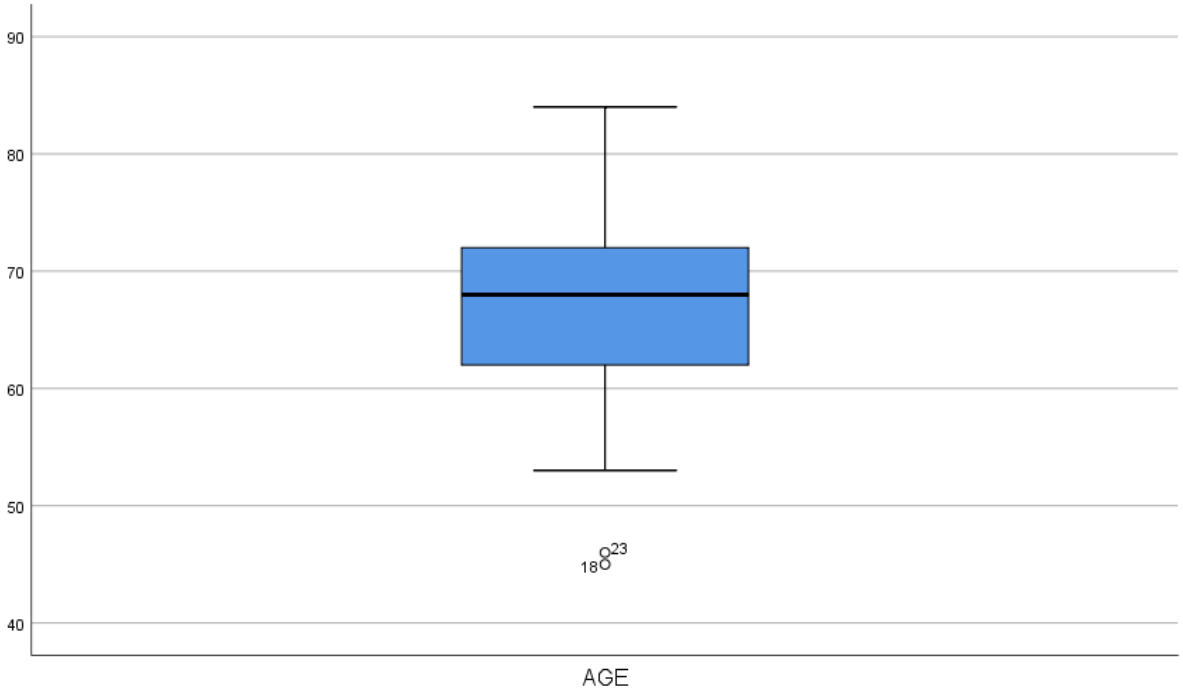
*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

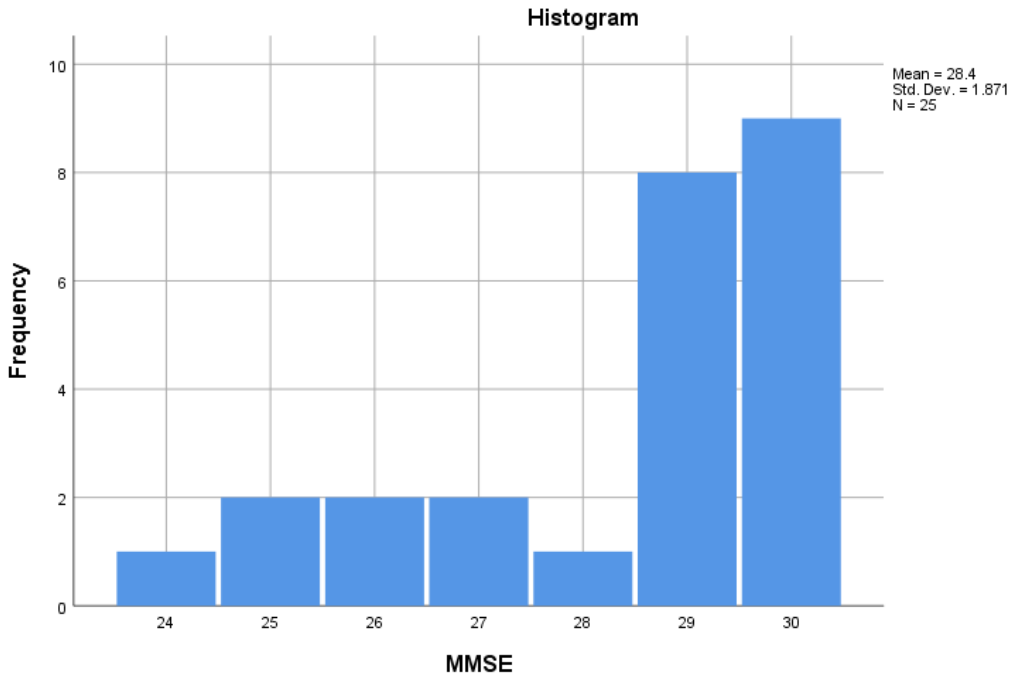
AGE

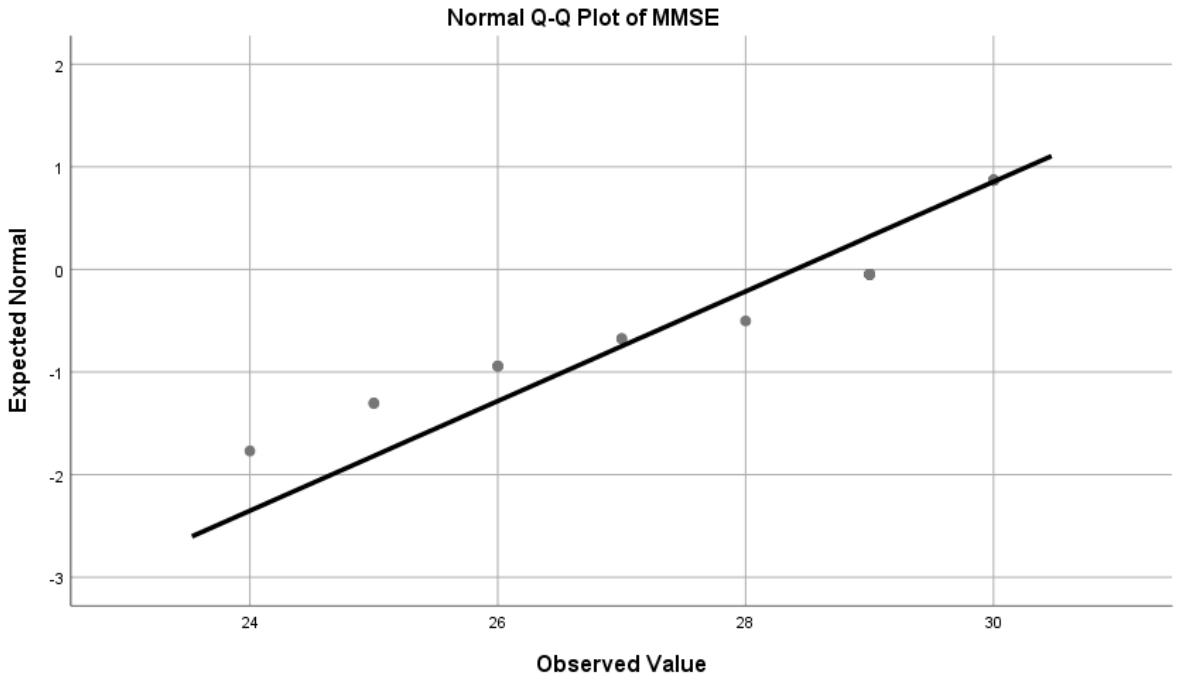


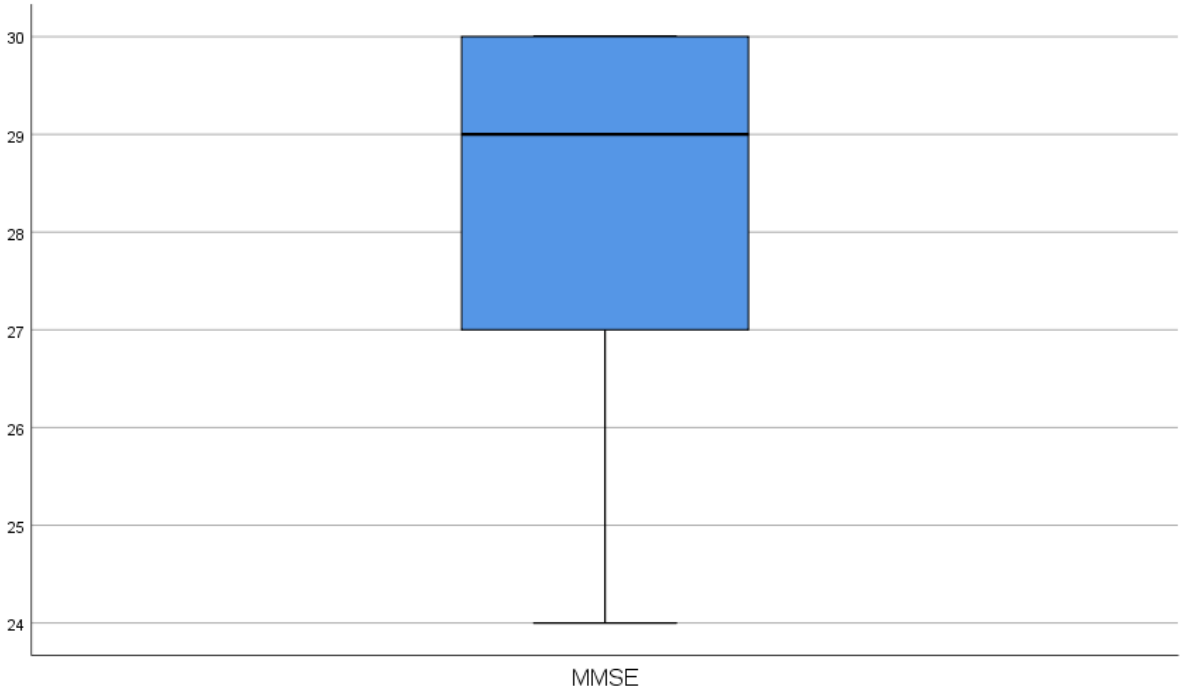

Normal Q-Q Plot of AGE
Expected Normal
Observed Value
3
2
1
0
-1
-2
-3
40
50
60
70
80
90


90
80
70
60
50
40
18
23
AGE

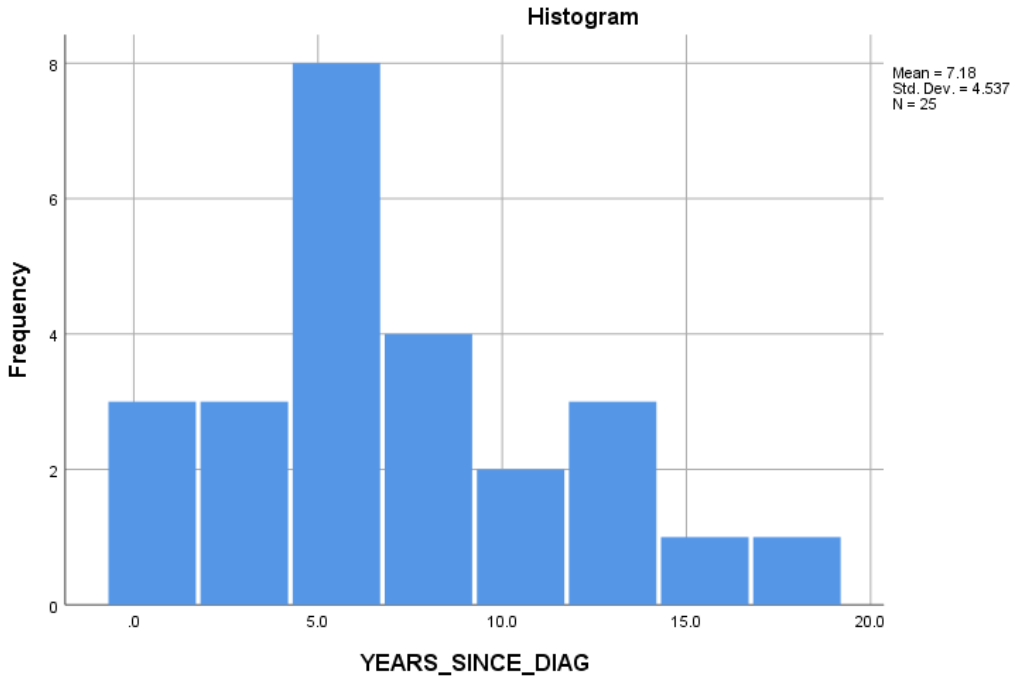
MMSE

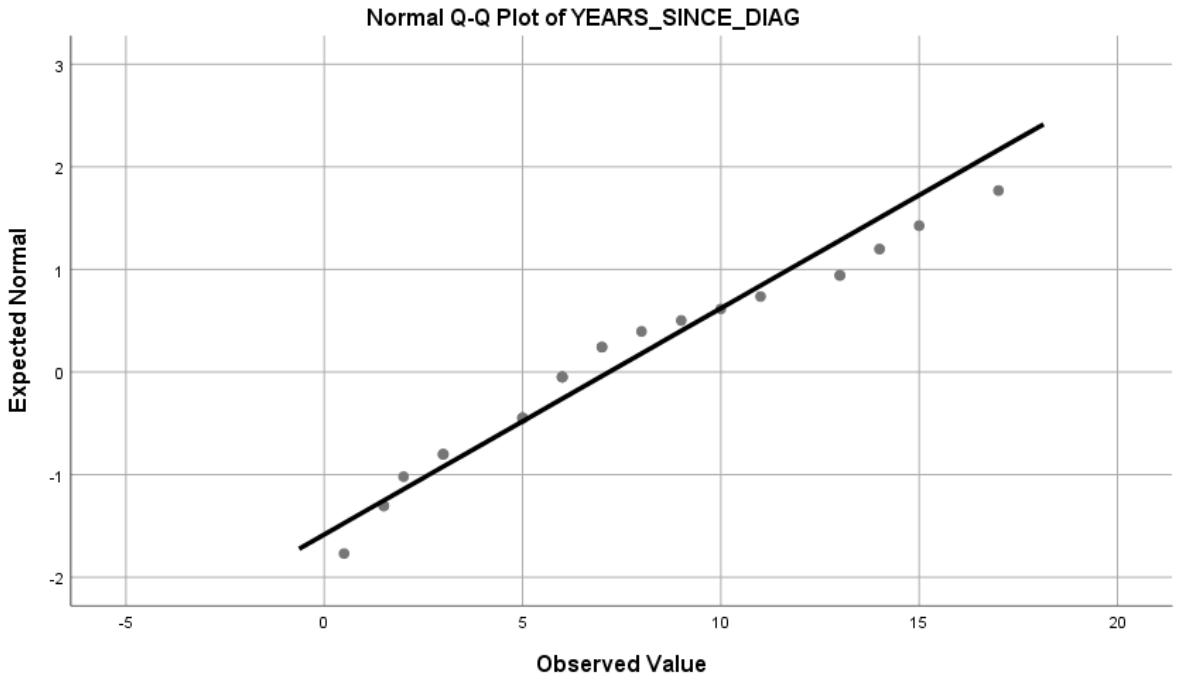

Histogram
Mean = 28.4
Std. Dev. = 1.871
N = 25
Frequency
MMSE
0
2
4
6
8
10
24
25
26
27
28
29
30

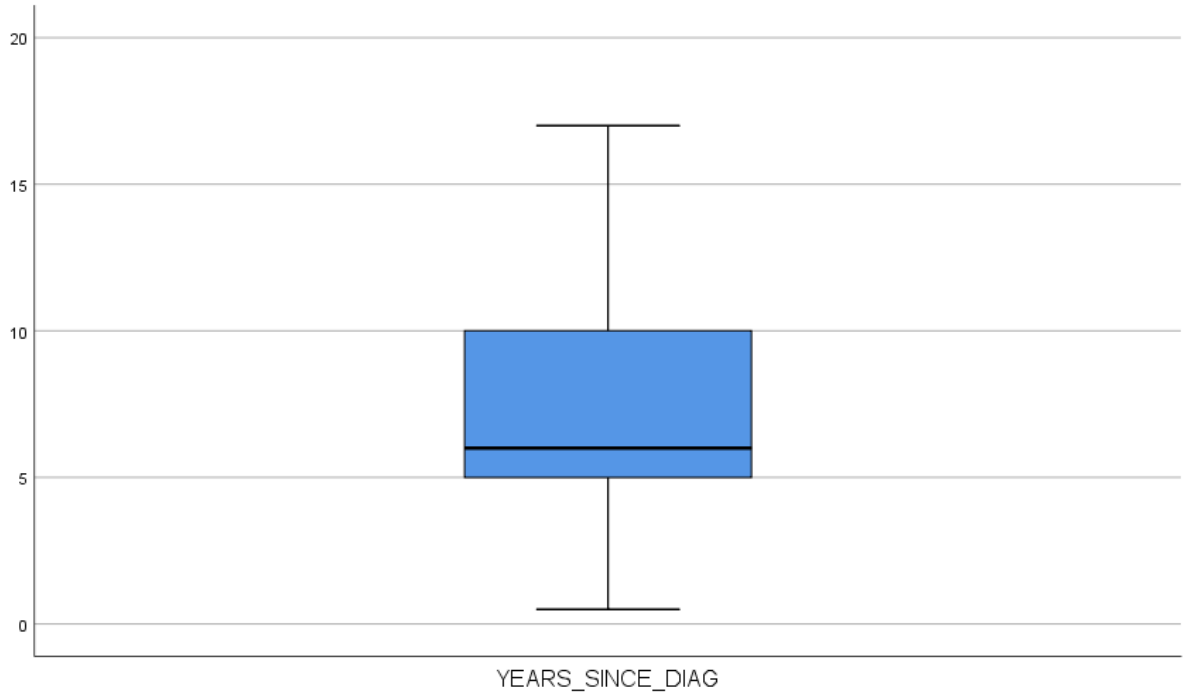

Normal Q-Q Plot of MMSE
Expected Normal
Observed Value
2
1
0
-1
-2
-3
24
26
28
30



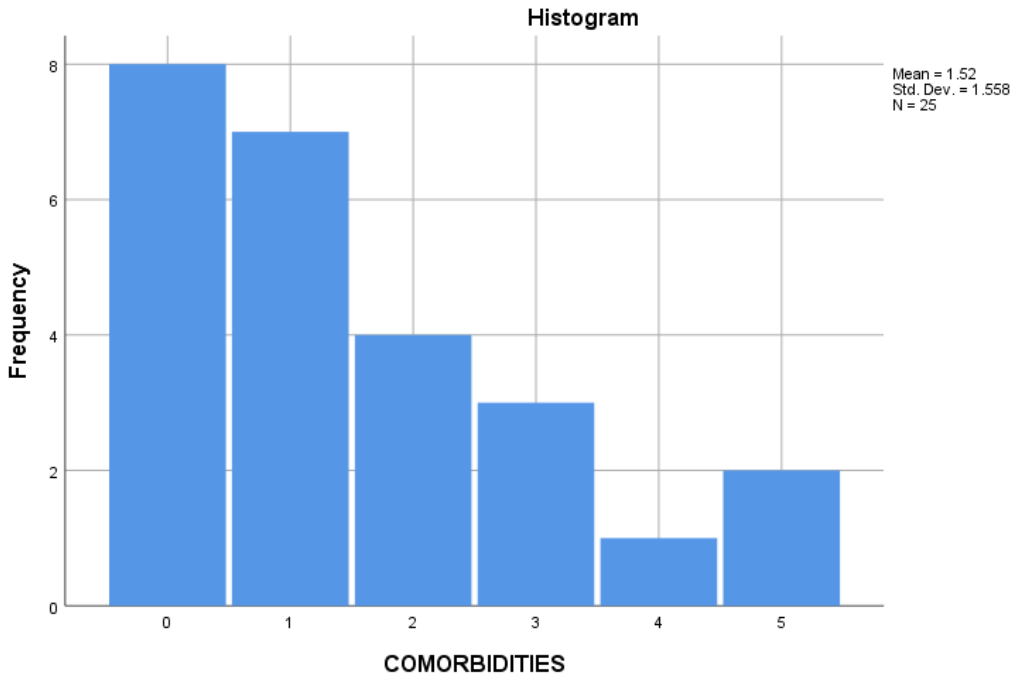
YEARS_SINCE_DIAG

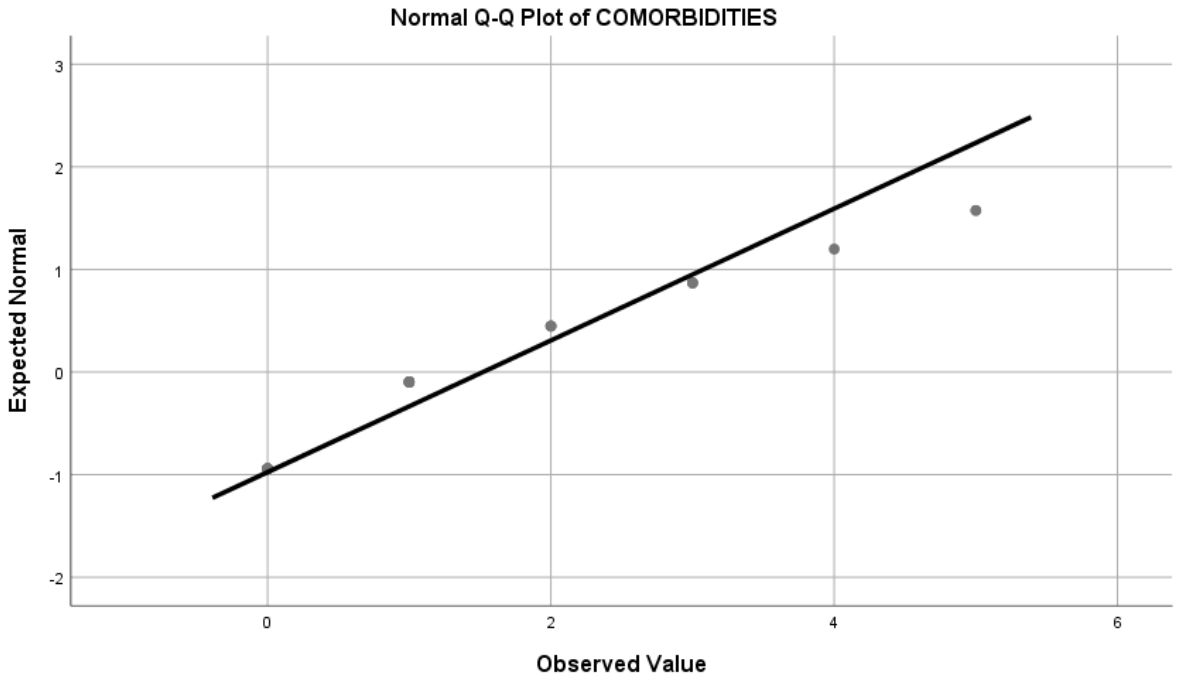


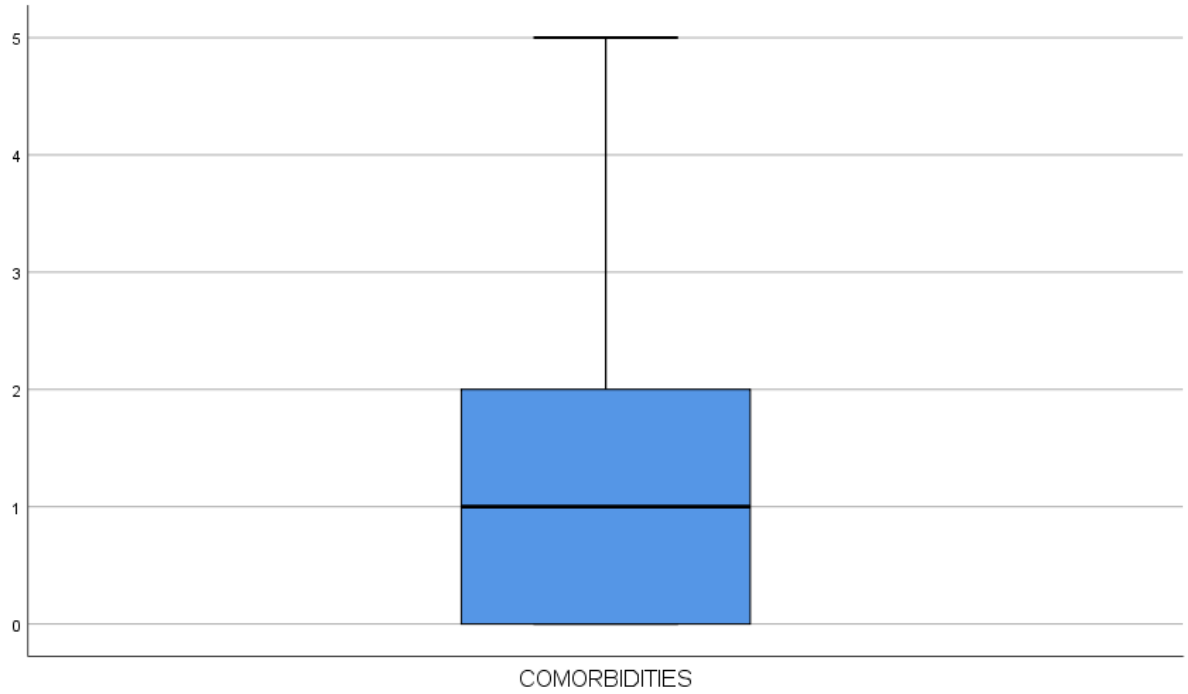

Normal Q-Q Plot of YEARS_SINCE_DIAG
Expected Normal
Observed Value
3
2
1
0
-1
-2
-5
0
5
10
15
20


20
15
10
5
0
YEARS_SINCE_DIAG

COMORBIDITIES






5
4
3
2
1
0
COMORBIDITIES

```
T-TEST GROUPS=FALLS_CAT(1 2)
 /MISSING=ANALYSIS
 /VARIABLES=AGE YEARS_SINCE_DIAG
 /CRITERIA=CI(.95).
```

T-Test

Group Statistics

	Falls categories	N	Mean	Std. Deviation	Std. Error Mean
AGE	1	7	64.57	12.381	4.680
	2	18	66.06	8.370	1.973
YEARS_SINCE_DIAG	1	7	9.286	5.7652	2.1791
	2	18	6.361	3.8456	.9064

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means
		F	Sig.	t
AGE	Equal variances assumed	.984	.332	-.348
	Equal variances not assumed			-.292
YEARS_SINCE_DIAG	Equal variances assumed	3.169	.088	1.483
	Equal variances not assumed			1.239

Independent Samples Test

		t-test for Equality of Means		
		df	Sig. (2-tailed)	Mean Difference

AGE	Equal variances assumed	23	.731	-1.484
	Equal variances not assumed	8.231	.777	-1.484
YEARS_SINCE_DIAG	Equal variances assumed	23	.152	2.9246
	Equal variances not assumed	8.170	.250	2.9246

Independent Samples Test

		t-test for Equality of Means		
			95% Confidence Interval of the Difference	
		Std. Error Difference	Lower	Upper
AGE	Equal variances assumed	4.267	-10.311	7.343
	Equal variances not assumed	5.078	-13.138	10.170
YEARS_SINCE_DIAG	Equal variances assumed	1.9721	-1.1550	7.0042
	Equal variances not assumed	2.3601	-2.4981	8.3473

```
*Nonparametric Tests: Independent Samples.
NPTESTS
  /INDEPENDENT TEST (MMSE) GROUP (FALLS_CAT) MANN_WHITNEY
  /MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE
  /CRITERIA ALPHA=0.05  CILEVEL=95.
```

Nonparametric Tests

null : null

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of MMSE is the same across categories of Falls categories.	Independent-Samples Mann-Whitney U Test	.085[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

*Nonparametric Tests: Independent Samples.

NPTESTS

/INDEPENDENT TEST (COMORBIDITIES) GROUP (FALLS_CAT) MANN_WHITNEY

/MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE

/CRITERIA ALPHA=0.05 CILEVEL=95.

Nonparametric Tests

null : null

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of COMORBIDITIES is the same across categories of Falls categories.	Independent-Samples Mann-Whitney U Test	.929[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

```
CROSSTABS
  /TABLES=SEX BY FALLS_CAT
  /FORMAT=AVALUE TABLES
  /STATISTICS=CHISQ
  /CELLS=COUNT ROW
  /COUNT ROUND CELL.
```

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
SEX * Falls categories	25	100.0%	0	0.0%	25	100.0%

SEX * Falls categories Crosstabulation

			Falls categories		
			1	2	Total
SEX	1	Count	5	14	19
		% within SEX	26.3%	73.7%	100.0%
	2	Count	2	4	6
		% within SEX	33.3%	66.7%	100.0%
Total		Count	7	18	25
		% within SEX	28.0%	72.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.111[a]	1	.739		

Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.109	1	.742		
Fisher's Exact Test				1.000	.557
N of Valid Cases	25				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 1.68.

b. Computed only for a 2x2 table

```
CROSSTABS
  /TABLES=H_and_Y BY FALLS_CAT
  /FORMAT=AVALUE TABLES
  /STATISTICS=CHISQ
  /CELLS=COUNT ROW
  /COUNT ROUND CELL.
```

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
H and Y * Falls categories	25	100.0%	0	0.0%	25	100.0%

H and Y * Falls categories Crosstabulation

			Falls categories		
			1	2	Total
H and Y	1	Count	0	13	13
		% within H and Y	0.0%	100.0%	100.0%
	2	Count	6	4	10
		% within H and Y	60.0%	40.0%	100.0%

3	Count	1	1	2
	% within H and Y	50.0%	50.0%	100.0%
Total	Count	7	18	25
	% within H and Y	28.0%	72.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	10.615[a]	2	.005
Likelihood Ratio	13.415	2	.001
N of Valid Cases	25		

a. 4 cells (66.7%) have expected count less than 5. The minimum expected count is .56.

```
CROSSTABS
  /TABLES=WALK_AID BY FALLS_CAT
  /FORMAT=AVALUE TABLES
  /STATISTICS=CHISQ
  /CELLS=COUNT ROW
  /COUNT ROUND CELL.
```

Crosstabs

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
WALK_AID * Falls categories	25	100.0%	0	0.0%	25	100.0%

WALK_AID * Falls categories Crosstabulation

			Falls categories		
			1	2	Total
WALK_AID	1	Count	6	17	23
		% within WALK_AID	26.1%	73.9%	100.0%
	2	Count	1	0	1
		% within WALK_AID	100.0%	0.0%	100.0%
	4	Count	0	1	1
		% within WALK_AID	0.0%	100.0%	100.0%
Total		Count	7	18	25
		% within WALK_AID	28.0%	72.0%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	3.002[a]	2	.223
Likelihood Ratio	3.245	2	.197
N of Valid Cases	25		

a. 4 cells (66.7%) have expected count less than 5. The minimum expected count is .28.

```
EXAMINE VARIABLES=TUG_STD_TIME TUG_MAN_TIME TUG_COG_TIME LTEST_STD_TIME
LTEST_MAN_TIME
  LTEST_COG_TIME BY FALLS_CAT
 /PLOT BOXPLOT HISTOGRAM NPPLOT
 /COMPARE GROUPS
 /STATISTICS DESCRIPTIVES EXTREME
 /CINTERVAL 95
 /MISSING LISTWISE
 /NOTOTAL.
```

Explore

Falls categories

Case Processing Summary

		Cases				
		Valid		Missing		Total
	Falls categories	N	Percent	N	Percent	N
TUG_STD_TIME	1	7	100.0%	0	0.0%	7
	2	18	100.0%	0	0.0%	18
TUG_MAN_TIME	1	7	100.0%	0	0.0%	7
	2	18	100.0%	0	0.0%	18
TUG_COG_TIME	1	7	100.0%	0	0.0%	7
	2	18	100.0%	0	0.0%	18
L-TEST_STD_TIME	1	7	100.0%	0	0.0%	7
	2	18	100.0%	0	0.0%	18
L-TEST_MAN_TIME	1	7	100.0%	0	0.0%	7
	2	18	100.0%	0	0.0%	18
L-TEST_COG_TIME	1	7	100.0%	0	0.0%	7

2	18	100.0%	0	0.0%	18

Case Processing Summary

		Cases Total Percent
	Falls categories	
TUG_STD_TIME	1	100.0%
	2	100.0%
TUG_MAN_TIME	1	100.0%
	2	100.0%
TUG_COG_TIME	1	100.0%
	2	100.0%
L-TEST_STD_TIME	1	100.0%
	2	100.0%
L-TEST_MAN_TIME	1	100.0%
	2	100.0%
L-TEST_COG_TIME	1	100.0%
	2	100.0%

Descriptives

	Falls categories			Statistic	Std. Error
TUG_STD_TIME	1	Mean		11.086	1.3891
		95% Confidence Interval for Mean	Lower Bound	7.687	
			Upper Bound	14.485	
		5% Trimmed Mean		10.851	
		Median		9.600	
		Variance		13.508	
		Std. Deviation		3.6753	

		Minimum		7.6	
		Maximum		18.8	
		Range		11.2	
		Interquartile Range		2.9	
		Skewness		1.904	.794
		Kurtosis		4.094	1.587
	2	Mean		9.733	.8142
		95% Confidence Interval for Mean	Lower Bound	8.015	
			Upper Bound	11.451	
		5% Trimmed Mean		9.387	
		Median		8.900	
		Variance		11.933	
		Std. Deviation		3.4544	
		Minimum		5.7	
		Maximum		20.0	
		Range		14.3	
		Interquartile Range		3.0	
		Skewness		1.836	.536
		Kurtosis		3.910	1.038
TUG_MAN_TIME	1	Mean		11.543	1.6059
		95% Confidence Interval for Mean	Lower Bound	7.613	
			Upper Bound	15.472	
		5% Trimmed Mean		11.264	
		Median		10.600	
		Variance		18.053	
		Std. Deviation		4.2489	
		Minimum		7.7	
		Maximum		20.4	

		Range		12.7	
		Interquartile Range		4.2	
		Skewness		1.844	.794
		Kurtosis		3.857	1.587
	2	Mean		10.906	1.1340
		95% Confidence Interval for Mean	Lower Bound	8.513	
			Upper Bound	13.298	
		5% Trimmed Mean		10.240	
		Median		9.350	
		Variance		23.146	
		Std. Deviation		4.8111	
		Minimum		6.6	
		Maximum		27.2	
		Range		20.6	
		Interquartile Range		2.6	
		Skewness		2.665	.536
		Kurtosis		7.959	1.038
TUG_COG_TIME	1	Mean		13.129	2.1223
		95% Confidence Interval for Mean	Lower Bound	7.935	
			Upper Bound	18.322	
		5% Trimmed Mean		12.787	
		Median		11.900	
		Variance		31.529	
		Std. Deviation		5.6151	
		Minimum		8.0	
		Maximum		24.4	
		Range		16.4	
		Interquartile Range		6.8	

		Skewness		1.567	.794
		Kurtosis		2.747	1.587
	2	Mean		12.222	1.5868
		95% Confidence Interval for Mean	Lower Bound	8.874	
			Upper Bound	15.570	
		5% Trimmed Mean		11.514	
		Median		9.700	
		Variance		45.322	
		Std. Deviation		6.7321	
		Minimum		6.9	
		Maximum		30.3	
		Range		23.4	
		Interquartile Range		4.8	
		Skewness		2.179	.536
		Kurtosis		4.090	1.038
L-TEST_STD_TIME	1	Mean		26.443	3.7621
		95% Confidence Interval for Mean	Lower Bound	17.237	
			Upper Bound	35.648	
		5% Trimmed Mean		25.714	
		Median		23.800	
		Variance		99.076	
		Std. Deviation		9.9537	
		Minimum		18.2	
		Maximum		47.8	
		Range		29.6	
		Interquartile Range		8.3	
		Skewness		2.075	.794
		Kurtosis		4.840	1.587

	2	Mean		23.344	1.8967
		95% Confidence Interval for Mean	Lower Bound	19.343	
			Upper Bound	27.346	
		5% Trimmed Mean		22.260	
		Median		21.600	
		Variance		64.753	
		Std. Deviation		8.0469	
		Minimum		15.0	
		Maximum		51.2	
		Range		36.2	
		Interquartile Range		5.4	
		Skewness		2.698	.536
		Kurtosis		8.769	1.038
L-TEST_MAN_TIME	1	Mean		27.457	3.8618
		95% Confidence Interval for Mean	Lower Bound	18.008	
			Upper Bound	36.907	
		5% Trimmed Mean		26.697	
		Median		24.200	
		Variance		104.396	
		Std. Deviation		10.2174	
		Minimum		19.0	
		Maximum		49.6	
		Range		30.6	
		Interquartile Range		7.0	
		Skewness		2.170	.794
		Kurtosis		5.193	1.587
	2	Mean		25.828	2.6735
			Lower Bound	20.187	

		95% Confidence Interval for Mean	Upper Bound	31.468	
		5% Trimmed Mean		24.109	
		Median		23.300	
		Variance		128.655	
		Std. Deviation		11.3426	
		Minimum		15.7	
		Maximum		66.9	
		Range		51.2	
		Interquartile Range		6.0	
		Skewness		3.121	.536
		Kurtosis		11.019	1.038
L-TEST_COG_TIME	1	Mean		29.729	4.9123
		95% Confidence Interval for Mean	Lower Bound	17.709	
			Upper Bound	41.748	
		5% Trimmed Mean		28.826	
		Median		26.000	
		Variance		168.912	
		Std. Deviation		12.9966	
		Minimum		19.0	
		Maximum		56.7	
		Range		37.7	
		Interquartile Range		14.0	
		Skewness		1.808	.794
		Kurtosis		3.698	1.587
	2	Mean		27.928	2.9496
		95% Confidence Interval for Mean	Lower Bound	21.705	
			Upper Bound	34.151	

	5% Trimmed Mean	26.103	
	Median	24.650	
	Variance	156.607	
	Std. Deviation	12.5143	
	Minimum	17.0	
	Maximum	71.7	
	Range	54.7	
	Interquartile Range	7.1	
	Skewness	2.876	.536
	Kurtosis	9.307	1.038

Extreme Values[a]

	Falls categories			Case Number	Value
TUG_STD_TIME	1	Highest	1	4	18.8
			2	14	12.2
			3	1	10.6
		Lowest	1	18	7.6
			2	16	9.3
			3	6	9.5
	2	Highest	1	11	20.0
			2	10	15.5
			3	20	12.5
			4	22	11.3
			5	24	10.4
		Lowest	1	3	5.7
			2	25	6.7
			3	21	6.8
			4	9	7.3

			5	8	7.7
TUG_MAN_TIME	1	Highest	1	4	20.4
			2	14	12.8
			3	6	11.1
		Lowest	1	18	7.7
			2	16	8.6
			3	13	9.6
	2	Highest	1	11	27.2
			2	10	18.1
			3	22	12.8
			4	20	11.9
			5	5	11.2
		Lowest	1	3	6.6
			2	21	7.1
			3	25	7.7
			4	2	8.5
			5	8	8.8
TUG_COG_TIME	1	Highest	1	4	24.4
			2	1	15.4
			3	14	13.4
		Lowest	1	18	8.0
			2	16	8.6
			3	13	10.2
	2	Highest	1	10	30.3
			2	11	29.0
			3	20	14.9
			4	24	14.1
			5	17	13.2

		Lowest	1	21	6.9
			2	25	7.0
			3	3	8.0
			4	8	8.4
			5	2	8.7
L-TEST_STD_TIME	1	Highest	1	4	47.8
			2	14	27.6
			3	13	24.9
		Lowest	1	18	18.2
			2	16	19.3
			3	1	23.5
	2	Highest	1	11	51.2
			2	10	32.9
			3	20	26.6
			4	24	25.9
			5	22	24.4
		Lowest	1	3	15.0
			2	21	16.5
			3	9	17.9
			4	25	19.2
			5	19	19.4
L-TEST_MAN_TIME	1	Highest	1	4	49.6
			2	14	28.1
			3	1	26.1
		Lowest	1	16	19.0
			2	18	21.1
			3	13	24.1
	2	Highest	1	11	66.9

			2	10	38.3
			3	20	27.9
			4	24	27.3
			5	22	26.0
		Lowest	1	3	15.7
			2	21	17.7
			3	25	19.5
			4	7	20.2
			5	8	20.4
L-TEST_COG_TIME	1	Highest	1	4	56.7
			2	1	33.2
			3	14	30.1
		Lowest	1	18	19.0
			2	16	19.2
			3	13	23.9
	2	Highest	1	11	71.7
			2	10	44.7
			3	20	31.8
			4	19	29.2
			5	17	28.7
		Lowest	1	21	17.0
			2	3	19.0
			3	25	20.4
			4	7	20.6
			5	2	22.1

a. The requested number of extreme values exceeds the number of data points. A smaller number of extremes is displayed.

Tests of Normality

	Falls categories	Kolmogorov-Smirnov[a] Statistic	df	Sig.	Shapiro-Wilk Statistic	df
TUG_STD_TIME	1	.267	7	.142	.792	7
	2	.201	18	.052	.831	18
TUG_MAN_TIME	1	.256	7	.184	.815	7
	2	.253	18	.003	.683	18
TUG_COG_TIME	1	.200	7	.200*	.857	7
	2	.268	18	.001	.674	18
L-TEST_STD_TIME	1	.311	7	.040	.753	7
	2	.264	18	.002	.708	18
L-TEST_MAN_TIME	1	.332	7	.019	.736	7
	2	.316	18	.000	.622	18
L-TEST_COG_TIME	1	.252	7	.200*	.808	7
	2	.293	18	.000	.653	18

Tests of Normality

	Falls categories	Shapiro-Wilk[a] Sig.
TUG_STD_TIME	1	.034
	2	.004
TUG_MAN_TIME	1	.058
	2	.000
TUG_COG_TIME	1	.142
	2	.000
L-TEST_STD_TIME	1	.014
	2	.000
L-TEST_MAN_TIME	1	.009

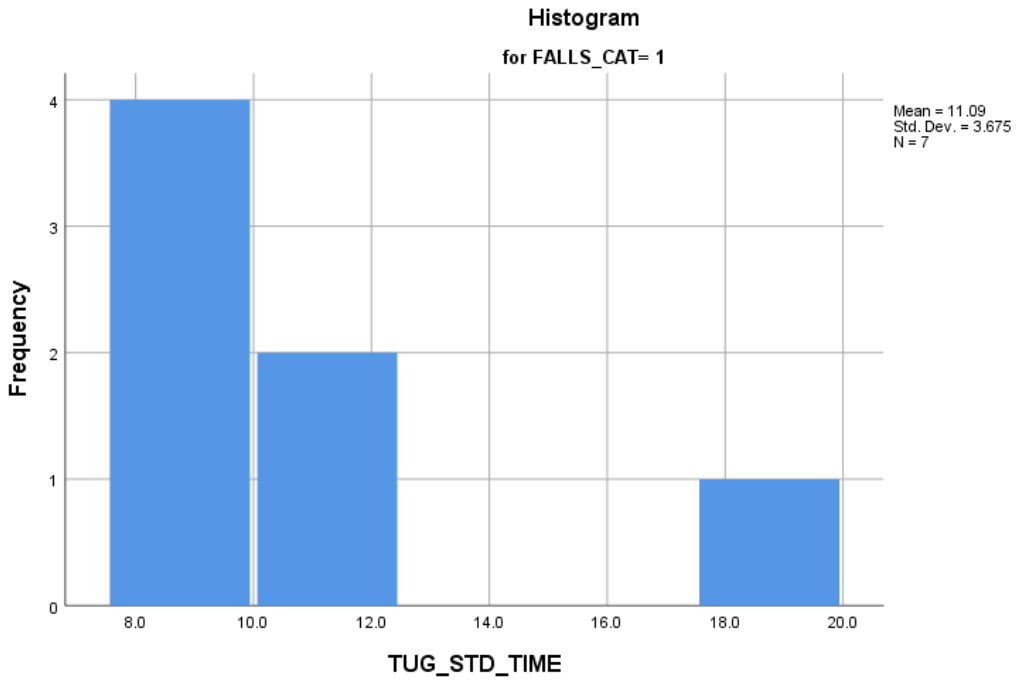
	2	.000
L-TEST_COG_TIME	1	.049
	2	.000

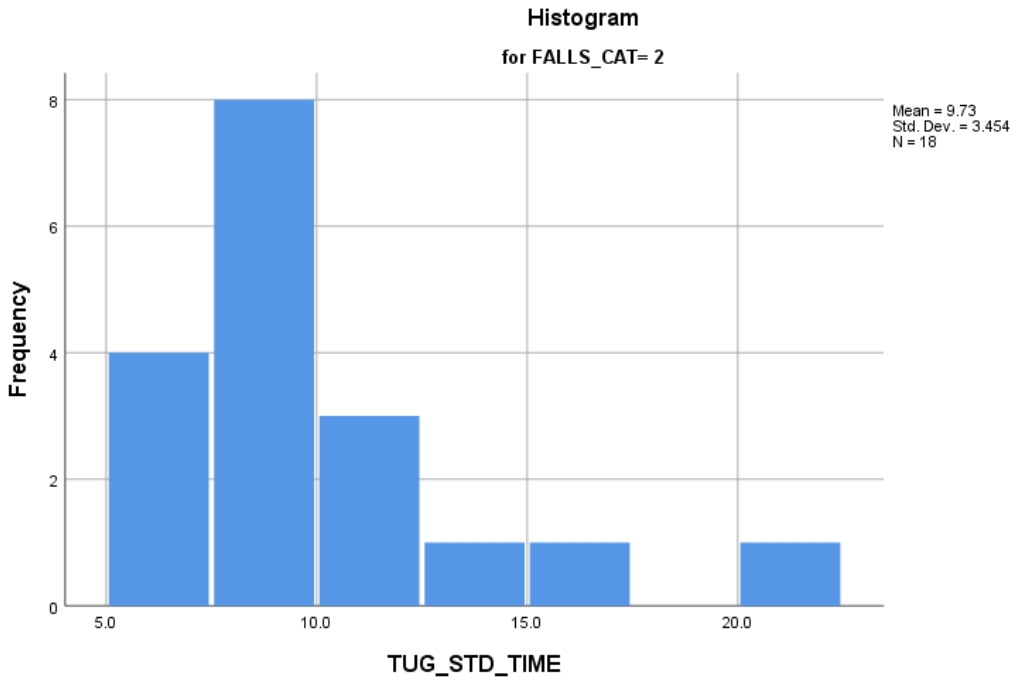
*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

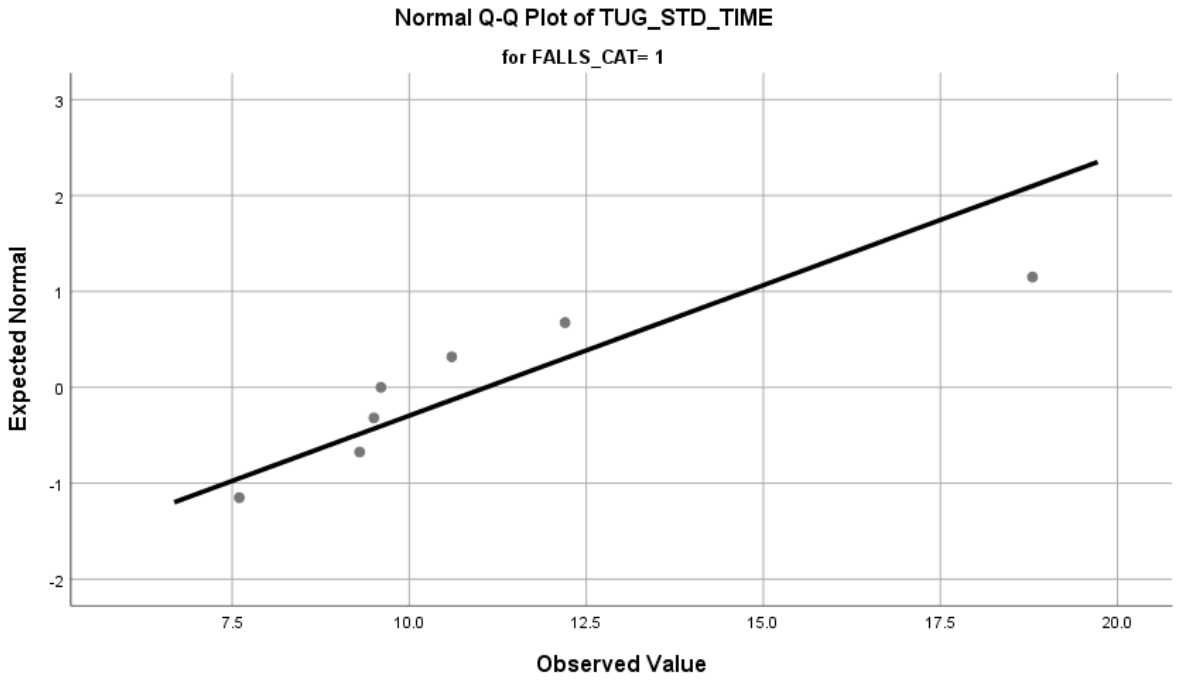
TUG_STD_TIME

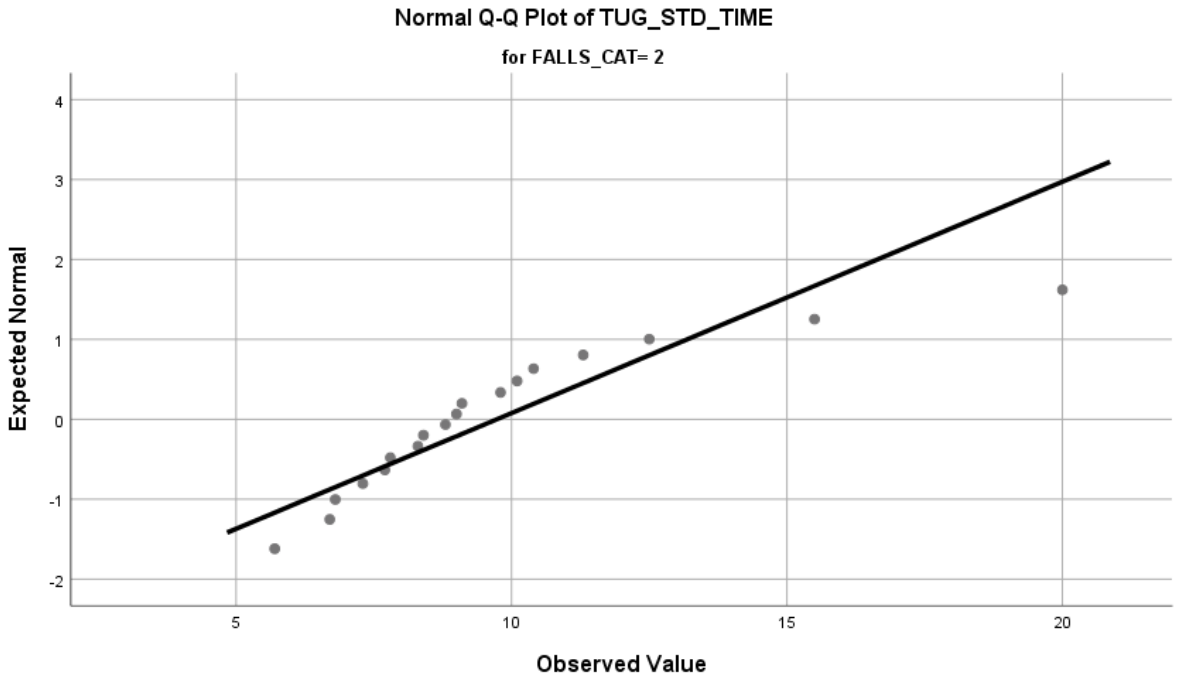
Histograms

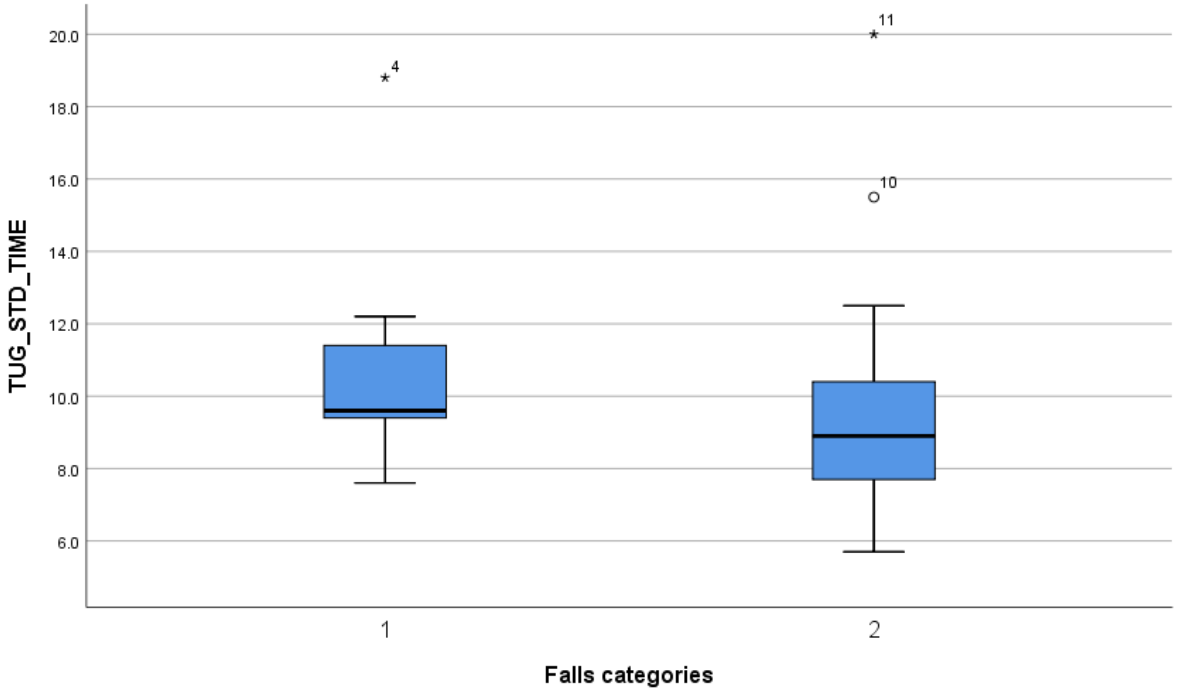




Normal Q-Q Plots

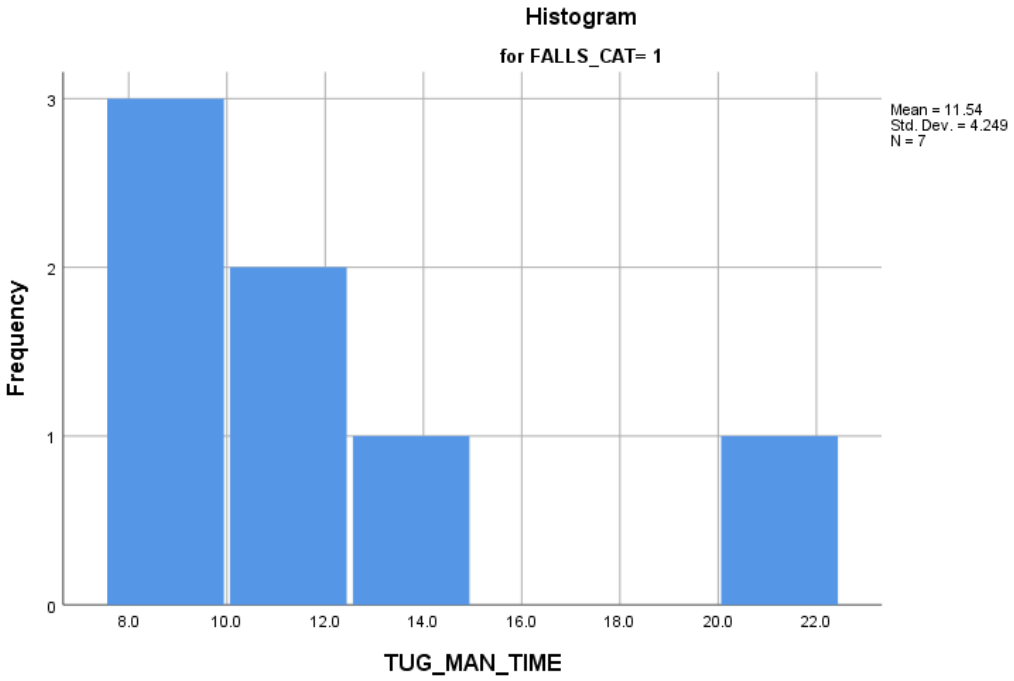


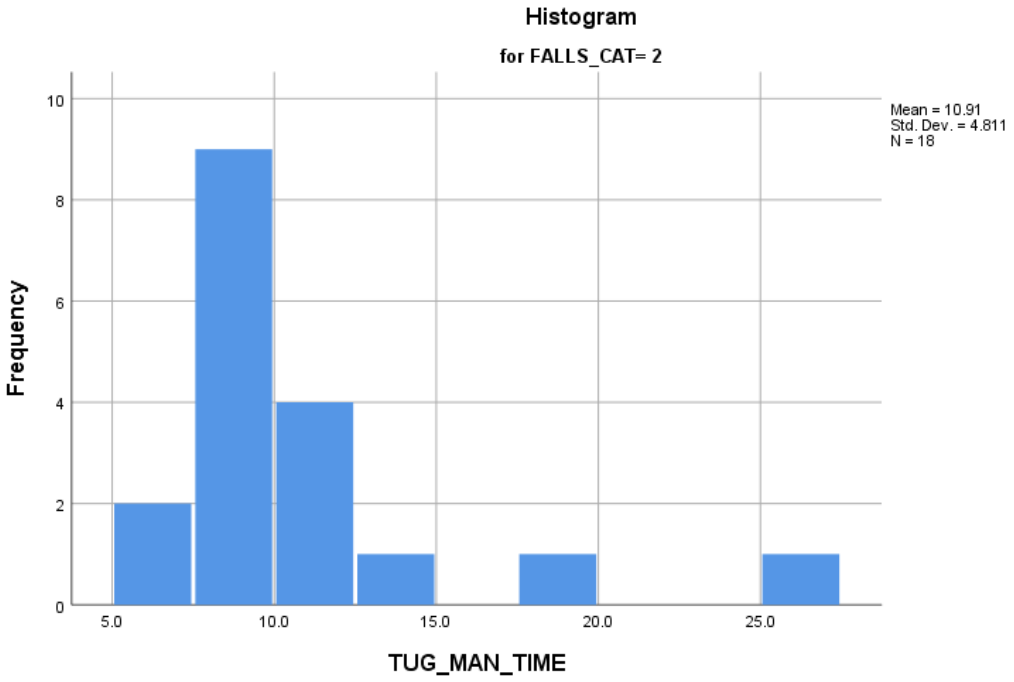

Normal Q-Q Plot of TUG_STD_TIME
for FALLS_CAT= 2
Expected Normal
Observed Value
4
3
2
1
0
-1
-2
5
10
15
20


TUG_STD_TIME
Falls categories
20.0
18.0
16.0
14.0
12.0
10.0
8.0
6.0
4
11
10
1
2

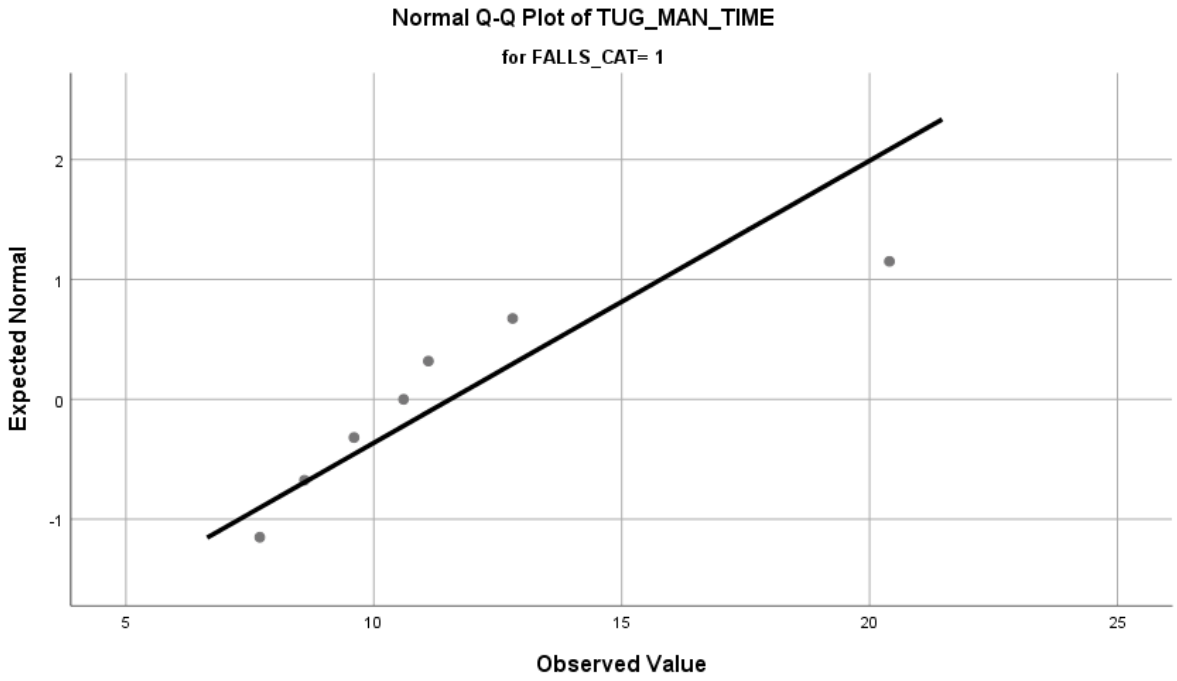
TUG_MAN_TIME

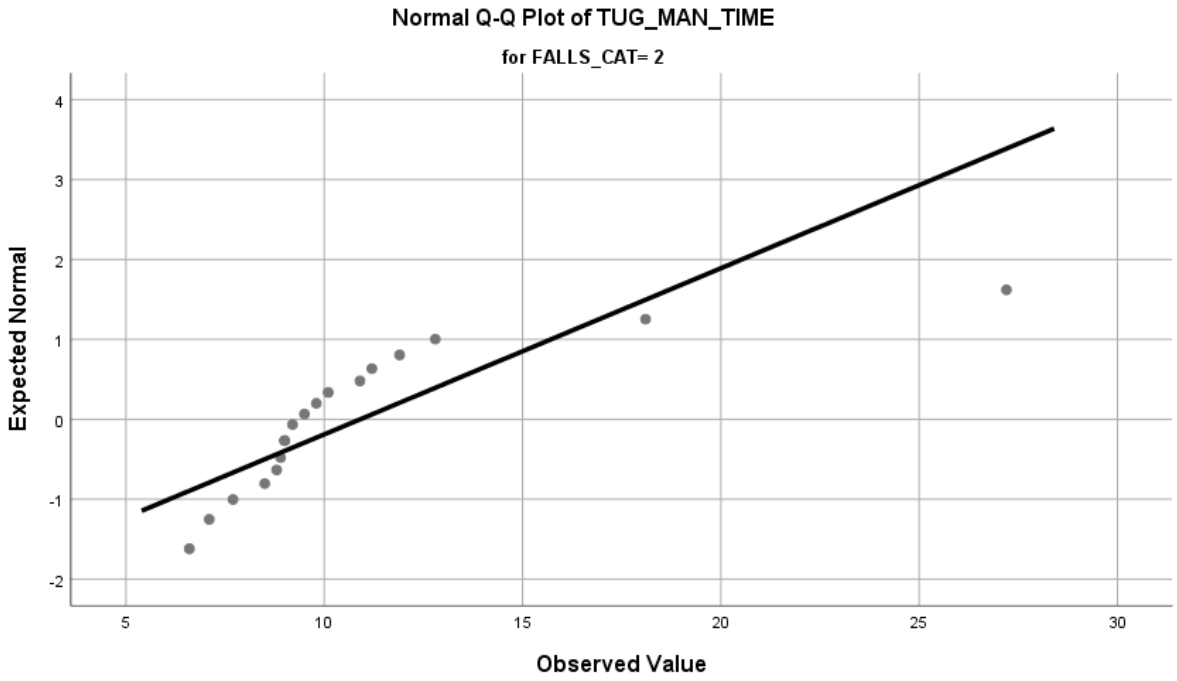
Histograms

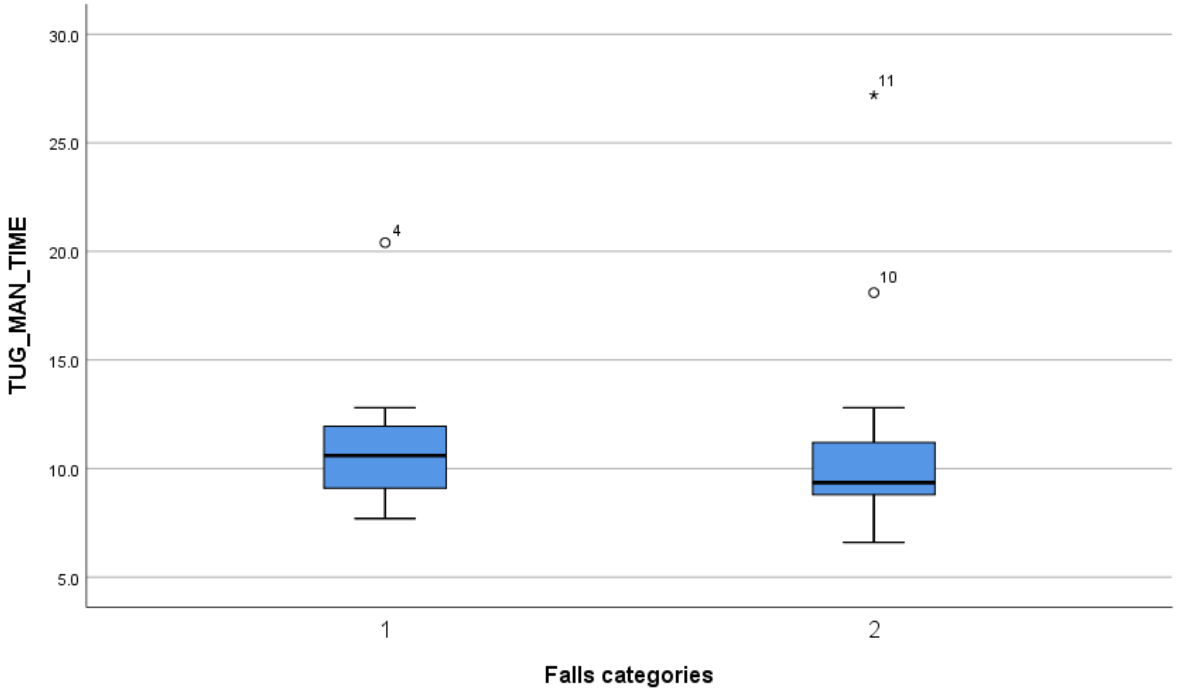




Normal Q-Q Plots

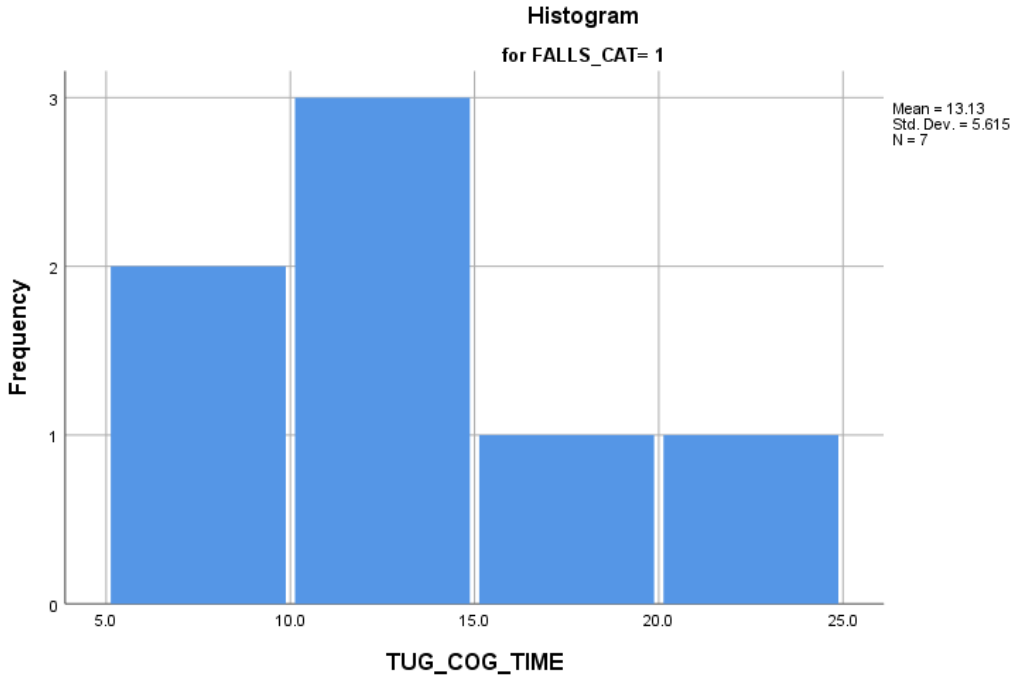


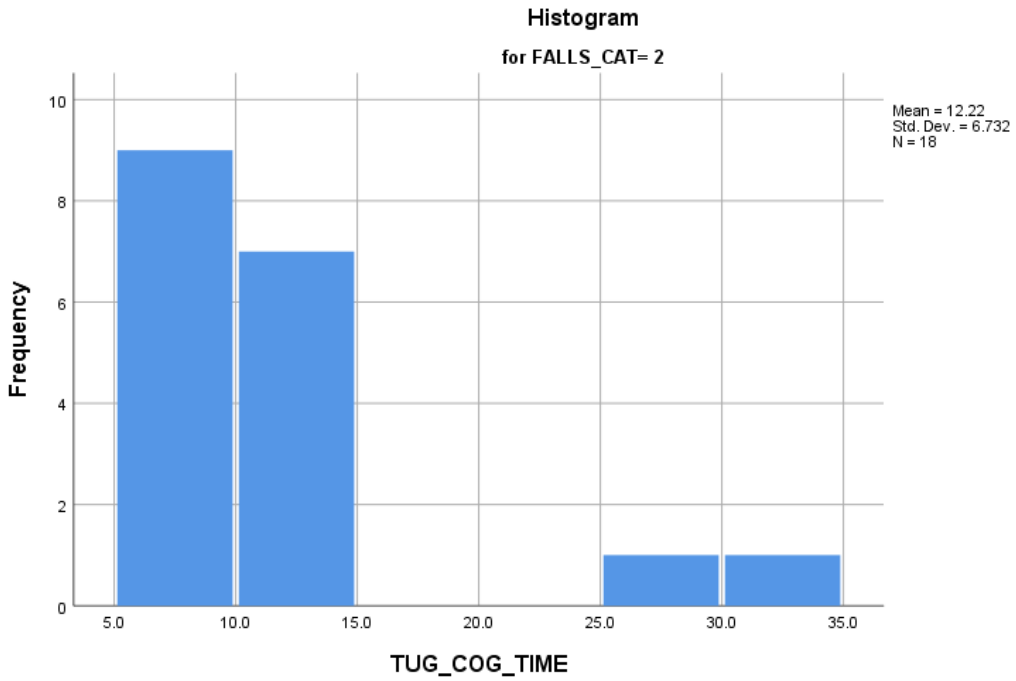




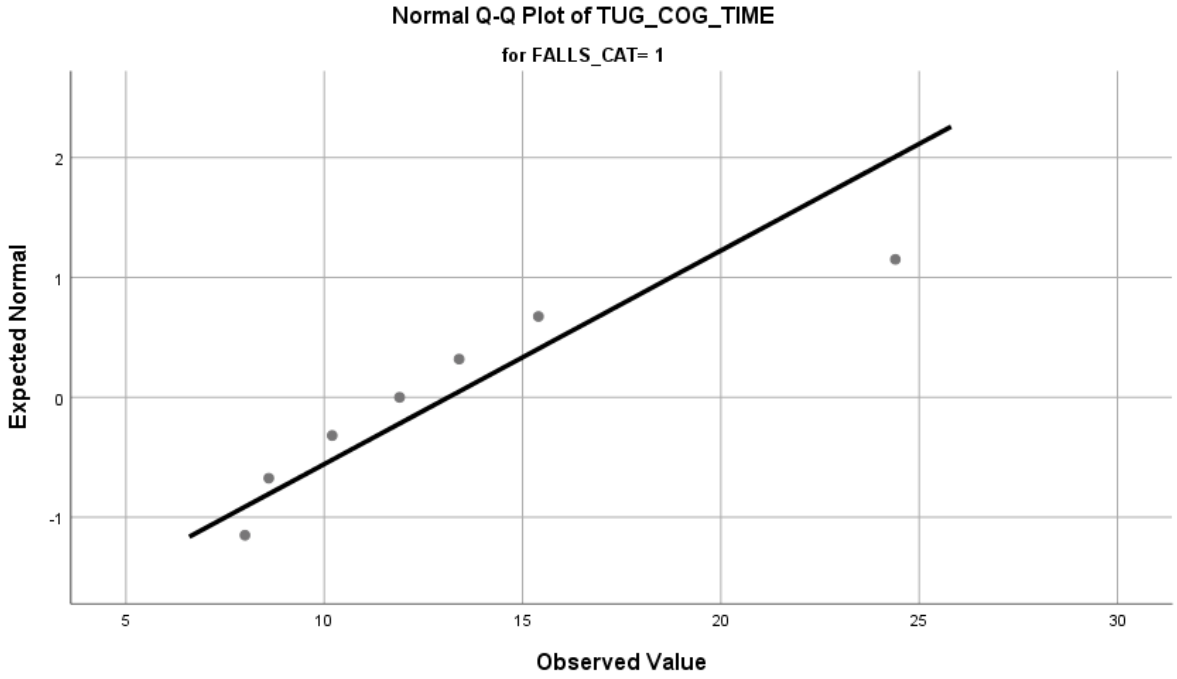
TUG_COG_TIME

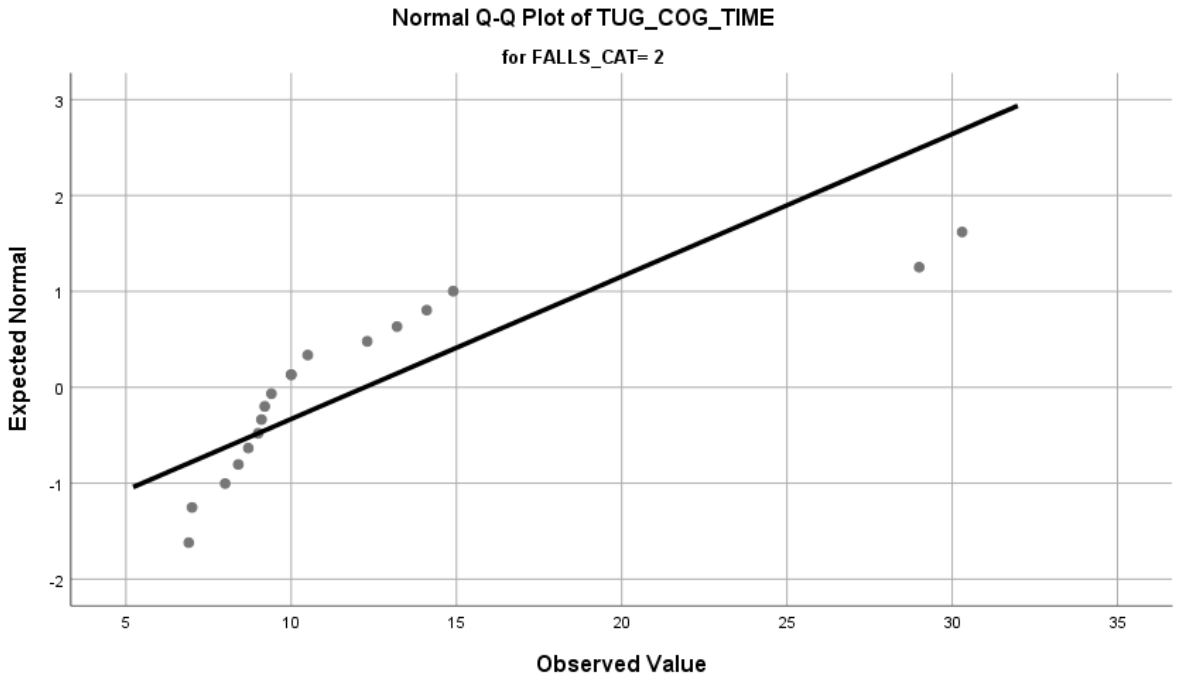
Histograms

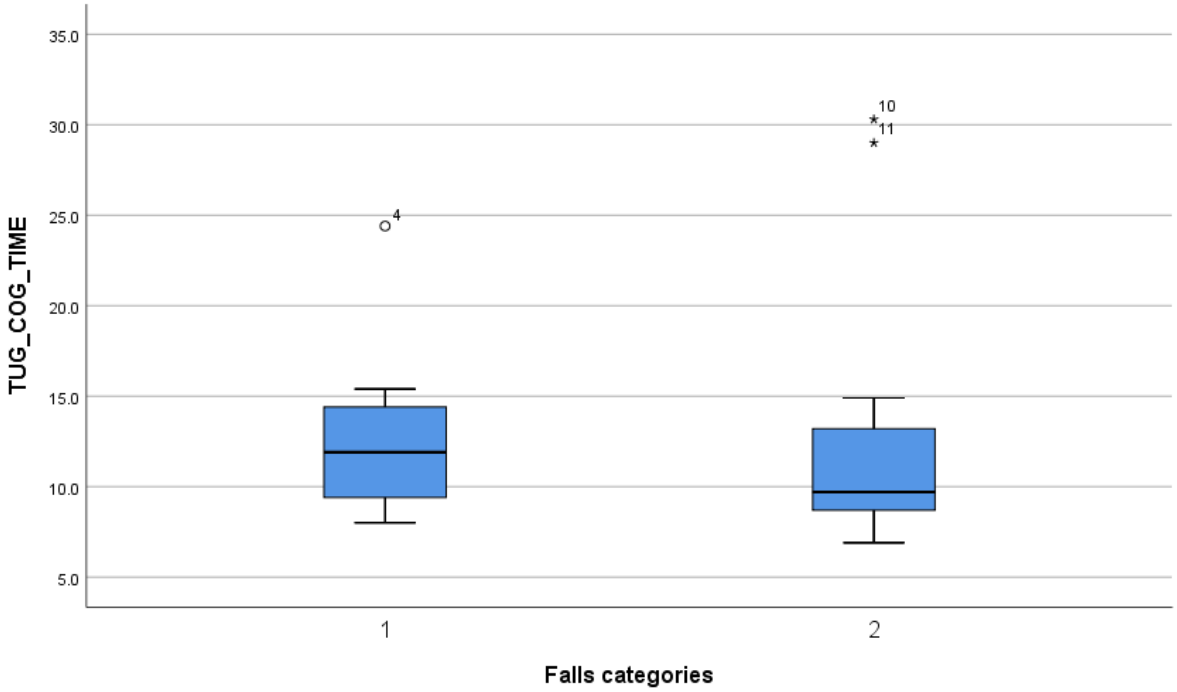




Normal Q-Q Plots

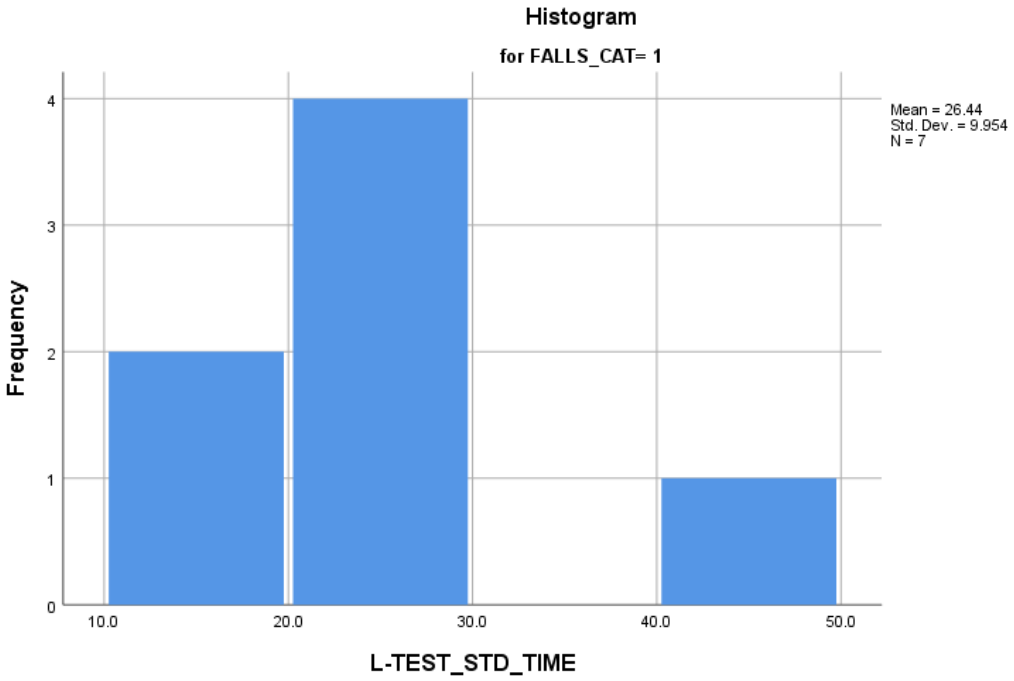


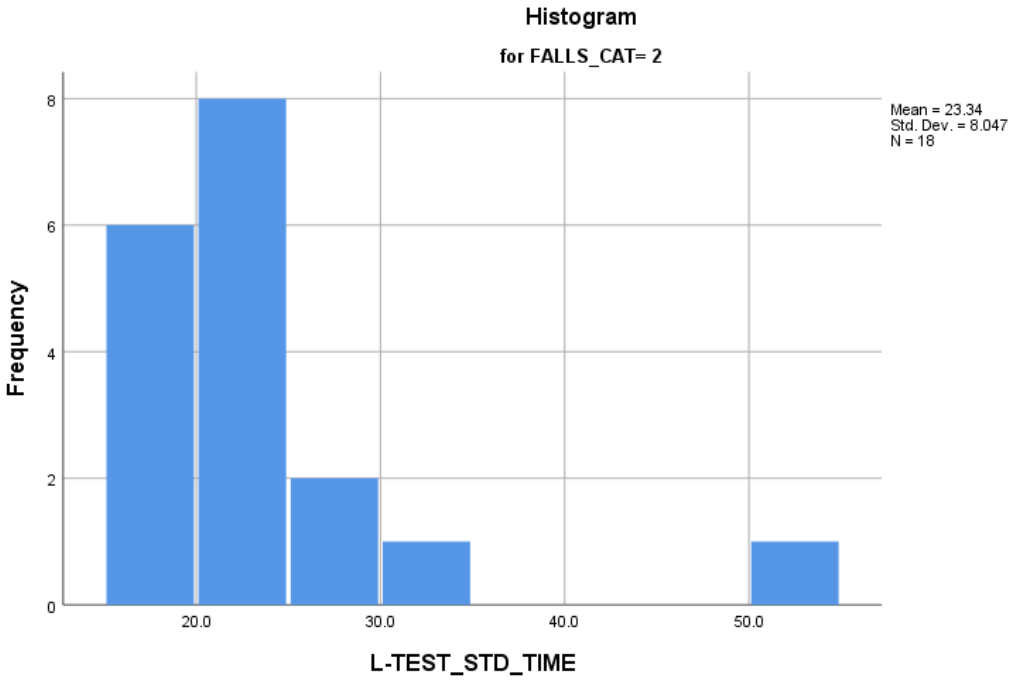

Normal Q-Q Plot of TUG_COG_TIME
for FALLS_CAT= 2
Expected Normal
Observed Value
3
2
1
0
-1
-2
5
10
15
20
25
30
35


TUG_COG_TIME
Falls categories
35.0
30.0
25.0
20.0
15.0
10.0
5.0
1
2
4
10
11

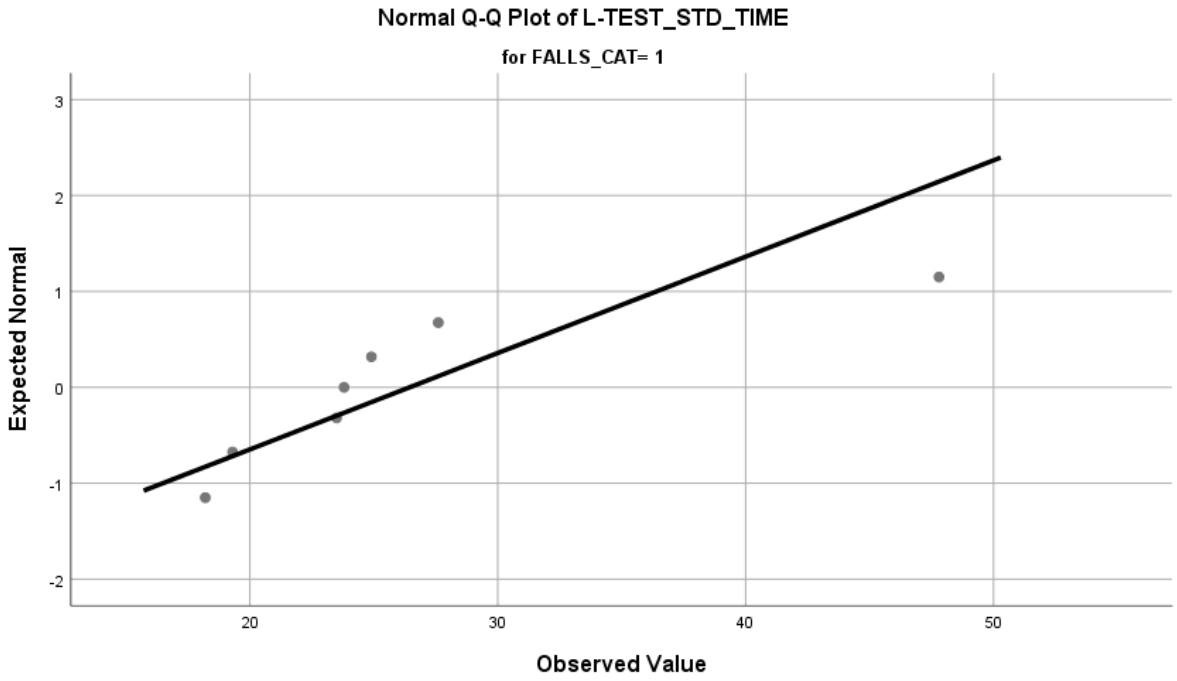
L-TEST_STD_TIME

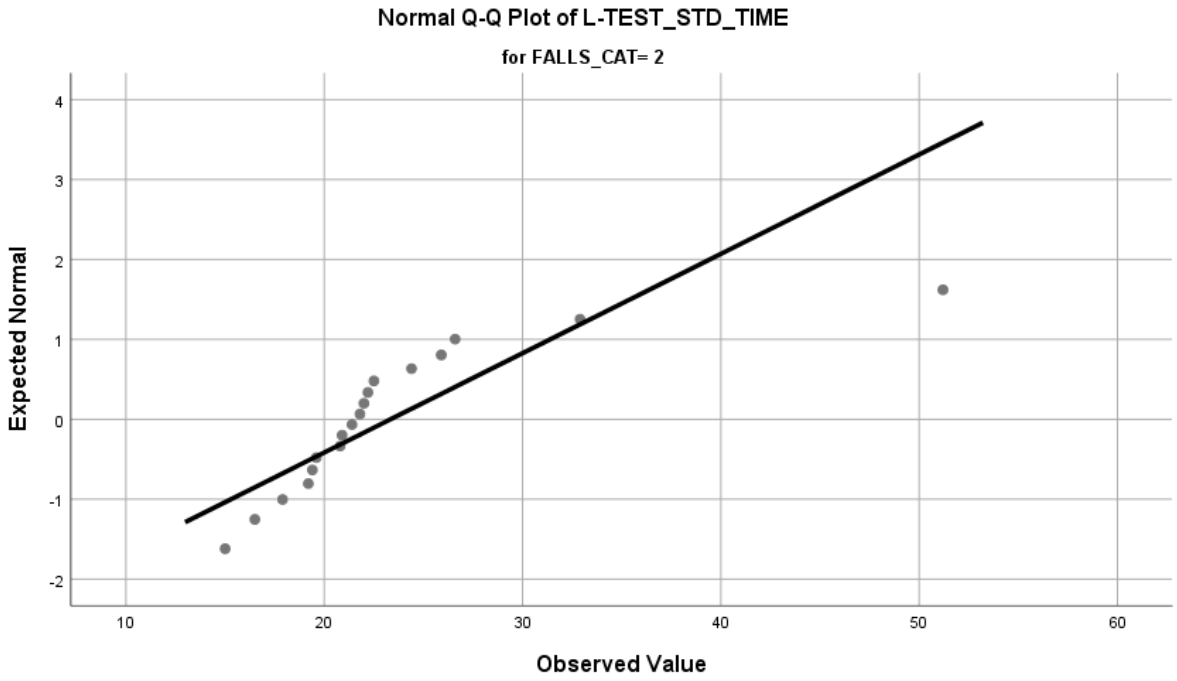
Histograms

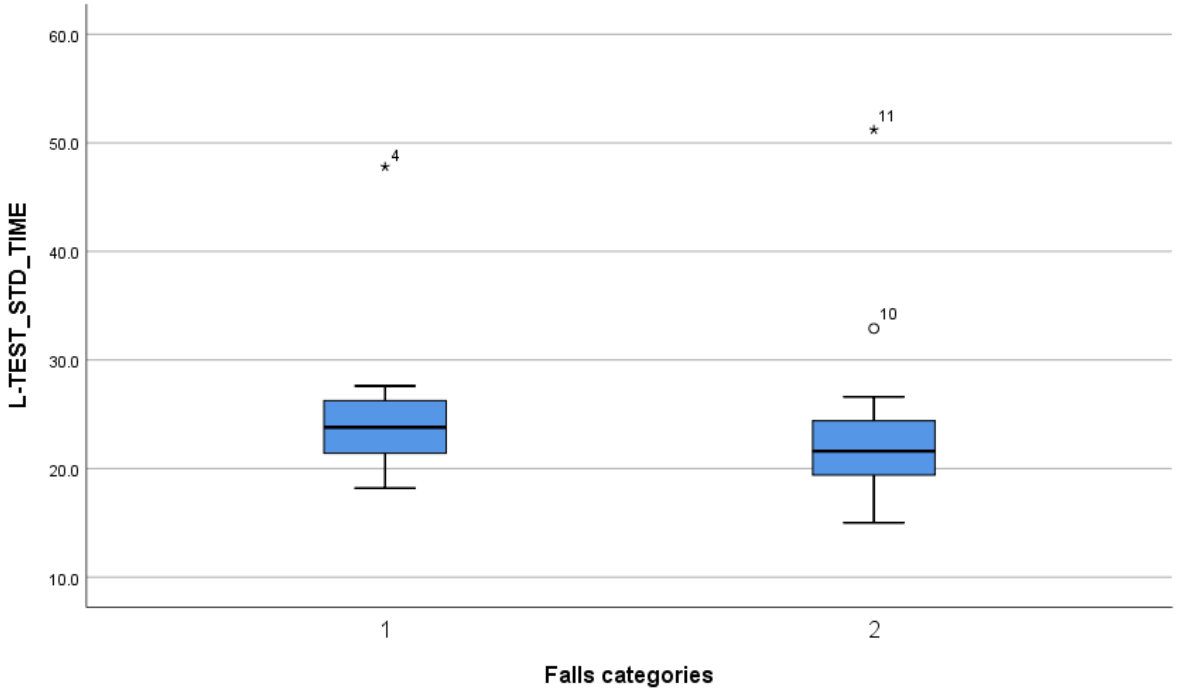




Normal Q-Q Plots

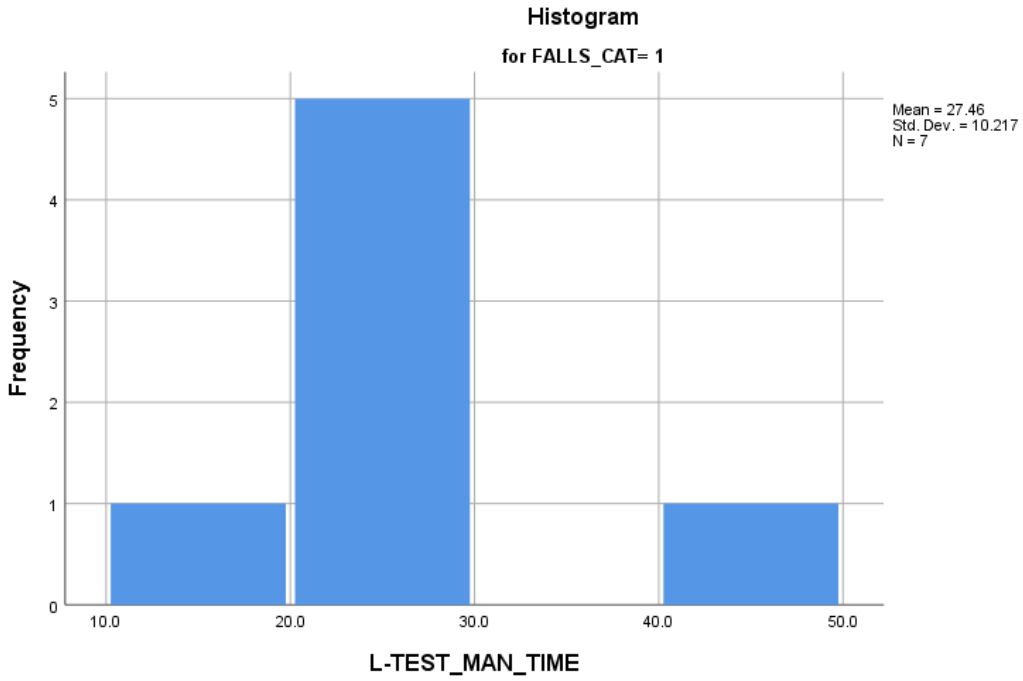


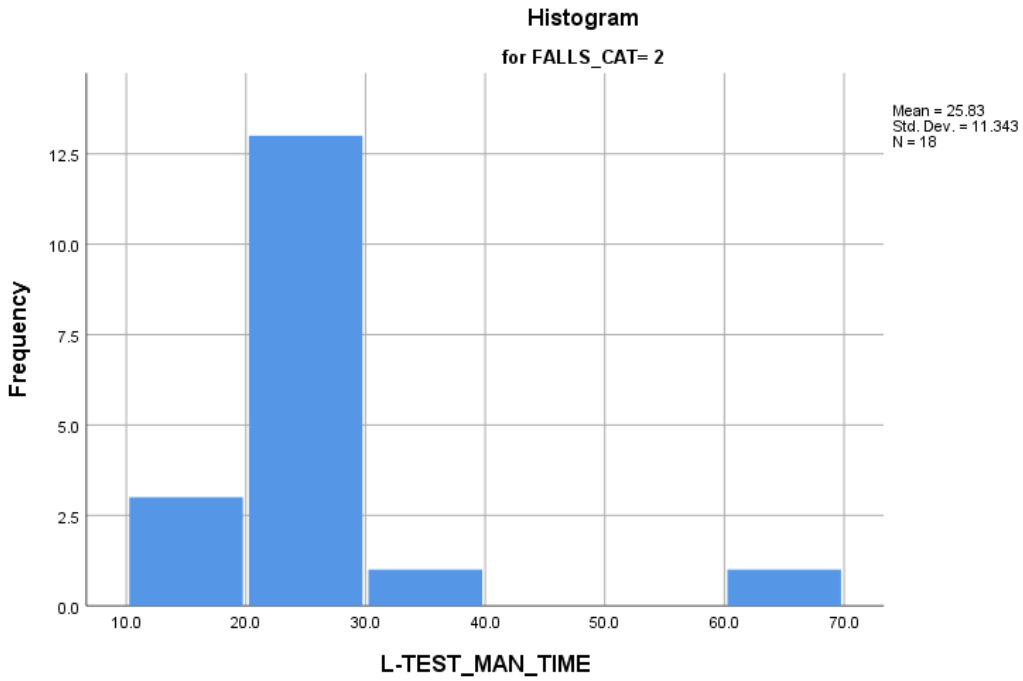




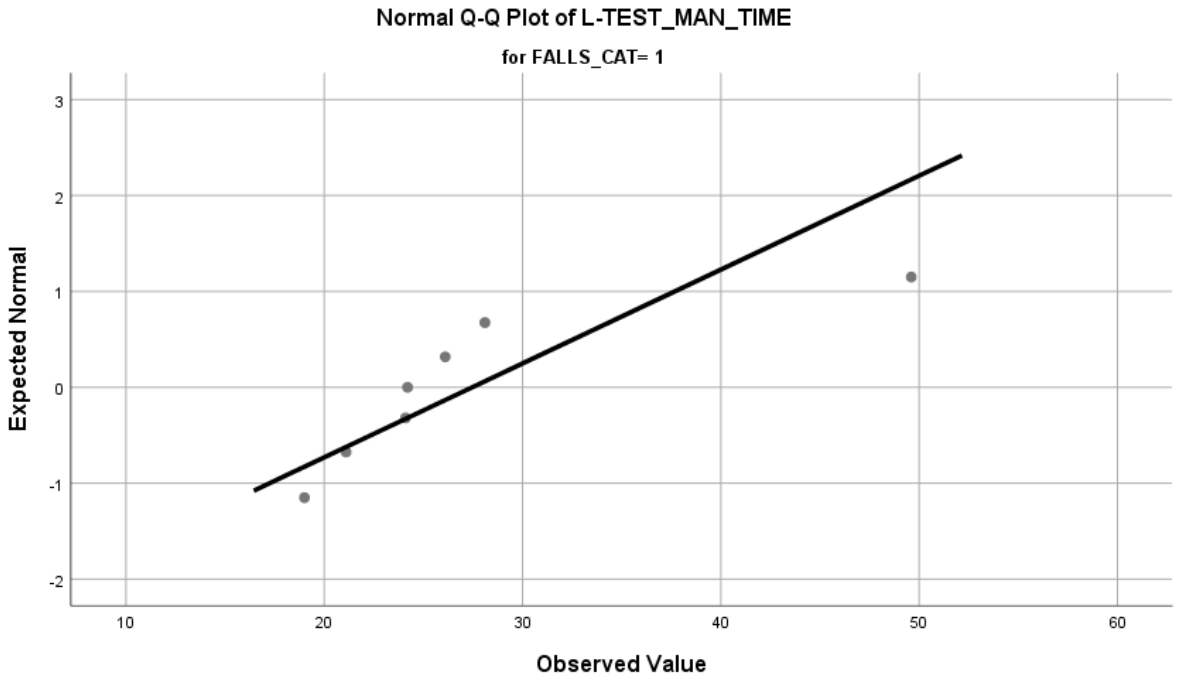
L-TEST_MAN_TIME

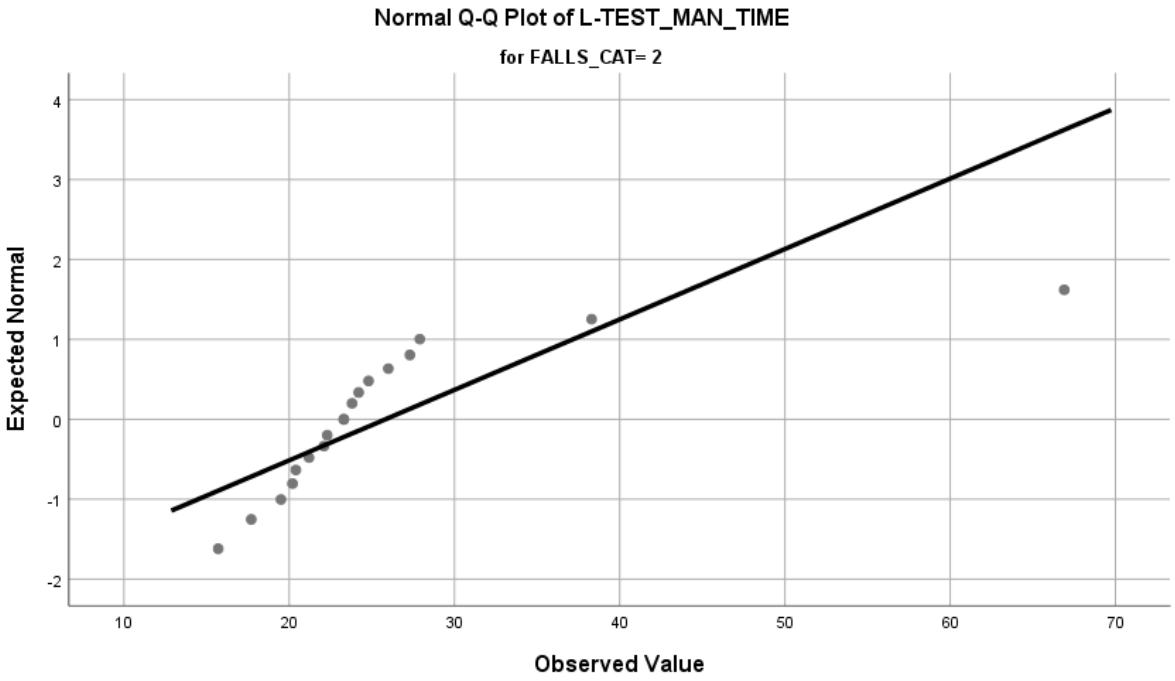
Histograms

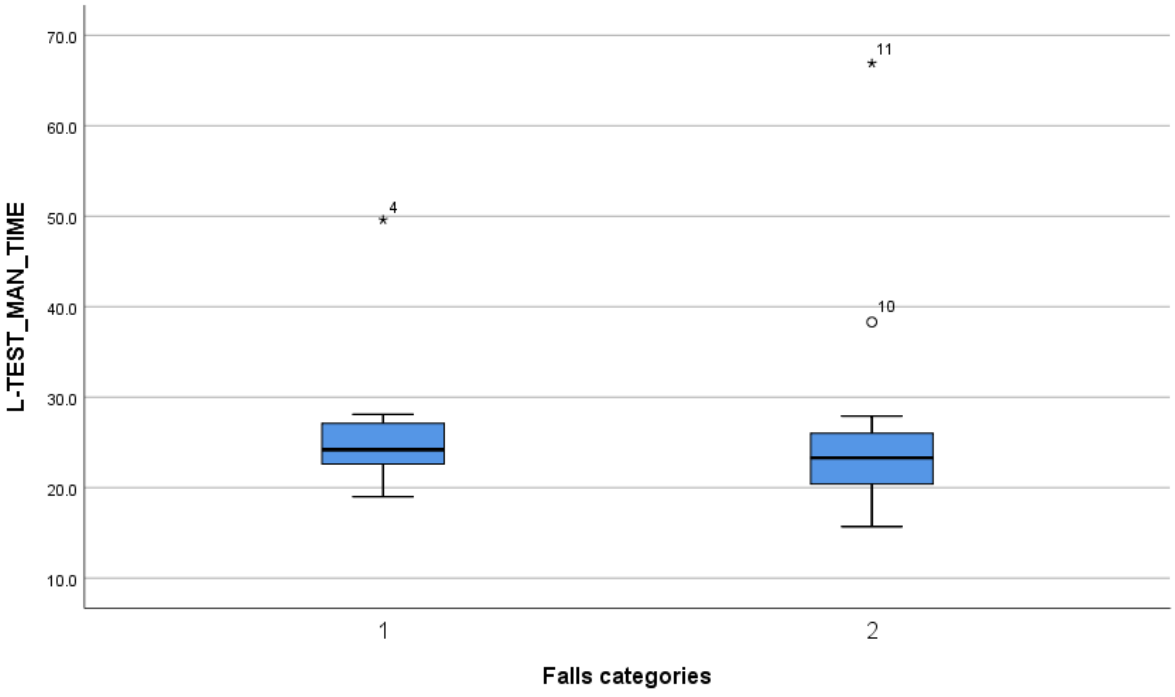




Normal Q-Q Plots

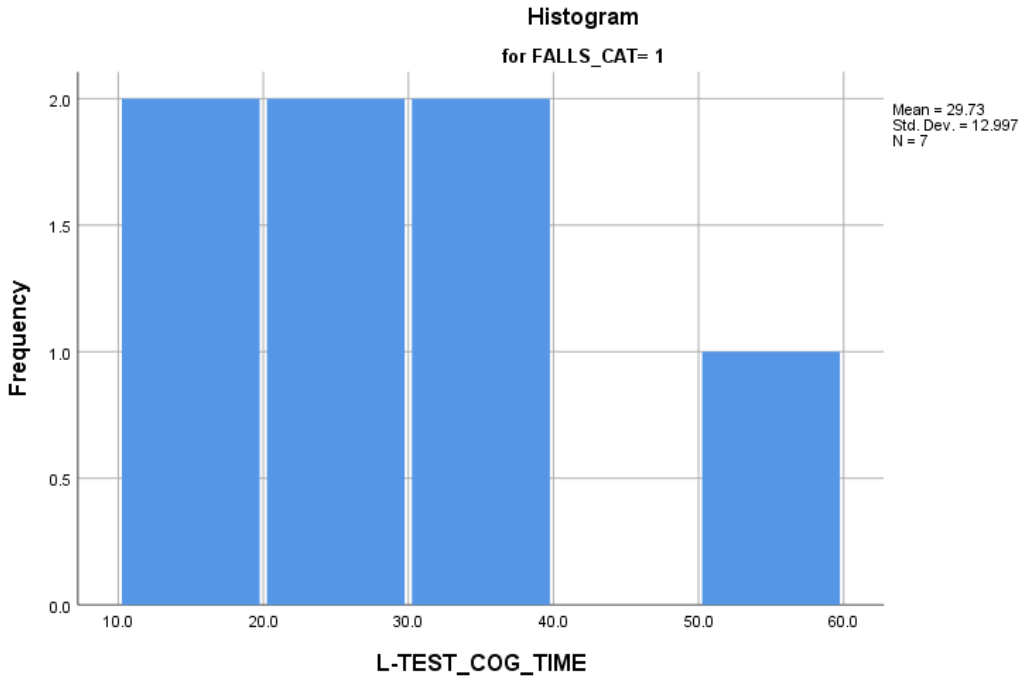


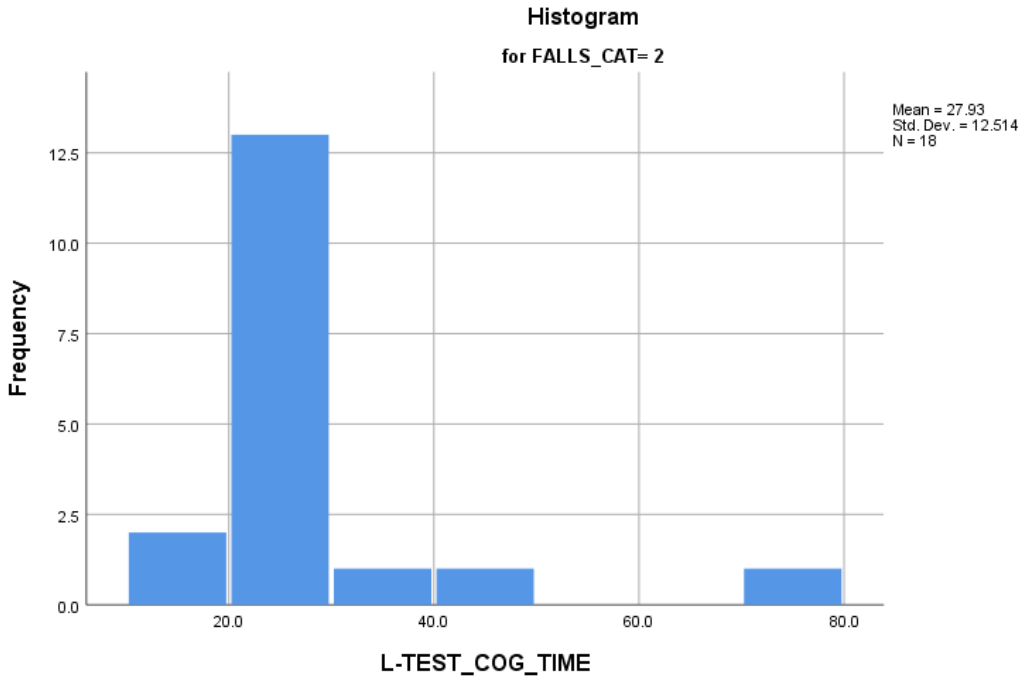

Normal Q-Q Plot of L-TEST_MAN_TIME
for FALLS_CAT= 2
Expected Normal
Observed Value
4
3
2
1
0
-1
-2
10
20
30
40
50
60
70


L-TEST_MAN_TIME
Falls categories
70.0
60.0
50.0
40.0
30.0
20.0
10.0
11
4
10
1
2

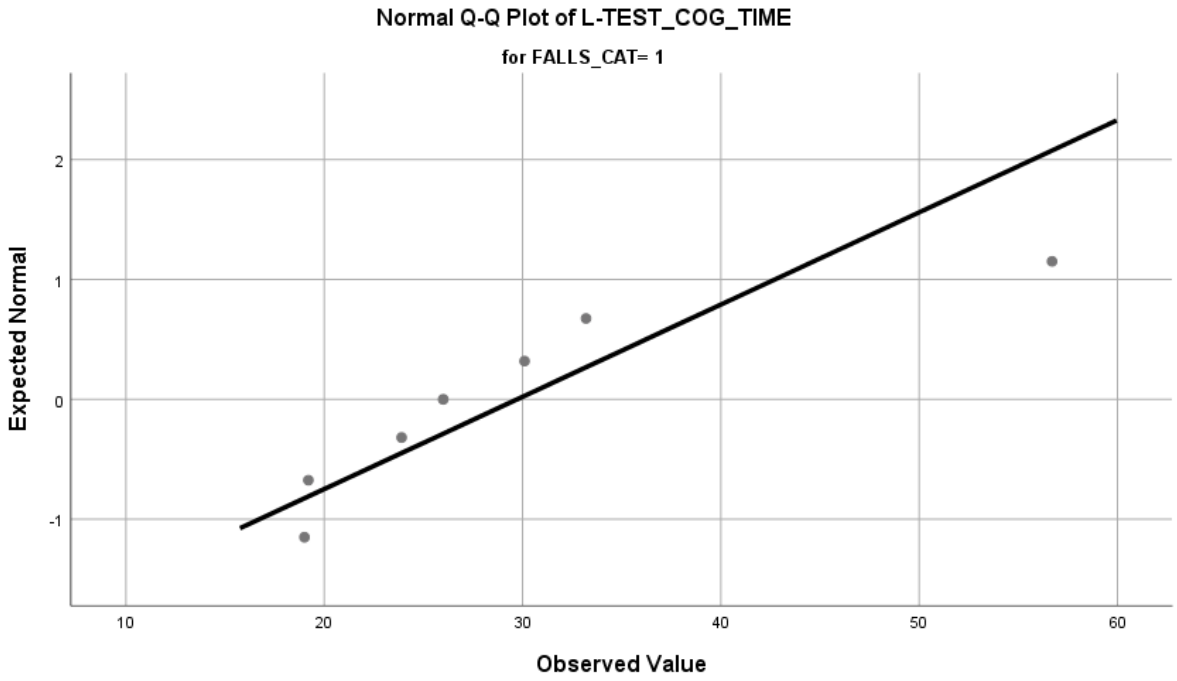
L-TEST_COG_TIME

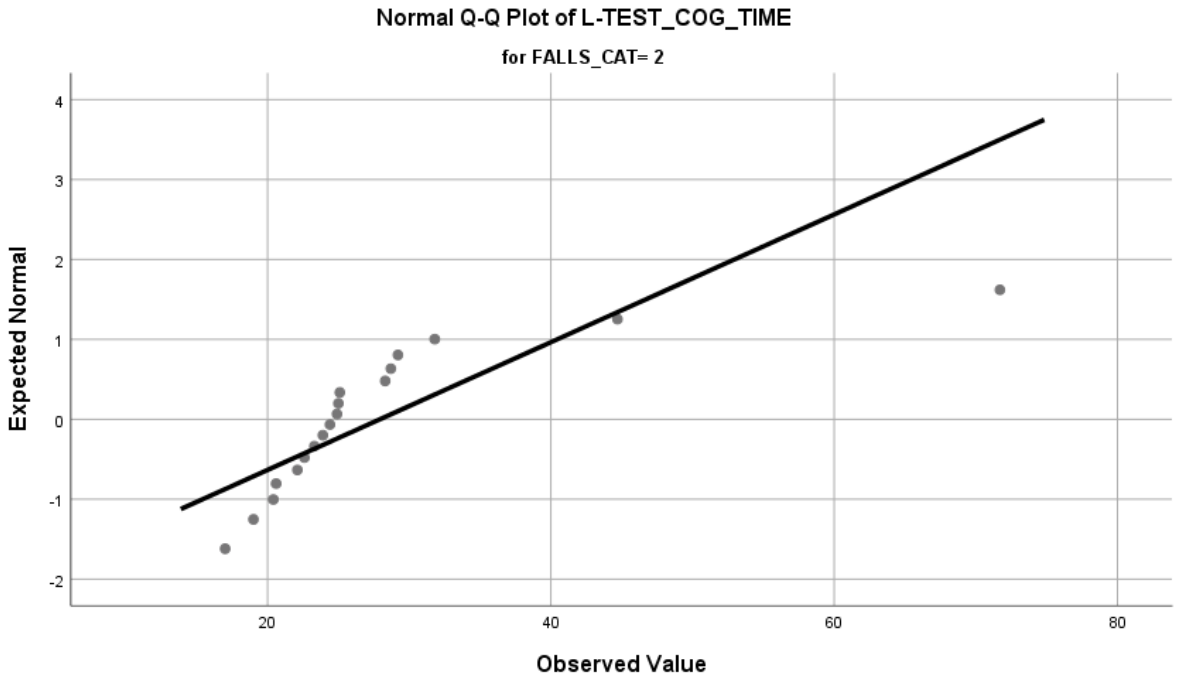
Histograms

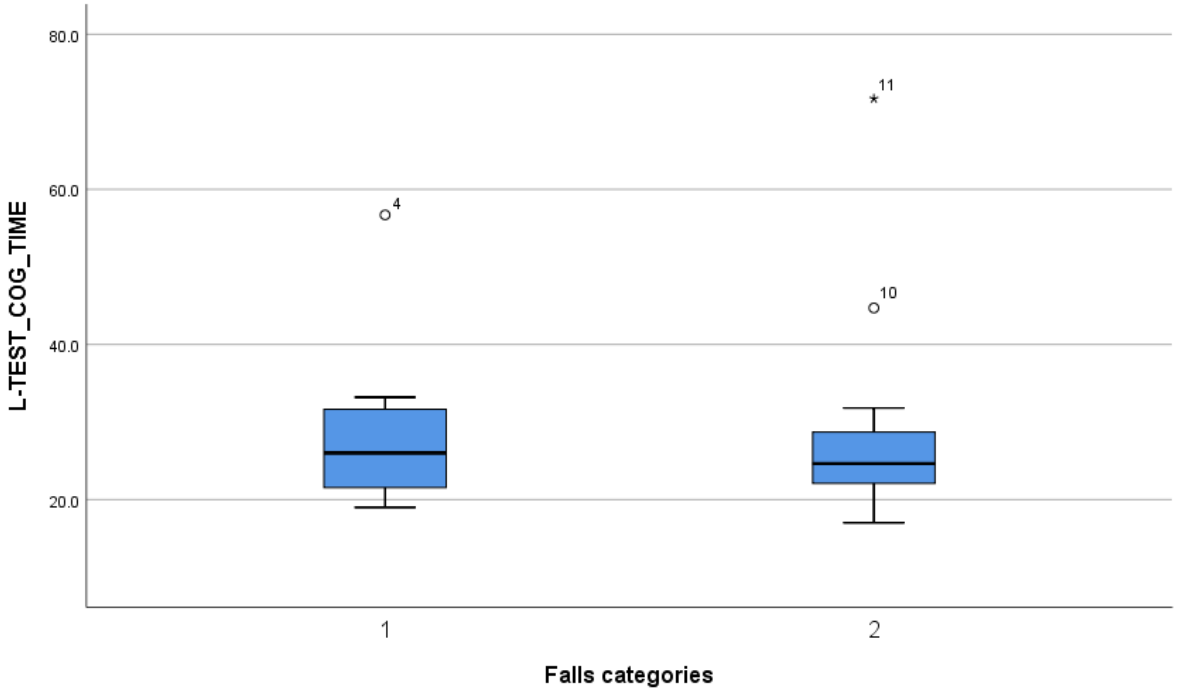




Normal Q-Q Plots






80.0
60.0
40.0
20.0
L-TEST_COG_TIME
11
4
10
1
2
Falls categories

```
CORRELATIONS
  /VARIABLES=TUG_STD_TIME LTEST_STD_TIME
  /PRINT=TWOTAIL NOSIG
  /STATISTICS DESCRIPTIVES
  /MISSING=PAIRWISE.
```

Correlations

Descriptive Statistics

	Mean	Std. Deviation	N
TUG_STD_TIME	10.112	3.4948	25
L-TEST_STD_TIME	24.212	8.5236	25

Correlations

		TUG_STD_TIME	L-TEST_STD_TIME
TUG_STD_TIME	Pearson Correlation	1	.970**
	Sig. (2-tailed)		.000
	N	25	25
L-TEST_STD_TIME	Pearson Correlation	.970**	1
	Sig. (2-tailed)	.000	
	N	25	25

**. Correlation is significant at the 0.01 level (2-tailed).

```
NONPAR CORR
  /VARIABLES=TUG_STD_TIME LTEST_STD_TIME
  /PRINT=SPEARMAN TWOTAIL NOSIG
  /MISSING=PAIRWISE.
```

Nonparametric Correlations

a. Based on availability of workspace memory

Correlations

			TUG_STD_TIME	L-TEST_STD_TIME
Spearman's rho	TUG_STD_TIME	Correlation Coefficient	1.000	.938**
		Sig. (2-tailed)	.	.000
		N	25	25
	L-TEST_STD_TIME	Correlation Coefficient	.938**	1.000
		Sig. (2-tailed)	.000	.
		N	25	25

**. Correlation is significant at the 0.01 level (2-tailed).

```
CORRELATIONS
  /VARIABLES=TUG_MAN_TIME LTEST_MAN_TIME
  /PRINT=TWOTAIL NOSIG
  /STATISTICS DESCRIPTIVES
  /MISSING=PAIRWISE.
```

Correlations

Descriptive Statistics

	Mean	Std. Deviation	N
TUG_MAN_TIME	11.084	4.5819	25
L-TEST_MAN_TIME	26.284	10.8530	25

Correlations

		TUG_MAN_TIME	L-TEST_MAN_TIME
TUG_MAN_TIME	Pearson Correlation	1	.984**
	Sig. (2-tailed)		.000
	N	25	25
L-TEST_MAN_TIME	Pearson Correlation	.984**	1
	Sig. (2-tailed)	.000	
	N	25	25

**. Correlation is significant at the 0.01 level (2-tailed).

```
NONPAR CORR
  /VARIABLES=TUG_MAN_TIME LTEST_MAN_TIME
  /PRINT=SPEARMAN TWOTAIL NOSIG
  /MISSING=PAIRWISE.
```

Nonparametric Correlations

a. Based on availability of workspace memory

Correlations

			TUG_MAN_TIME	L-TEST_MAN_TIME
Spearman's rho	TUG_MAN_TIME	Correlation Coefficient	1.000	.945**
		Sig. (2-tailed)	.	.000
		N	25	25
	L-TEST_MAN_TIME	Correlation Coefficient	.945**	1.000
		Sig. (2-tailed)	.000	.

N	25	25

**. Correlation is significant at the 0.01 level (2-tailed).

```
CORRELATIONS
  /VARIABLES=TUG_COG_TIME LTEST_COG_TIME
  /PRINT=TWOTAIL NOSIG
  /STATISTICS DESCRIPTIVES
  /MISSING=PAIRWISE.
```

Correlations

Descriptive Statistics

	Mean	Std. Deviation	N
TUG_COG_TIME	12.476	6.3370	25
L-TEST_COG_TIME	28.432	12.4032	25

Correlations

		TUG_COG_TIME	L-TEST_COG_TIME
TUG_COG_TIME	Pearson Correlation	1	.920**
	Sig. (2-tailed)		.000
	N	25	25
L-TEST_COG_TIME	Pearson Correlation	.920**	1
	Sig. (2-tailed)	.000	
	N	25	25

**. Correlation is significant at the 0.01 level (2-tailed).

```
NONPAR CORR
  /VARIABLES=TUG_COG_TIME LTEST_COG_TIME
  /PRINT=SPEARMAN TWOTAIL NOSIG
  /MISSING=PAIRWISE.
```

Nonparametric Correlations

a. Based on availability of workspace memory

Correlations

			TUG_COG_TIME	L-TEST_COG_TIME
Spearman's rho	TUG_COG_TIME	Correlation Coefficient	1.000	.926**
		Sig. (2-tailed)	.	.000
		N	25	25
	L-TEST_COG_TIME	Correlation Coefficient	.926**	1.000
		Sig. (2-tailed)	.000	.
		N	25	25

**. Correlation is significant at the 0.01 level (2-tailed).

```
RECODE FALLS (1 thru 4=1) (Lowest thru 0=2) INTO FALLS_CAT.
VARIABLE LABELS  FALLS_CAT 'Falls categories'.
EXECUTE.
DATASET ACTIVATE DataSet1.

SAVE OUTFILE='E:\n=25 final sample 15th March.sav'
  /COMPRESSED.
NPAR TESTS
  /M-W= TUG_STD_TIME TUG_MAN_TIME TUG_COG_TIME BY FALLS_CAT(1 2)
```

/MISSING ANALYSIS.

NPar Tests

a. Based on availability of workspace memory.

Mann-Whitney Test

Ranks

	Falls categories	N	Mean Rank	Sum of Ranks
TUG_STD_TIME	1	7	15.86	111.00
	2	18	11.89	214.00
	Total	25		
TUG_MAN_TIME	1	7	14.57	102.00
	2	18	12.39	223.00
	Total	25		
TUG_COG_TIME	1	7	14.79	103.50
	2	18	12.31	221.50
	Total	25		

Test Statistics[a]

	TUG_STD_TIME	TUG_MAN_TIME	TUG_COG_TIME
Mann-Whitney U	43.000	52.000	50.500
Wilcoxon W	214.000	223.000	221.500
Z	-1.210	-.666	-.757
Asymp. Sig. (2-tailed)	.226	.505	.449
Exact Sig. [2*(1-tailed Sig.)]	.244[b]	.534[b]	.458[b]

a. Grouping Variable: Falls categories

b. Not corrected for ties.

*Nonparametric Tests: Independent Samples.

NPTESTS

/INDEPENDENT TEST (TUG_STD_TIME TUG_MAN_TIME TUG_COG_TIME LTEST_STD_TIME LTEST_MAN_TIME LTEST_COG_TIME) GROUP (FALLS_CAT) MANN_WHITNEY

/MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE

/CRITERIA ALPHA=0.05 CILEVEL=95.

Nonparametric Tests

null : null

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of TUG_STD_TIME is the same across categories of Falls categories.	Independent-Samples Mann-Whitney U Test	.244[1]	Retain the null hypothesis.
2	The distribution of TUG_MAN_TIME is the same across categories of Falls categories.	Independent-Samples Mann-Whitney U Test	.534[1]	Retain the null hypothesis.
3	The distribution of TUG_COG_TIME is the same across categories of Falls categories.	Independent-Samples Mann-Whitney U Test	.458[1]	Retain the null hypothesis.
4	The distribution of L-TEST_STD_TIME is the same across categories of Falls categories.	Independent-Samples Mann-Whitney U Test	.326[1]	Retain the null hypothesis.
5	The distribution of L-TEST_MAN_TIME is the same across categories of Falls categories.	Independent-Samples Mann-Whitney U Test	.423[1]	Retain the null hypothesis.
6	The distribution of L-TEST_COG_TIME is the same across categories of Falls categories.	Independent-Samples Mann-Whitney U Test	.657[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

```
MEANS TABLES=TUG_STD_TIME TUG_MAN_TIME TUG_COG_TIME LTEST_STD_TIME
LTEST_MAN_TIME LTEST_COG_TIME BY
  FALLS_CAT
 /CELLS=COUNT MEDIAN.
```

Means

Case Processing Summary

	Cases					
	Included		Excluded		Total	
	N	Percent	N	Percent	N	Percent
TUG_STD_TIME * Falls categories	25	100.0%	0	0.0%	25	100.0%
TUG_MAN_TIME * Falls categories	25	100.0%	0	0.0%	25	100.0%
TUG_COG_TIME * Falls categories	25	100.0%	0	0.0%	25	100.0%
L-TEST_STD_TIME * Falls categories	25	100.0%	0	0.0%	25	100.0%
L-TEST_MAN_TIME * Falls categories	25	100.0%	0	0.0%	25	100.0%
L-TEST_COG_TIME * Falls categories	25	100.0%	0	0.0%	25	100.0%

Report

Falls categories		TUG_STD_TIME	TUG_MAN_TIME	TUG_COG_TIME	L-TEST_STD_TIME	L-TEST_MAN_TIME
1	N	7	7	7	7	7
	Median	9.600	10.600	11.900	23.800	24.200
2	N	18	18	18	18	18
	Median	8.900	9.350	9.700	21.600	23.300

Total	N	25	25	25	25	25
	Median	9.300	9.600	10.000	22.000	23.800

Report

Falls categories		L-TEST_COG_TIME
1	N	7
	Median	26.000
2	N	18
	Median	24.650
Total	N	25
	Median	24.900

```
GET
  FILE='E:\n=25 final sample 15th March.sav'.
DATASET NAME DataSet1 WINDOW=FRONT.
T-TEST GROUPS=Faller_nonfaller(1 0)
  /MISSING=ANALYSIS
  /VARIABLES=LTEST_COG_DTC
  /CRITERIA=CI(.95).
```

T-Test

[DataSet1] E:\n=25 final sample 15th March.sav

Group Statistics

	Falls categories	N	Mean	Std. Deviation	Std. Error Mean
L-TEST_COG_DTC	1	7	12.529	13.8411	5.2314
	0	18	18.078	15.3579	3.6199

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means
		F	Sig.	t
L-TEST_COG_DTC	Equal variances assumed	.840	.369	-.832
	Equal variances not assumed			-.872

Independent Samples Test

		t-test for Equality of Means		
		df	Sig. (2-tailed)	Mean Difference
L-TEST_COG_DTC	Equal variances assumed	23	.414	-5.5492
	Equal variances not assumed	12.139	.400	-5.5492

Independent Samples Test

		t-test for Equality of Means		
		Std. Error Difference	95% Confidence Interval of the Difference	
			Lower	Upper
L-TEST_COG_DTC	Equal variances assumed	6.6713	-19.3499	8.2515
	Equal variances not assumed	6.3617	-19.3927	8.2943

```
T-TEST GROUPS=Faller_nonfaller(1 0)
 /MISSING=ANALYSIS
 /VARIABLES=TUG_MAN_DTC
 /CRITERIA=CI(.95).
```

T-Test

Group Statistics

	Falls categories	N	Mean	Std. Deviation	Std. Error Mean
TUG_MAN_DTC	1	7	5.014	7.9836	3.0175
	0	18	10.811	9.3427	2.2021

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means	
		F	Sig.	t	df
TUG_MAN_DTC	Equal variances assumed	.198	.661	-1.445	23
	Equal variances not assumed			-1.552	12.810

Independent Samples Test

		t-test for Equality of Means		
		Sig. (2-tailed)	Mean Difference	Std. Error Difference
TUG_MAN_DTC	Equal variances assumed	.162	-5.7968	4.0125
	Equal variances not assumed	.145	-5.7968	3.7356

Independent Samples Test

		t-test for Equality of Means	
		95% Confidence Interval of the Difference	
		Lower	Upper
TUG_MAN_DTC	Equal variances assumed	-14.0973	2.5036
	Equal variances not assumed	-13.8793	2.2856

*Nonparametric Tests: Independent Samples.

NPTESTS

/INDEPENDENT TEST (LTEST_MAN_DTC) GROUP (Faller_nonfaller) MANN_WHITNEY

/MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE

/CRITERIA ALPHA=0.05 CILEVEL=95.

Nonparametric Tests

null : null

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of L-TEST_MAN_DTC is the same across categories of Falls categories.	Independent-Samples Mann-Whitney U Test	.141[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05

[1]Exact significance is displayed for this test.

*Nonparametric Tests: Independent Samples.

NPTESTS

/INDEPENDENT TEST (TUG_COG_DTC) GROUP (Faller_nonfaller) MANN_WHITNEY

/MISSING SCOPE=ANALYSIS USERMISSING=EXCLUDE

/CRITERIA ALPHA=0.05 CILEVEL=95.

Nonparametric Tests

null : null

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of TUG_COG_DTC is the same across categories of Falls categories.	Independent-Samples Mann-Whitney U Test	.790[1]	Retain the null hypothesis.

Asymptotic significances are displayed. The significance level is .05.

[1]Exact significance is displayed for this test.

```
EXAMINE VARIABLES=TUG_COG_DTC LTEST_COG_DTC BY Falls_faller_nonfaller
  /PLOT BOXPLOT HISTOGRAM NPPLOT
  /COMPARE GROUPS
  /STATISTICS DESCRIPTIVES EXTREME
  /CINTERVAL 95
  /MISSING LISTWISE
  /NOTOTAL.
```

Explore

Falls yes no

Case Processing Summary

		Cases				
		Valid		Missing		Total
	Falls yes no	N	Percent	N	Percent	N
TUG_COG_DTC	0	18	100.0%	0	0.0%	18
	1	7	100.0%	0	0.0%	7
L-TEST_COG_DTC	0	18	100.0%	0	0.0%	18
	1	7	100.0%	0	0.0%	7

Case Processing Summary

		Cases
		Total
	Falls yes no	Percent
TUG_COG_DTC	0	100.0%
	1	100.0%
L-TEST_COG_DTC	0	100.0%
	1	100.0%

Descriptives

	Falls yes no			Statistic	Std. Error
TUG_COG_DTC	0	Mean		84.811	3.0879
		95% Confidence Interval for Mean	Lower Bound	78.296	
			Upper Bound	91.326	
		5% Trimmed Mean		85.901	
		Median		89.150	
		Variance		171.628	
		Std. Deviation		13.1007	
		Minimum		51.1	
		Maximum		98.9	
		Range		47.8	
		Interquartile Range		22.2	
		Skewness		-1.043	.536
		Kurtosis		.850	1.038
	1	Mean		87.743	4.9928
		95% Confidence Interval for Mean	Lower Bound	75.526	
			Upper Bound	99.960	
		5% Trimmed Mean		87.664	
		Median		91.000	
		Variance		174.500	
		Std. Deviation		13.2098	
		Minimum		68.8	
		Maximum		108.1	
		Range		39.3	
		Interquartile Range		17.6	
		Skewness		.071	.794
		Kurtosis		-.489	1.587

L-TEST_COG_DTC	0	Mean		85.944	2.4379
		95% Confidence Interval for Mean	Lower Bound	80.801	
			Upper Bound	91.088	
		5% Trimmed Mean		86.249	
		Median		89.950	
		Variance		106.983	
		Std. Deviation		10.3432	
		Minimum		66.4	
		Maximum		100.0	
		Range		33.6	
		Interquartile Range		19.0	
		Skewness		-.575	.536
		Kurtosis		-1.069	1.038
	1	Mean		91.257	4.1996
		95% Confidence Interval for Mean	Lower Bound	80.981	
			Upper Bound	101.533	
		5% Trimmed Mean		91.675	
		Median		91.700	
		Variance		123.456	
		Std. Deviation		11.1111	
		Minimum		70.8	
		Maximum		104.2	
		Range		33.4	
		Interquartile Range		16.2	
		Skewness		-.994	.794
		Kurtosis		1.130	1.587

Extreme Values[a]

	Falls yes no			Case Number	Value
TUG_COG_DTC	0	Highest	1	23	98.9
			2	21	98.5
			3	15	96.7
			4	2	96.5
			5	5	96.2
		Lowest	1	10	51.1
			2	11	69.0
			3	3	71.2
			4	24	73.7
			5	17	74.2
	1	Highest	1	16	108.1
			2	18	95.0
			3	13	94.1
		Lowest	1	1	68.8
			2	4	77.4
			3	6	79.8
L-TEST_COG_DTC	0	Highest	1	22	100.0
			2	21	97.0
			3	15	95.3
			4	7	95.1
			5	2	94.1
		Lowest	1	19	66.4
			2	11	71.4
			3	9	71.6
			4	10	73.6
			5	17	75.9

	1	Highest	1	13	104.2
			2	16	100.5
			3	18	95.8
		Lowest	1	1	70.8
			2	4	84.3
			3	6	91.5

a. The requested number of extreme values exceeds the number of data points. A smaller number of extremes is displayed.

Tests of Normality

		Kolmogorov-Smirnov[a]			Shapiro-Wilk	
	Falls yes no	Statistic	df	Sig.	Statistic	df
TUG_COG_DTC	0	.161	18	.200*	.892	18
	1	.169	7	.200*	.968	7
L-TEST_COG_DTC	0	.190	18	.085	.908	18
	1	.223	7	.200*	.936	7

Tests of Normality

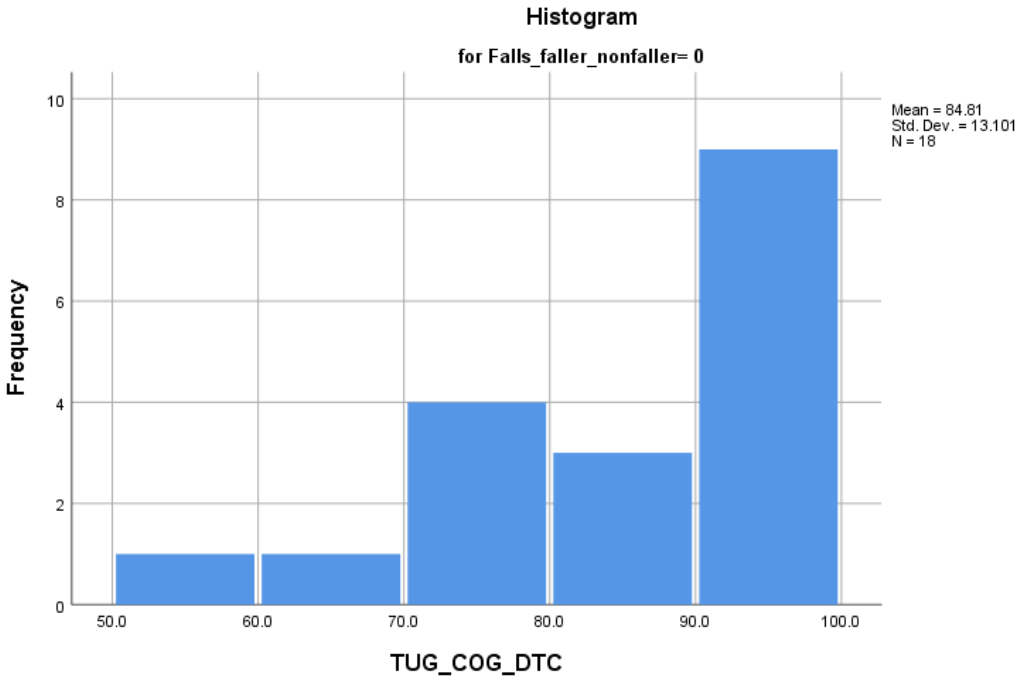
		Shapiro-Wilk[a]
	Falls yes no	Sig.
TUG_COG_DTC	0	.041
	1	.885
L-TEST_COG_DTC	0	.078
	1	.601

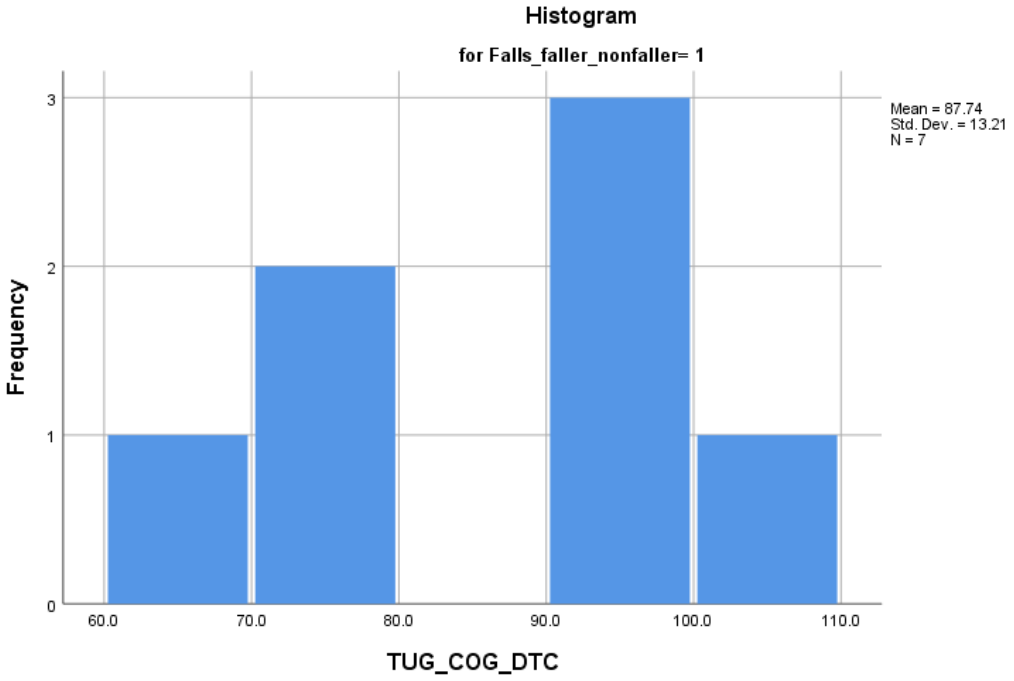
*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

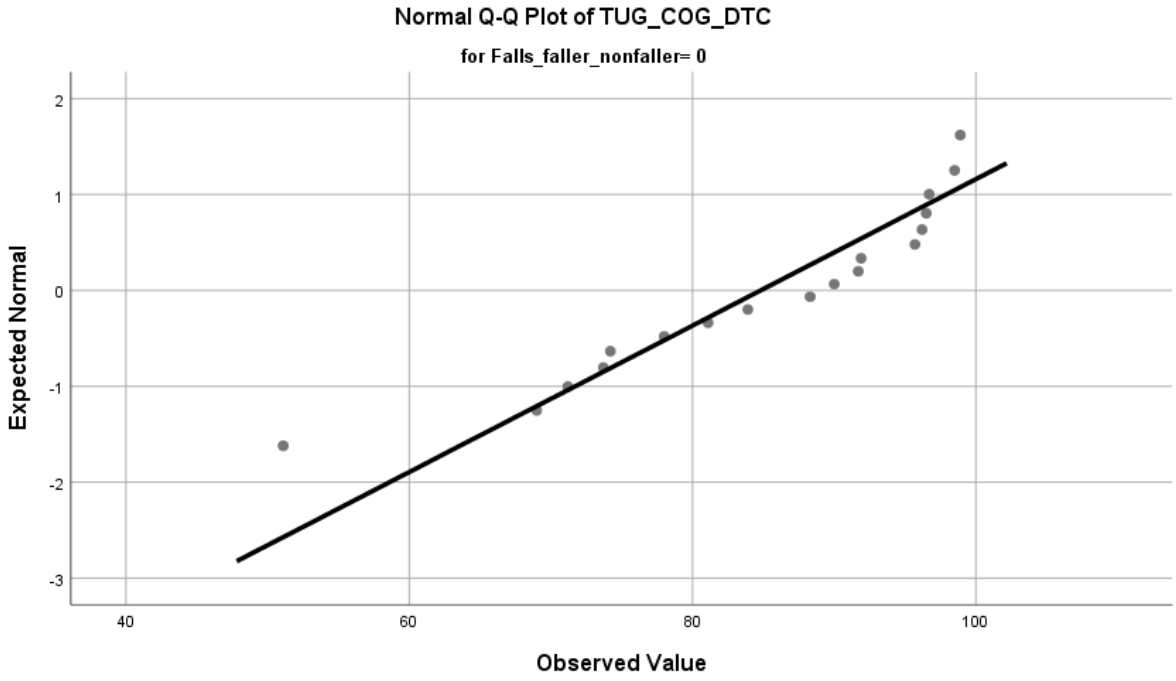
TUG_COG_DTC

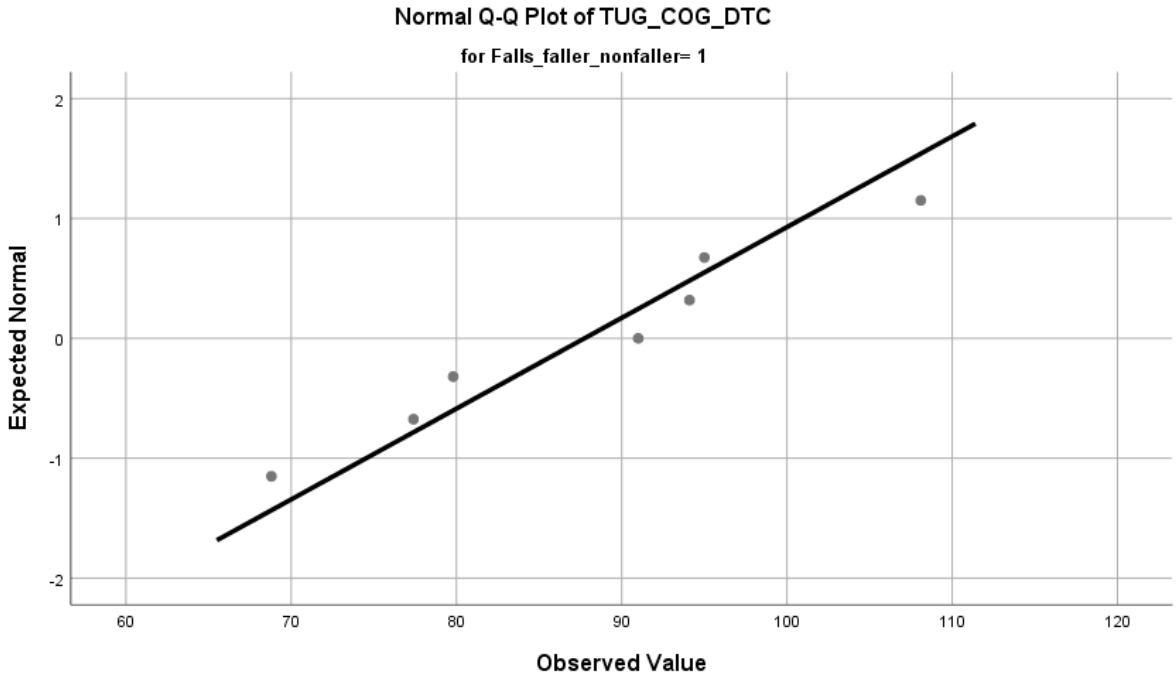
Histograms

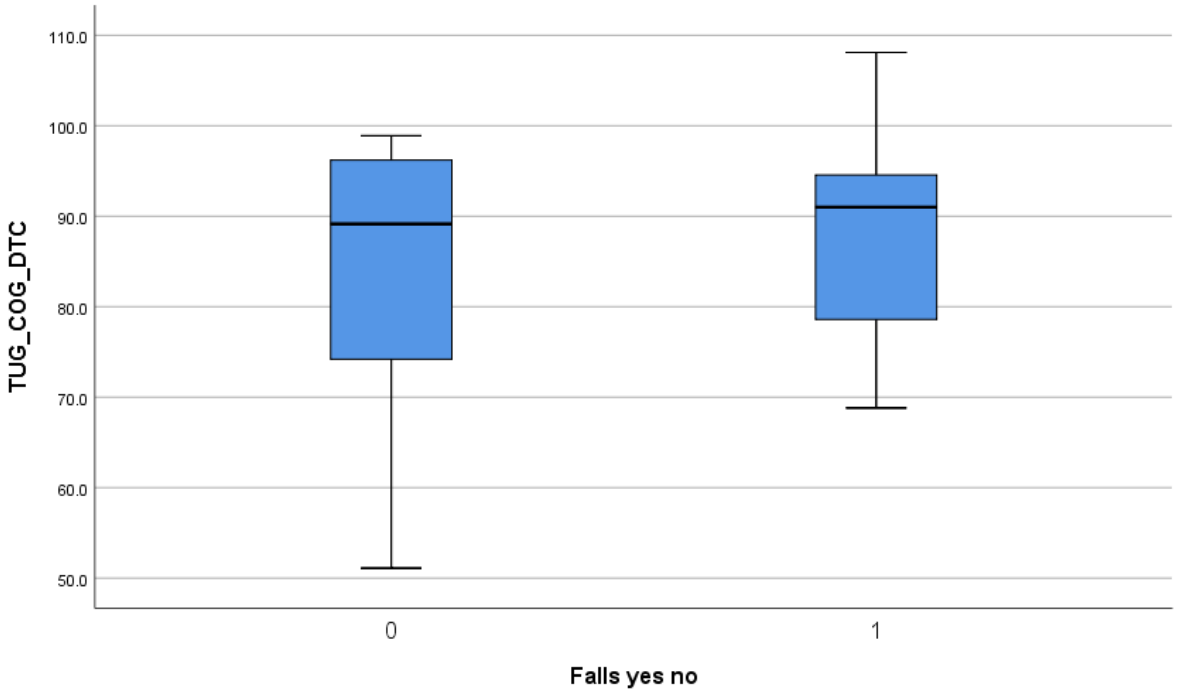




Normal Q-Q Plots






110.0
100.0
90.0
80.0
70.0
60.0
50.0
TUG_COG_DTC
0
1
Falls yes no

```
EXAMINE VARIABLES=TUG_MAN_DTC LTEST_MAN_DTC BY Falls_faller_nonfaller
  /PLOT BOXPLOT HISTOGRAM NPPLOT
  /COMPARE GROUPS
  /STATISTICS DESCRIPTIVES EXTREME
  /CINTERVAL 95
  /MISSING LISTWISE
  /NOTOTAL.
```

Explore

Falls yes no

Case Processing Summary

		Cases				
		Valid		Missing		Total
	Falls yes no	N	Percent	N	Percent	N
TUG_MAN_DTC	0	18	100.0%	0	0.0%	18
	1	7	100.0%	0	0.0%	7
L-TEST_MAN_DTC	0	18	100.0%	0	0.0%	18
	1	7	100.0%	0	0.0%	7

Case Processing Summary

		Cases
		Total
	Falls yes no	Percent
TUG_MAN_DTC	0	100.0%
	1	100.0%
L-TEST_MAN_DTC	0	100.0%
	1	100.0%

Descriptives

	Falls yes no			Statistic	Std. Error
TUG_MAN_DTC	0	Mean		90.822	1.7259
		95% Confidence Interval for Mean	Lower Bound	87.181	
			Upper Bound	94.464	
		5% Trimmed Mean		90.997	
		Median		91.200	
		Variance		53.616	
		Std. Deviation		7.3223	
		Minimum		73.5	
		Maximum		105.0	
		Range		31.5	
		Interquartile Range		9.9	
		Skewness		-.374	.536
		Kurtosis		.717	1.038
	1	Mean		97.114	2.6765
		95% Confidence Interval for Mean	Lower Bound	90.565	
			Upper Bound	103.663	
		5% Trimmed Mean		97.144	
		Median		98.700	
		Variance		50.145	
		Std. Deviation		7.0813	
		Minimum		85.6	
		Maximum		108.1	
		Range		22.5	
		Interquartile Range		7.9	
		Skewness		-.184	.794
		Kurtosis		.712	1.587

L-TEST_MAN_DTC	0	Mean		92.161	1.6694
		95% Confidence Interval for Mean	Lower Bound	88.639	
			Upper Bound	95.683	
		5% Trimmed Mean		92.462	
		Median		94.350	
		Variance		50.163	
		Std. Deviation		7.0826	
		Minimum		76.5	
		Maximum		102.4	
		Range		25.9	
		Interquartile Range		7.4	
		Skewness		-1.015	.536
		Kurtosis		.336	1.038
	1	Mean		96.286	2.3218
		95% Confidence Interval for Mean	Lower Bound	90.605	
			Upper Bound	101.967	
		5% Trimmed Mean		96.456	
		Median		98.200	
		Variance		37.735	
		Std. Deviation		6.1429	
		Minimum		86.2	
		Maximum		103.3	
		Range		17.1	
		Interquartile Range		11.6	
		Skewness		-.769	.794
		Kurtosis		-.433	1.587

Extreme Values[a]

	Falls yes no			Case Number	Value
TUG_MAN_DTC	0	Highest	1	20	105.0
			2	2	98.8
			3	15	97.8
			4	17	97.0
			5	21	95.8
		Lowest	1	11	73.5
			2	9	82.0
			3	19	84.8
			4	10	85.6
			5	3	86.4
	1	Highest	1	16	108.1
			2	1	100.0
			3	13	100.0
		Lowest	1	6	85.6
			2	4	92.1
			3	14	95.3
L-TEST_MAN_DTC	0	Highest	1	8	102.4
			2	12	99.5
			3	2	98.1
			4	7	97.0
			5	25	96.9
		Lowest	1	11	76.5
			2	19	80.2
			3	9	80.3
			4	10	85.9
			5	5	90.7

	1	Highest	1	13	103.3
			2	16	101.6
			3	6	98.3
		Lowest	1	18	86.2
			2	1	90.0
			3	4	96.4

a. The requested number of extreme values exceeds the number of data points. A smaller number of extremes is displayed.

Tests of Normality

		Kolmogorov-Smirnov[a]			Shapiro-Wilk	
	Falls yes no	Statistic	df	Sig.	Statistic	df
TUG_MAN_DTC	0	.094	18	.200*	.977	18
	1	.199	7	.200*	.969	7
L-TEST_MAN_DTC	0	.196	18	.066	.893	18
	1	.222	7	.200*	.921	7

Tests of Normality

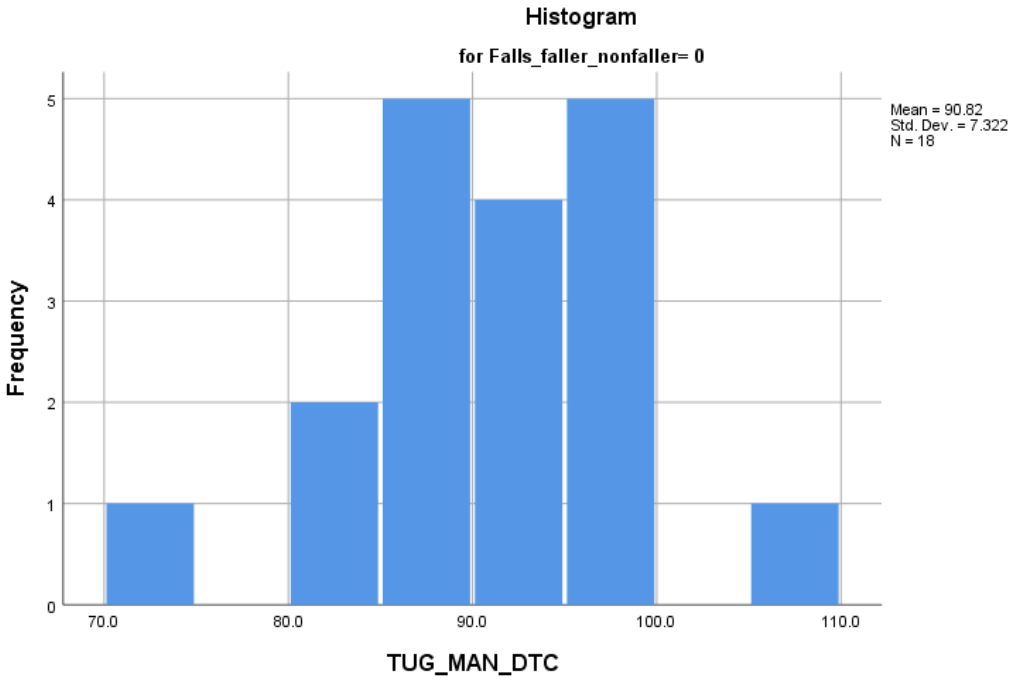
		Shapiro-Wilk[a]
	Falls yes no	Sig.
TUG_MAN_DTC	0	.913
	1	.893
L-TEST_MAN_DTC	0	.043
	1	.475

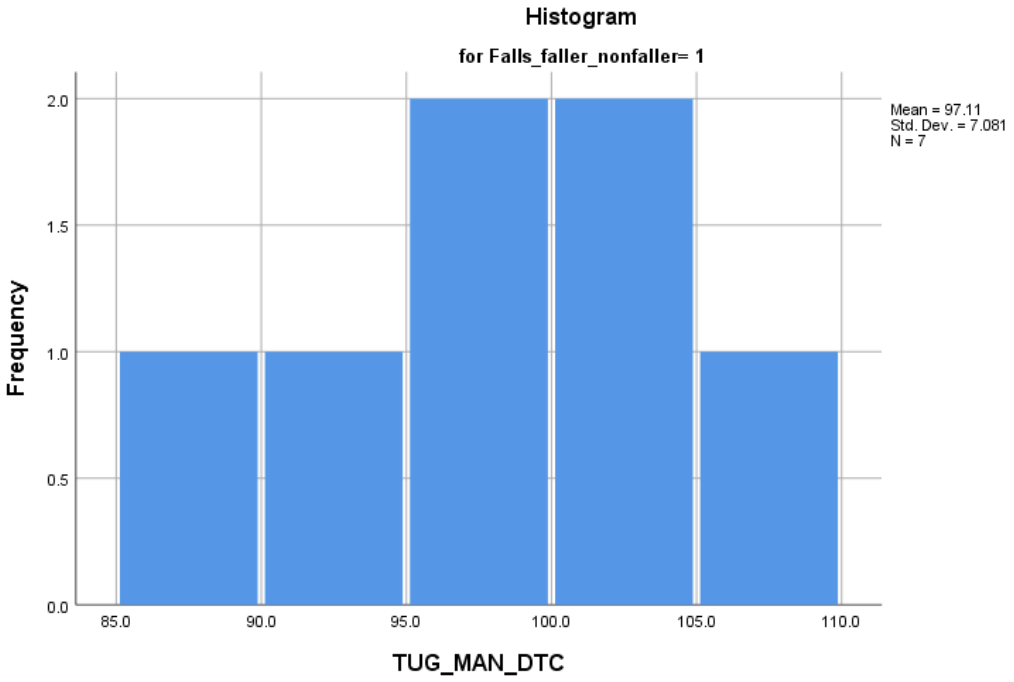
*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

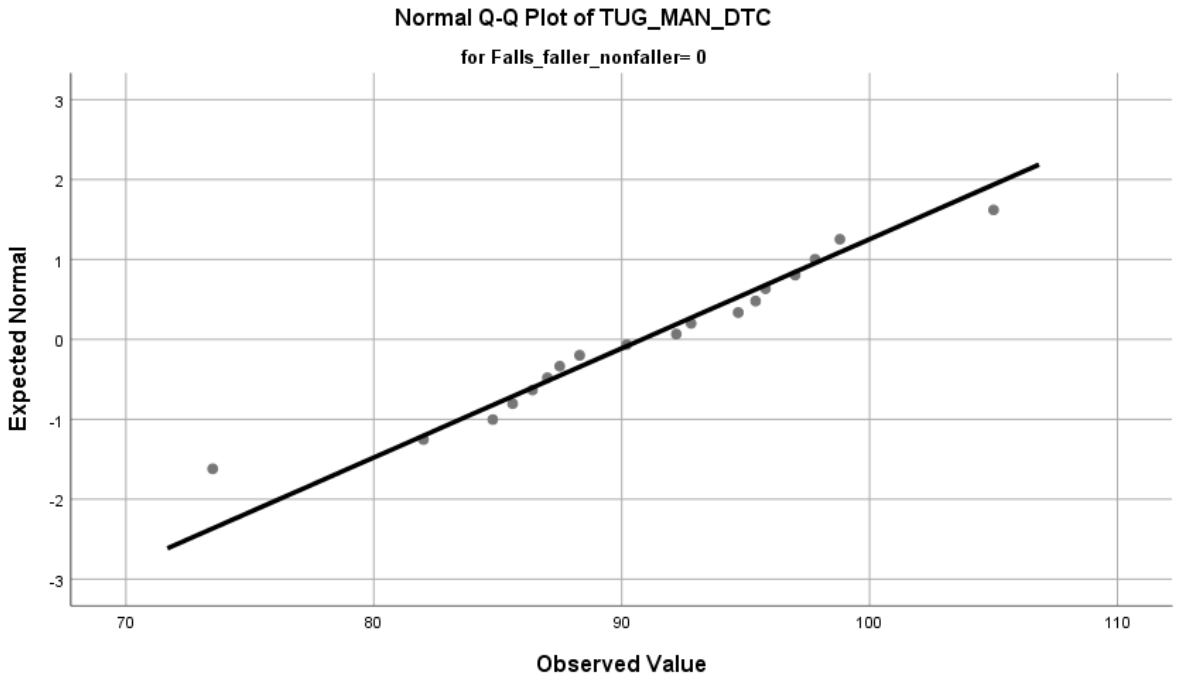
TUG_MAN_DTC

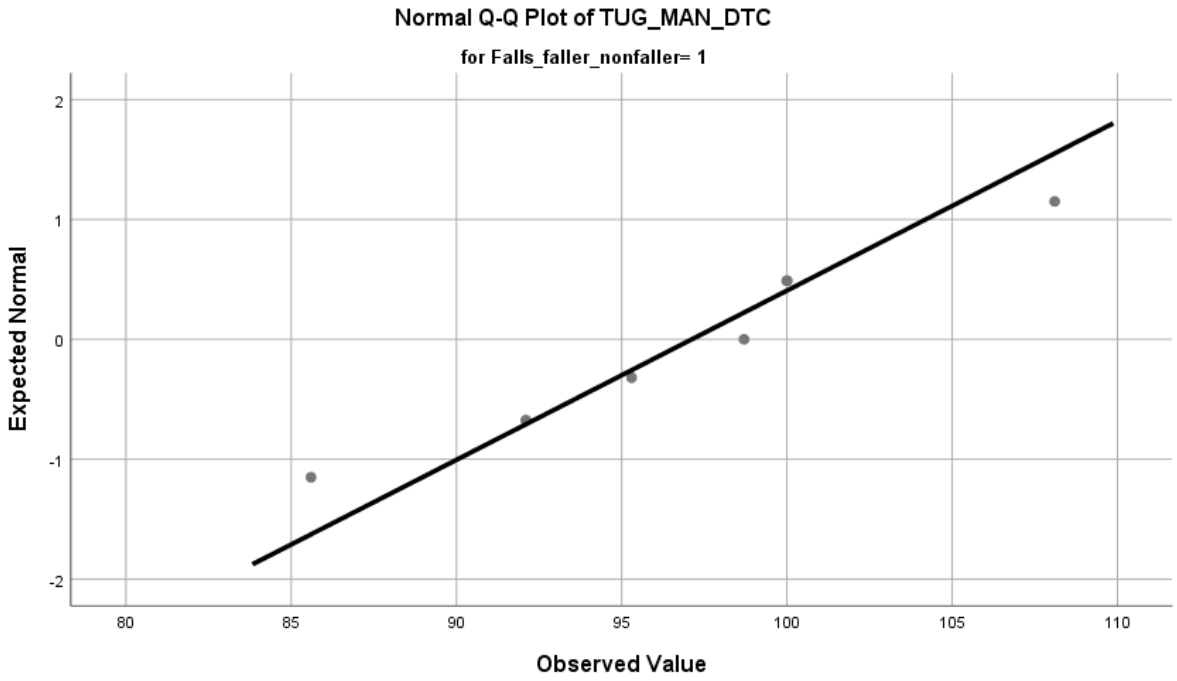
Histograms

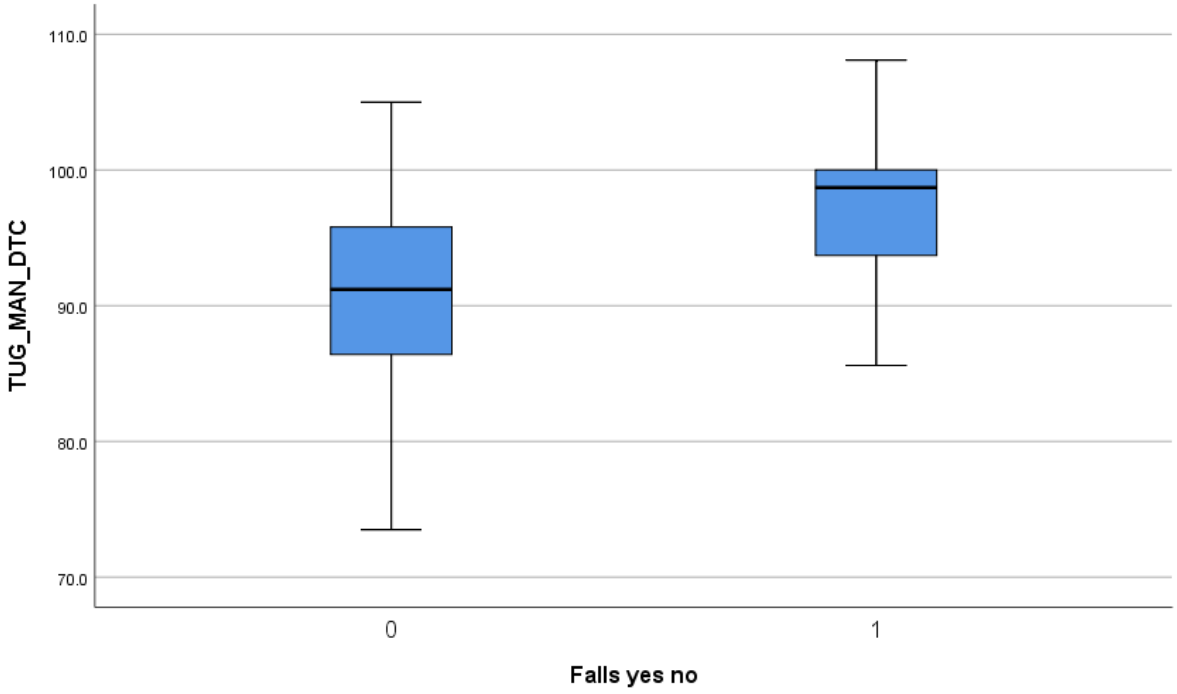




Normal Q-Q Plots

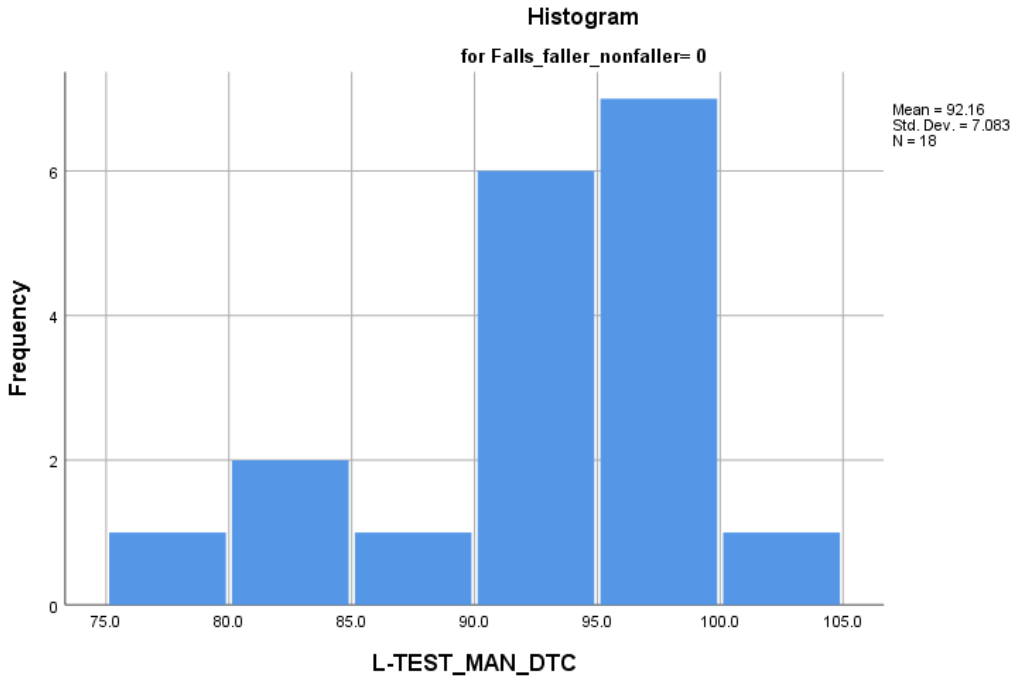


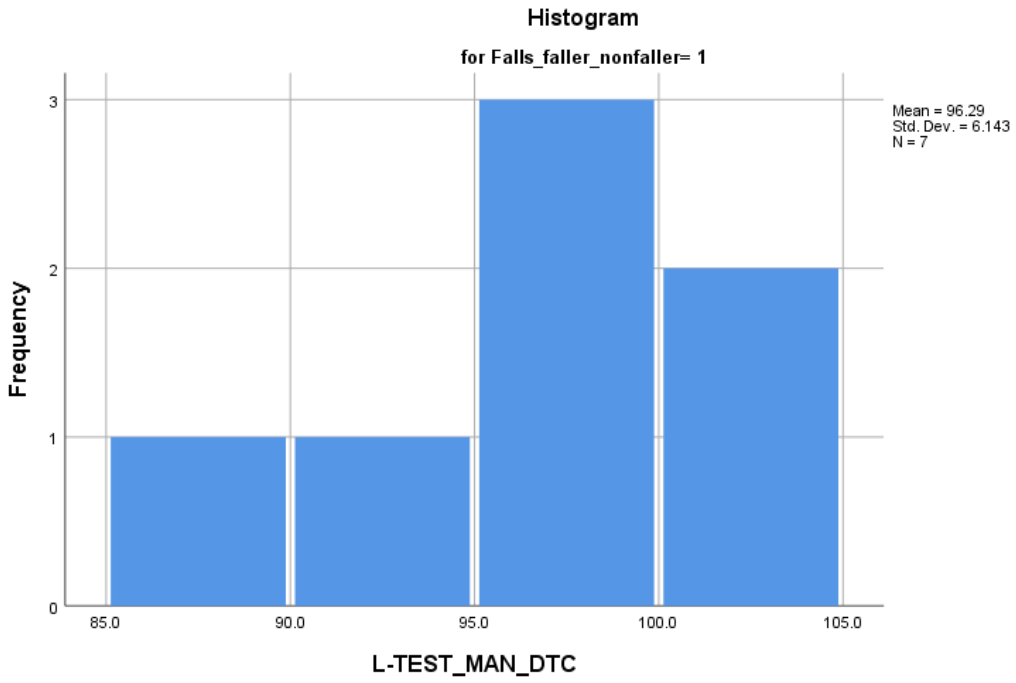




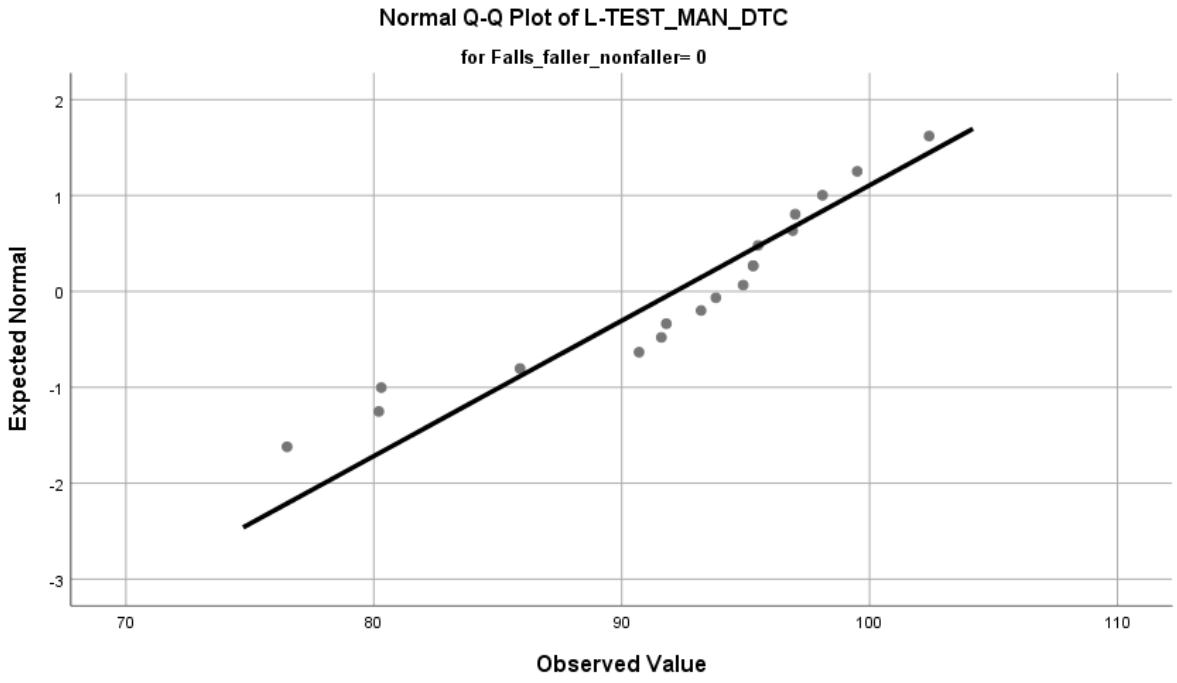
L-TEST_MAN_DTC

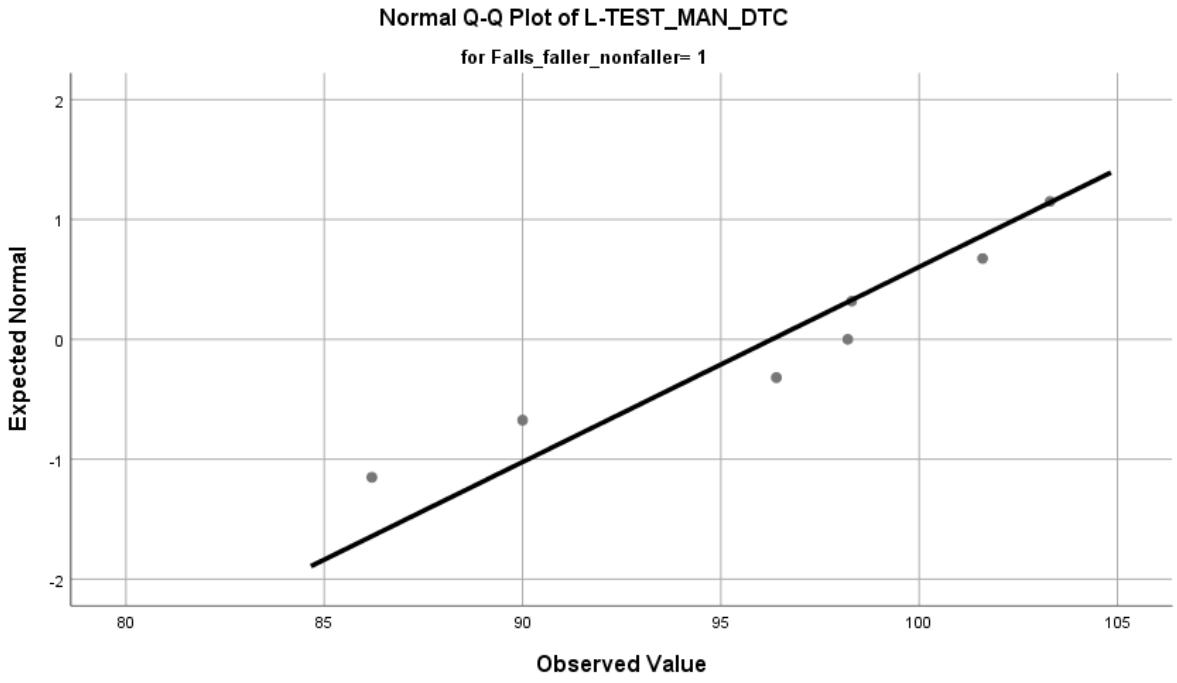
Histograms

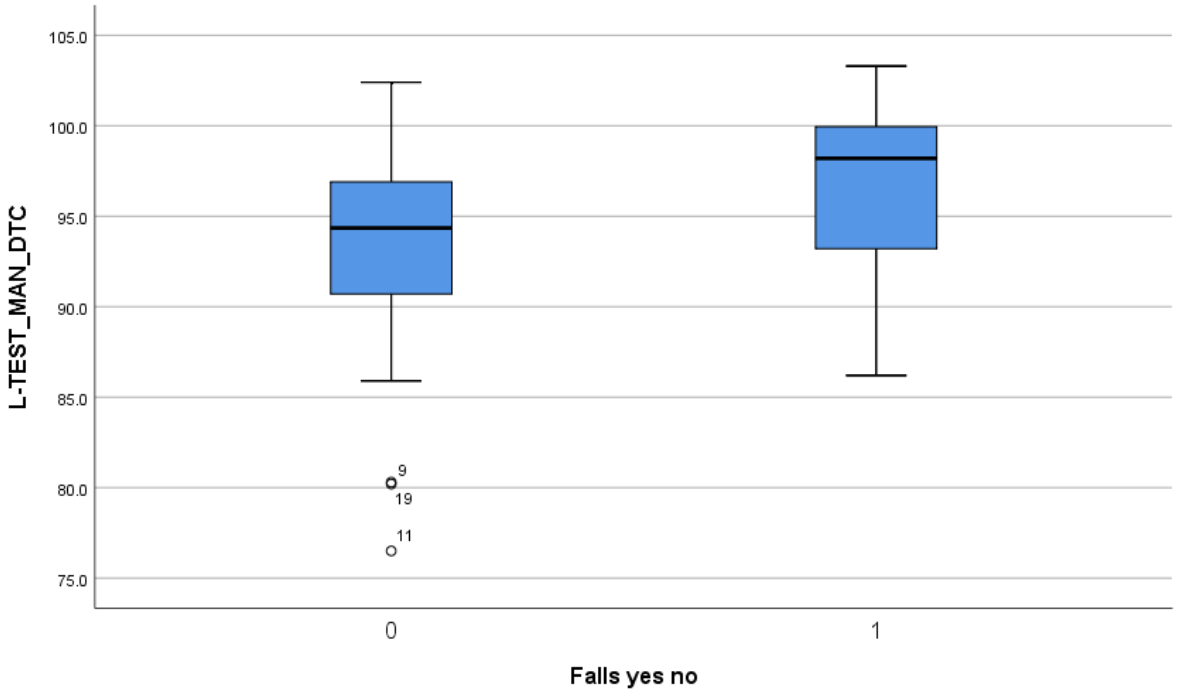




Normal Q-Q Plots

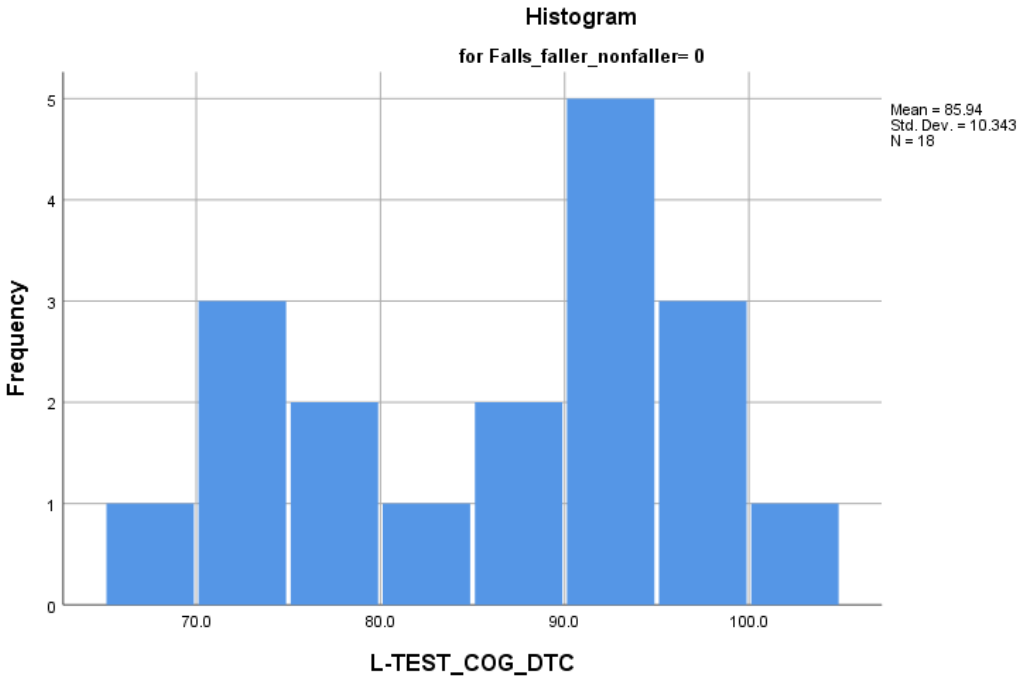


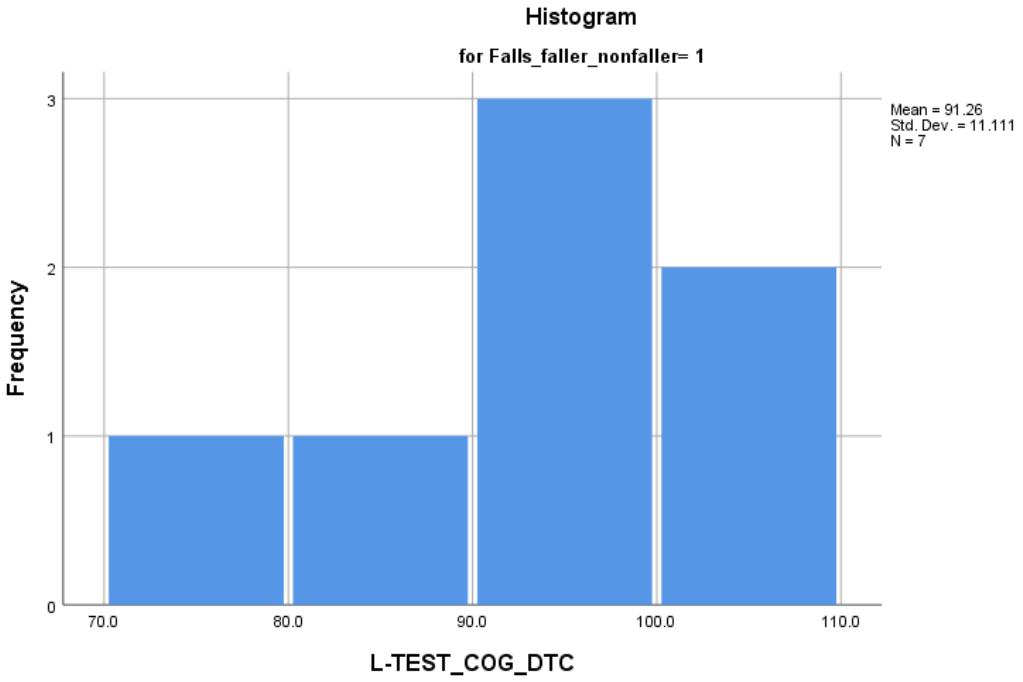

Normal Q-Q Plot of L-TEST_MAN_DTC
for Falls_faller_nonfaller= 1
Expected Normal
2
1
0
-1
-2
80
85
90
95
100
105
Observed Value


L-TEST_MAN_DTC
105.0
100.0
95.0
90.0
85.0
80.0
75.0
9
19
11
0
1
Falls yes no

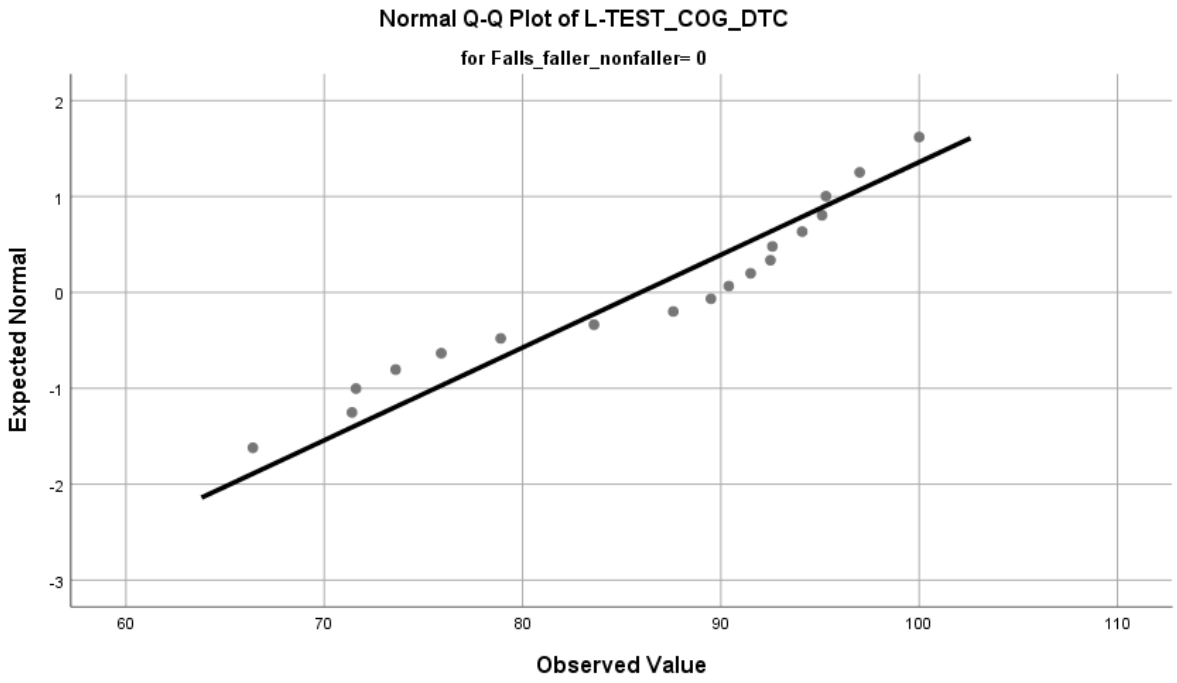
L-TEST_COG_DTC

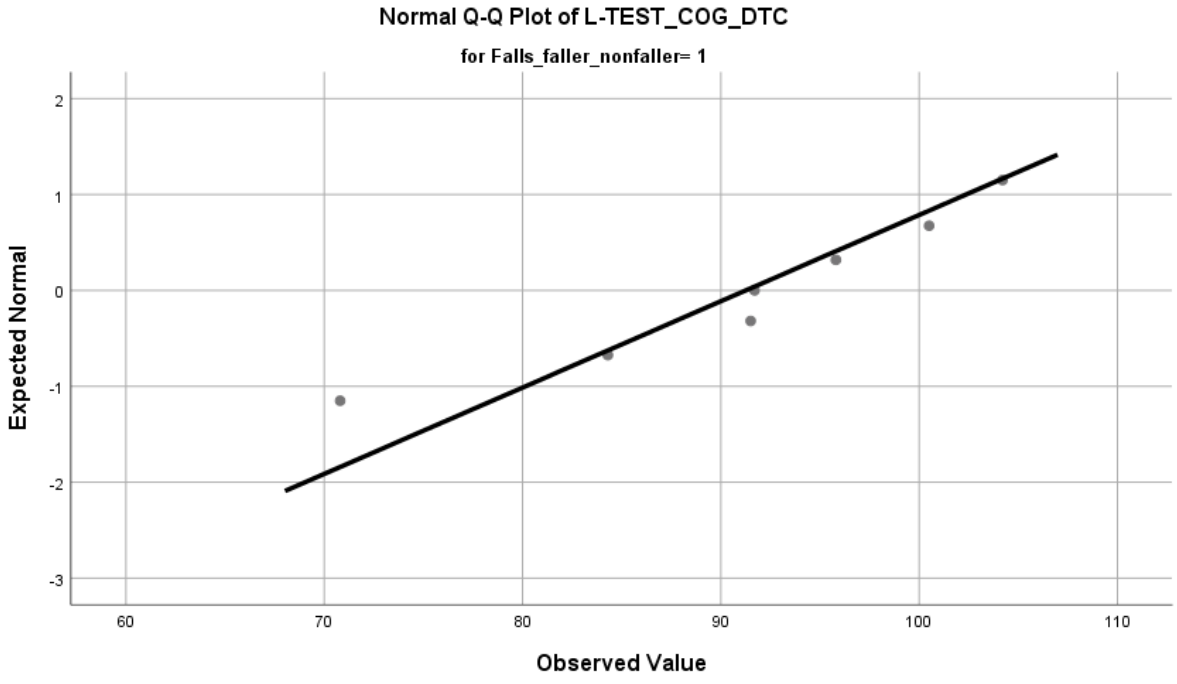
Histograms

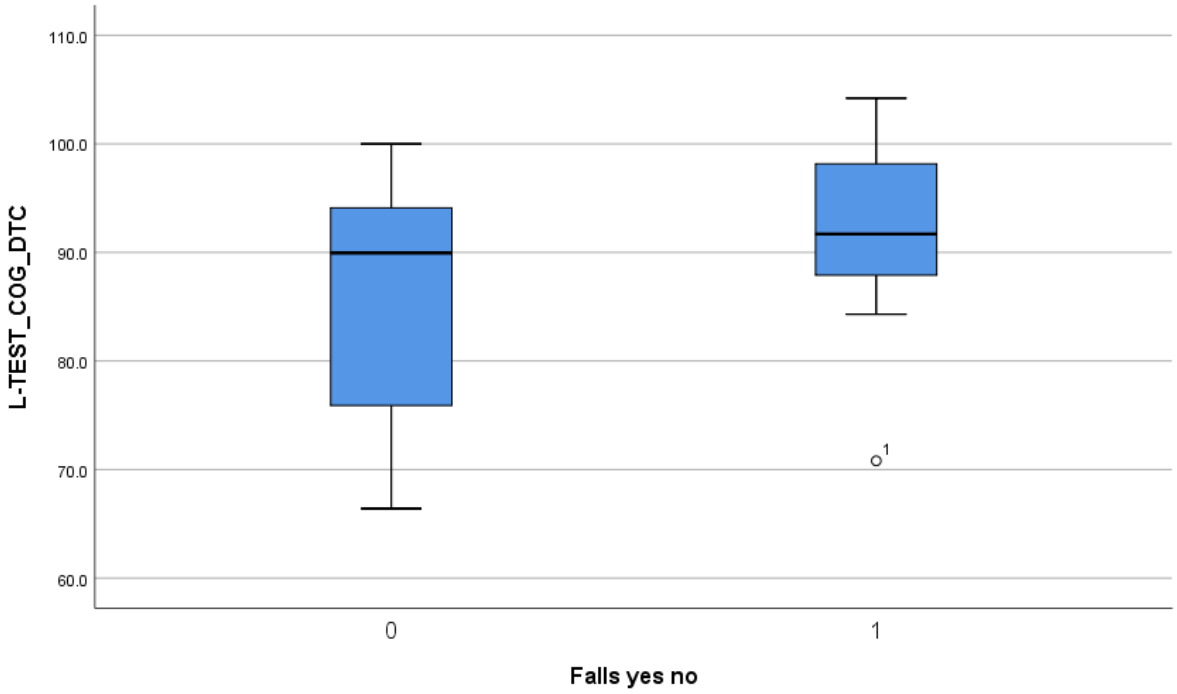




Normal Q-Q Plots






110.0
100.0
90.0
80.0
70.0
60.0
L-TEST_COG_DTC
1
0
1
Falls yes no

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
  /METHOD=ENTER TUG_STD_TIME
  /PRINT=CI(95)
  /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Block 0: Beginning Block

Classification Table[a,b]

			Predicted		
			Falls categories		Percentage
	Observed		0	1	Correct
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	TUG_STD_TIME	.786	1	.375
	Overall Statistics		.786	1	.375

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	.741	1	.389
	Block	.741	1	.389
	Model	.741	1	.389

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	28.907[a]	.029	.042

a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Classification Table[a]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 1	Falls categories	0	17	1	94.4
		1	7	0	.0
	Overall Percentage				68.0

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	TUG_STD_TIME	.107	.124	.746	1	.388	1.113
	Constant	-2.051	1.380	2.208	1	.137	.129

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	TUG_STD_TIME	.873	1.418

Constant			

a. Variable(s) entered on step 1: TUG_STD_TIME.

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
 /METHOD=ENTER TUG_MAN_TIME
 /PRINT=CI(95)
 /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Block 0: Beginning Block

Classification Table[a,b]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	TUG_MAN_TIME	.102	1	.750
	Overall Statistics		.102	1	.750

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	.098	1	.755
	Block	.098	1	.755
	Model	.098	1	.755

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	29.550[a]	.004	.006

a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Classification Table[a]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 1	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	TUG_MAN_TIME	.030	.094	.100	1	.751	1.030
	Constant	-1.280	1.158	1.222	1	.269	.278

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	TUG_MAN_TIME	.856	1.240

Constant			

a. Variable(s) entered on step 1: TUG_MAN_TIME.

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
  /METHOD=ENTER TUG_COG_TIME
  /PRINT=CI(95)
  /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Block 0: Beginning Block

Classification Table[a,b]

			Predicted		
			Falls categories		Percentage
	Observed		0	1	Correct
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	TUG_COG_TIME	.107	1	.743
	Overall Statistics		.107	1	.743

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	.104	1	.747
	Block	.104	1	.747
	Model	.104	1	.747

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	29.544[a]	.004	.006

a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Classification Table[a]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 1	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	TUG_COG_TIME	.022	.069	.106	1	.744	1.023
	Constant	-1.228	.987	1.548	1	.213	.293

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	TUG_COG_TIME	.894	1.170

Constant		

a. Variable(s) entered on step 1: TUG_COG_TIME.

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
  /METHOD=ENTER LTEST_STD_TIME
  /PRINT=CI(95)
  /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Block 0: Beginning Block

Classification Table[a,b]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	L-TEST_STD_TIME	.694	1	.405
	Overall Statistics		.694	1	.405

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	.642	1	.423
	Block	.642	1	.423
	Model	.642	1	.423

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	29.006[a]	.025	.037

a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Classification Table[a]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 1	Falls categories	0	17	1	94.4
		1	7	0	.0
	Overall Percentage				68.0

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	L-TEST_STD_TIME	.040	.050	.651	1	.420	1.041
	Constant	-1.939	1.329	2.128	1	.145	.144

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	L-TEST_STD_TIME	.944	1.148

	Constant		

a. Variable(s) entered on step 1: L-TEST_STD_TIME.

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
  /METHOD=ENTER LTEST_COG_TIME
  /PRINT=CI(95)
  /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Block 0: Beginning Block

Classification Table[a,b]

			Predicted		
			Falls categories		Percentage
	Observed		0	1	Correct
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	L-TEST_COG_TIME	.111	1	.739
	Overall Statistics		.111	1	.739

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	.106	1	.745
	Block	.106	1	.745
	Model	.106	1	.745

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	29.542[a]	.004	.006

a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Classification Table[a]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 1	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	L-TEST_COG_TIME	.011	.035	.109	1	.741	1.012
	Constant	-1.275	1.106	1.330	1	.249	.279

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	L-TEST_COG_TIME	.945	1.083
	Constant		

a. Variable(s) entered on step 1: L-TEST_COG_TIME.

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
 /METHOD=ENTER LTEST_MAN_TIME
 /PRINT=CI(95)
 /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Block 0: Beginning Block

Classification Table[a,b]

			Predicted		
			Falls categories		Percentage
	Observed		0	1	Correct
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	L-TEST_MAN_TIME	.118	1	.731
	Overall Statistics		.118	1	.731

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	.113	1	.737
	Block	.113	1	.737
	Model	.113	1	.737

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	29.535[a]	.004	.006

a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Classification Table[a]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 1	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	L-TEST_MAN_TIME	.013	.039	.116	1	.733	1.014
	Constant	-1.302	1.150	1.283	1	.257	.272

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	L-TEST_MAN_TIME	.938	1.095
	Constant		

a. Variable(s) entered on step 1: L-TEST_MAN_TIME.

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
 /METHOD=ENTER AGE
 /PRINT=CI(95)
 /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Block 0: Beginning Block

Classification Table[a,b]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	AGE	.131	1	.718
	Overall Statistics		.131	1	.718

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	.130	1	.719
	Block	.130	1	.719
	Model	.130	1	.719

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	29.518[a]	.005	.007

a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Classification Table[a]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 1	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	AGE	-.017	.048	.130	1	.718	.983
	Constant	.184	3.144	.003	1	.953	1.201

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	AGE	.895	1.080

Constant		

a. Variable(s) entered on step 1: AGE.

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
 /METHOD=ENTER SEX
 /CONTRAST (SEX)=Indicator
 /PRINT=CI(95)
 /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Categorical Variables Codings

		Frequency	Parameter coding (1)
SEX	1	19	1.000
	2	6	.000

Block 0: Beginning Block

Classification Table[a,b]

			Predicted		
			Falls categories		Percentage Correct
	Observed		0	1	
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	SEX(1)	.111	1	.739

	Overall Statistics	.111	1	.739

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	.109	1	.742
	Block	.109	1	.742
	Model	.109	1	.742

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	29.539[a]	.004	.006

a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Classification Table[a]

			Predicted		
			Falls categories		Percentage Correct
	Observed		0	1	
Step 1	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	SEX(1)	-.336	1.011	.111	1	.739	.714
	Constant	-.693	.866	.641	1	.423	.500

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	SEX(1)	.099	5.178
	Constant		

a. Variable(s) entered on step 1: SEX.

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
 /METHOD=ENTER MMSE
 /PRINT=CI(95)
 /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Block 0: Beginning Block

Classification Table[a,b]

			Predicted		
			Falls categories		Percentage Correct
	Observed		0	1	
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	MMSE	3.593	1	.058
	Overall Statistics		3.593	1	.058

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	3.425	1	.064
	Block	3.425	1	.064
	Model	3.425	1	.064

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	26.223[a]	.128	.184

a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Classification Table[a]

			Predicted		
			Falls categories		Percentage Correct
	Observed		0	1	
Step 1	Falls categories	0	15	3	83.3
		1	5	2	28.6
	Overall Percentage				68.0

a. The cut value is .500

Variables in the Equation

	B	S.E.	Wald	df	Sig.	Exp(B)

Step 1[a]	MMSE	-.444	.251	3.128	1	.077	.641
	Constant	11.559	7.041	2.695	1	.101	104740.764

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	MMSE	.392	1.049
	Constant		

a. Variable(s) entered on step 1: MMSE.

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
  /METHOD=ENTER H_and_Y
  /PRINT=CI(95)
  /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Categorical Variables Codings[a]

			Parameter coding	
		Frequency	(1)	(2)
H and Y	1	13	1.000	.000
	2	10	.000	1.000
	3	2	.000	.000

a. This coding results in indicator coefficients.

Block 0: Beginning Block

Classification Table[a,b]

			Predicted		
			Falls categories		Percentage
	Observed		0	1	Correct
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	H and Y	10.615	2	.005
		H and Y(1)	10.532	1	.001
		H and Y(2)	8.466	1	.004
	Overall Statistics		10.615	2	.005

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	13.415	2	.001
	Block	13.415	2	.001
	Model	13.415	2	.001

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	16.233[a]	.415	.598

a. Estimation terminated at iteration number 20 because maximum iterations has been reached. Final solution cannot be found.

Classification Table[a]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 1	Falls categories	0	14	4	77.8
		1	1	6	85.7
	Overall Percentage				80.0

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	H and Y			.068	2	.967	
	H and Y(1)	-21.203	11147.524	.000	1	.998	.000
	H and Y(2)	.405	1.555	.068	1	.794	1.500
	Constant	.000	1.414	.000	1	1.000	1.000

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	H and Y		
	H and Y(1)	.000	.
	H and Y(2)	.071	31.575
	Constant		

a. Variable(s) entered on step 1: H and Y.

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
  /METHOD=ENTER YEARS_SINCE_DIAG
  /PRINT=CI(95)
  /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Block 0: Beginning Block

Classification Table[a,b]

			Predicted		
			Falls categories		Percentage
	Observed		0	1	Correct
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	YEARS_SINCE_DIAG	2.182	1	.140
	Overall Statistics		2.182	1	.140

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	2.154	1	.142
	Block	2.154	1	.142
	Model	2.154	1	.142

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	27.493[a]	.083	.119

a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Classification Table[a]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 1	Falls categories	0	17	1	94.4
		1	6	1	14.3
	Overall Percentage				72.0

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.
Step 1[a]	YEARS_SINCE_DIAG	.148	.104	2.016	1	.156
	Constant	-2.094	.979	4.573	1	.032

Variables in the Equation

			95% C.I.for EXP(B)	
		Exp(B)	Lower	Upper
Step 1[a]	YEARS_SINCE_DIAG	1.160	.945	1.423
	Constant	.123		

a. Variable(s) entered on step 1: YEARS_SINCE_DIAG.

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
 /METHOD=ENTER COMORBIDITIES
 /PRINT=CI(95)
 /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Block 0: Beginning Block

Classification Table[a,b]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	COMORBIDITIES	.229	1	.632
	Overall Statistics		.229	1	.632

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	.237	1	.626
	Block	.237	1	.626
	Model	.237	1	.626

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	29.411[a]	.009	.014

a. Estimation terminated at iteration number 4 because parameter estimates changed by less than .001.

Classification Table[a]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 1	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	COMORBIDITIES	-.148	.310	.226	1	.634	.863
	Constant	-.732	.616	1.411	1	.235	.481

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	COMORBIDITIES	.470	1.585

Constant		

a. Variable(s) entered on step 1: COMORBIDITIES.

```
LOGISTIC REGRESSION VARIABLES Faller_nonfaller
  /METHOD=ENTER WALK_AID
  /PRINT=CI(95)
  /CRITERIA=PIN(0.05) POUT(0.10) ITERATE(20) CUT(0.5).
```

Logistic Regression

Case Processing Summary

Unweighted Cases[a]		N	Percent
Selected Cases	Included in Analysis	25	100.0
	Missing Cases	0	.0
	Total	25	100.0
Unselected Cases		0	.0
Total		25	100.0

a. If weight is in effect, see classification table for the total number of cases.

Dependent Variable Encoding

Original Value	Internal Value
0	0
1	1

Categorical Variables Codings[a]

			Parameter coding	
		Frequency	(1)	(2)
WALK_AID	1	23	1.000	.000
	2	1	.000	1.000
	4	1	.000	.000

a. This coding results in indicator coefficients.

Block 0: Beginning Block

Classification Table[a,b]

			Predicted		
			Falls categories		Percentage
	Observed		0	1	Correct
Step 0	Falls categories	0	18	0	100.0
		1	7	0	.0
	Overall Percentage				72.0

a. Constant is included in the model.

b. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 0	Constant	-.944	.445	4.496	1	.034	.389

Variables not in the Equation

			Score	df	Sig.
Step 0	Variables	WALK_AID	3.002	2	.223
		WALK_AID(1)	.522	1	.470
		WALK_AID(2)	2.679	1	.102
	Overall Statistics		3.002	2	.223

Block 1: Method = Enter

Omnibus Tests of Model Coefficients

		Chi-square	df	Sig.
Step 1	Step	3.245	2	.197
	Block	3.245	2	.197
	Model	3.245	2	.197

Model Summary

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	26.402[a]	.122	.175

a. Estimation terminated at iteration number 20 because maximum iterations has been reached. Final solution cannot be found.

Classification Table[a]

Observed			Predicted		
			Falls categories		Percentage Correct
			0	1	
Step 1	Falls categories	0	18	0	100.0
		1	6	1	14.3
	Overall Percentage				76.0

a. The cut value is .500

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)
Step 1[a]	WALK_AID			.000	2	1.000	
	WALK_AID(1)	20.161	40192.991	.000	1	1.000	570167806.154
	WALK_AID(2)	42.406	56841.458	.000	1	.999	2609759984755696600.000
	Constant	-21.203	40192.991	.000	1	1.000	.000

Variables in the Equation

		95% C.I.for EXP(B)	
		Lower	Upper
Step 1[a]	WALK_AID		
	WALK_AID(1)	.000	.
	WALK_AID(2)	.000	.
	Constant		

a. Variable(s) entered on step 1: WALK_AID.

```
ROC LTEST_STD_TIME BY Faller_nonfaller (1)
  /PLOT=CURVE(REFERENCE)
  /PRINT=SE COORDINATES
  /CRITERIA=CUTOFF(INCLUDE) TESTPOS(LARGE) DISTRIBUTION(FREE) CI(95)
  /MISSING=EXCLUDE.
```

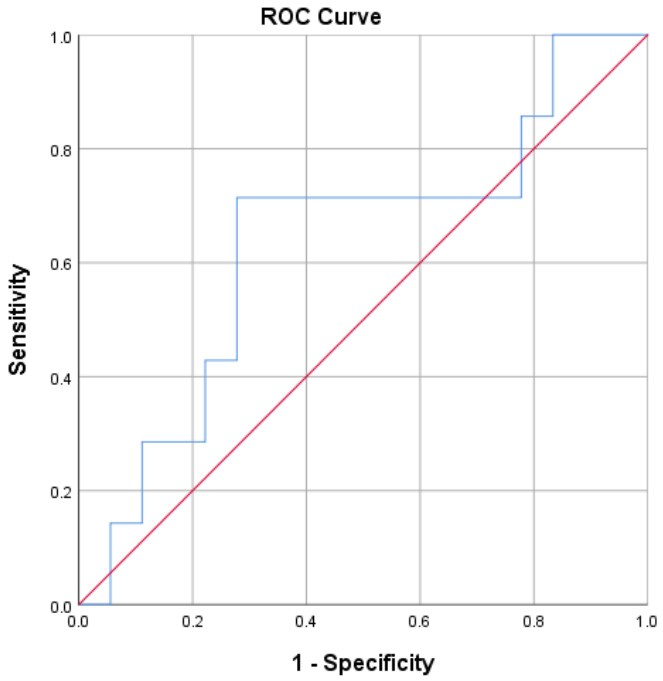
ROC Curve

Case Processing Summary

Falls categories	Valid N (listwise)
Positive[a]	7
Negative	18

Larger values of the test result variable(s) indicate stronger evidence for a positive actual state.

a. The positive actual state is 1.



Area Under the Curve

Test Result Variable(s): L-TEST_STD_TIME

Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.635	.130	.304	.380	.890

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

Coordinates of the Curve

Test Result Variable(s): L-TEST_STD_TIME

Positive if Greater Than or Equal To[a]	Sensitivity	1 - Specificity
14.000	1.000	1.000
15.750	1.000	.944
17.200	1.000	.889
18.050	1.000	.833
18.700	.857	.833
19.250	.857	.778
19.350	.714	.778
19.500	.714	.722
20.200	.714	.667
20.850	.714	.611
21.150	.714	.556
21.600	.714	.500
21.900	.714	.444

22.100	.714	.389
22.350	.714	.333
23.000	.714	.278
23.650	.571	.278
24.100	.429	.278
24.650	.429	.222
25.400	.286	.222
26.250	.286	.167
27.100	.286	.111
30.250	.143	.111
40.350	.143	.056
49.500	.000	.056
52.200	.000	.000

a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

```
ROC LTEST_MAN_TIME BY Faller_nonfaller (1)
 /PLOT=CURVE(REFERENCE)
 /PRINT=SE COORDINATES
 /CRITERIA=CUTOFF(INCLUDE) TESTPOS(LARGE) DISTRIBUTION(FREE) CI(95)
 /MISSING=EXCLUDE.
```

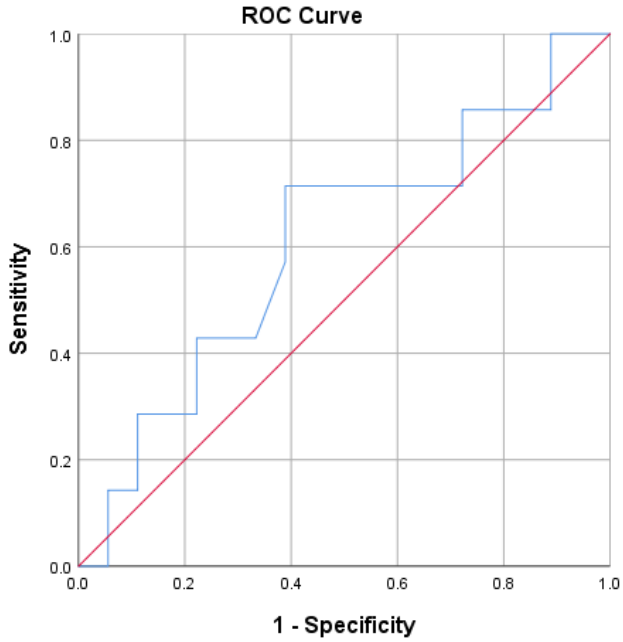
ROC Curve

Case Processing Summary

Falls categories	Valid N (listwise)
Positive[a]	7
Negative	18

Larger values of the test result variable(s) indicate stronger evidence for a positive actual state.

a. The positive actual state is 1.



Diagonal segments are produced by ties.

Area Under the Curve

Test Result Variable(s): L-TEST_MAN_TIME

Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound

.607	.130	.414	.353	.861

The test result variable(s): L-TEST_MAN_TIME has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

Coordinates of the Curve

Test Result Variable(s): L-TEST_MAN_TIME

Positive if Greater Than or Equal To[a]	Sensitivity	1 - Specificity
14.700	1.000	1.000
16.700	1.000	.944
18.350	1.000	.889
19.250	.857	.889
19.850	.857	.833
20.300	.857	.778
20.750	.857	.722
21.150	.714	.722
21.650	.714	.667
22.200	.714	.611
22.800	.714	.556
23.550	.714	.444
23.950	.714	.389
24.150	.571	.389
24.500	.429	.333
25.400	.429	.278

26.050	.429	.222
26.700	.286	.222
27.600	.286	.167
28.000	.286	.111
33.200	.143	.111
43.950	.143	.056
58.250	.000	.056
67.900	.000	.000

The test result variable(s): L-TEST_MAN_TIME has at least one tie between the positive actual state group and the negative actual state group.

a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

```
ROC LTEST_COG_TIME BY Faller_nonfaller (1)
 /PLOT=CURVE(REFERENCE)
 /PRINT=SE COORDINATES
 /CRITERIA=CUTOFF(INCLUDE) TESTPOS(LARGE) DISTRIBUTION(FREE) CI(95)
 /MISSING=EXCLUDE.
```

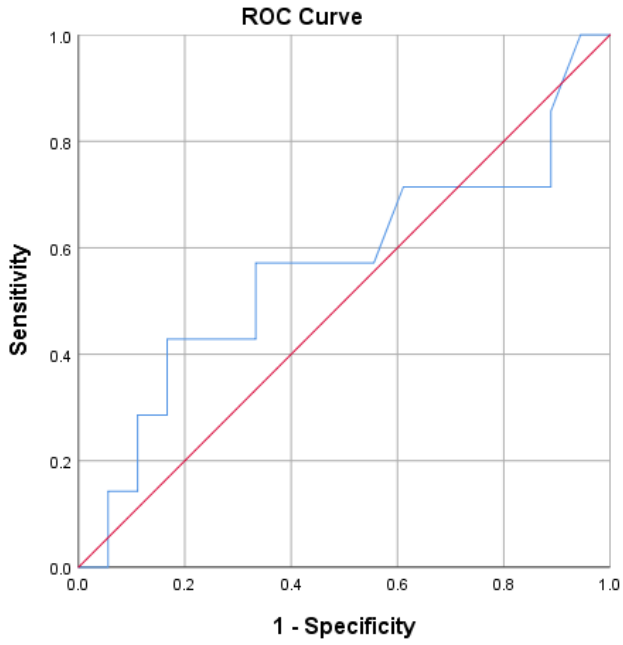
ROC Curve

Case Processing Summary

Falls categories	Valid N (listwise)
Positive[a]	7
Negative	18

Larger values of the test result variable(s) indicate stronger evidence for a positive actual state.

a. The positive actual state is 1.



Diagonal segments are produced by ties.

Area Under the Curve

Test Result Variable(s): L-TEST_COG_TIME

Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound

.563	.142	.628	.286	.841

The test result variable(s): L-TEST_COG_TIME has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

Coordinates of the Curve

Test Result Variable(s): L-TEST_COG_TIME

Positive if Greater Than or Equal To[a]	Sensitivity	1 - Specificity
16.000	1.000	1.000
18.000	1.000	.944
19.100	.857	.889
19.800	.714	.889
20.500	.714	.833
21.350	.714	.778
22.350	.714	.722
22.950	.714	.667
23.600	.714	.611
24.150	.571	.556
24.650	.571	.500
24.950	.571	.444
25.050	.571	.389
25.550	.571	.333
27.150	.429	.333
28.500	.429	.278

28.950	.429	.222
29.650	.429	.167
30.950	.286	.167
32.500	.286	.111
38.950	.143	.111
50.700	.143	.056
64.200	.000	.056
72.700	.000	.000

The test result variable(s): L-TEST_COG_TIME has at least one tie between the positive actual state group and the negative actual state group.

a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

```
ROC TUG_STD_TIME BY Faller_nonfaller (1)
 /PLOT=CURVE(REFERENCE)
 /PRINT=SE COORDINATES
 /CRITERIA=CUTOFF(INCLUDE) TESTPOS(LARGE) DISTRIBUTION(FREE) CI(95)
 /MISSING=EXCLUDE.
```

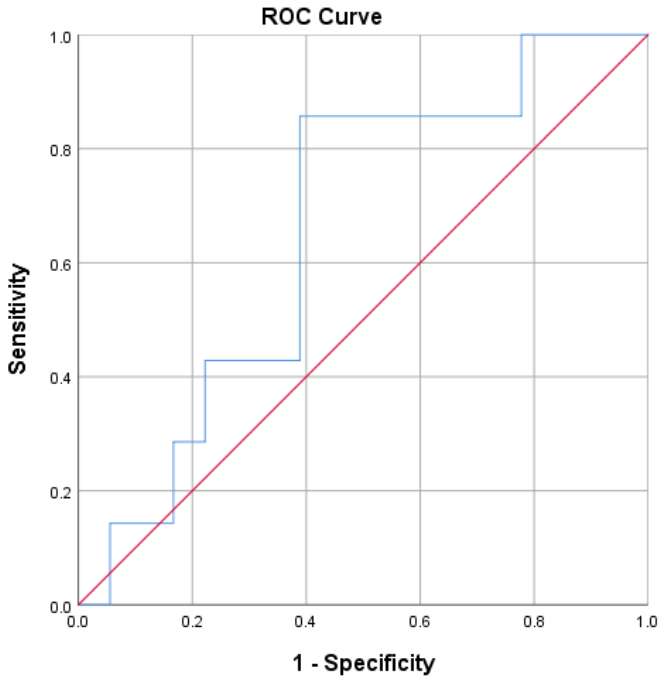
ROC Curve

Case Processing Summary

Falls categories	Valid N (listwise)
Positive[a]	7
Negative	18

Larger values of the test result variable(s) indicate stronger evidence for a positive actual state.

a. The positive actual state is 1.



Area Under the Curve

Test Result Variable(s): TUG_STD_TIME

Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound

.659	.115	.226	.432	.885

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

Coordinates of the Curve

Test Result Variable(s): TUG_STD_TIME

Positive if Greater Than or Equal To[a]	Sensitivity	1 - Specificity
4.700	1.000	1.000
6.200	1.000	.944
6.750	1.000	.889
7.050	1.000	.833
7.450	1.000	.778
7.650	.857	.778
7.750	.857	.722
8.050	.857	.667
8.350	.857	.611
8.600	.857	.556
8.900	.857	.500
9.050	.857	.444
9.200	.857	.389
9.400	.714	.389
9.550	.571	.389
9.700	.429	.389
9.950	.429	.333
10.250	.429	.278
10.500	.429	.222

10.950	.286	.222
11.750	.286	.167
12.350	.143	.167
14.000	.143	.111
17.150	.143	.056
19.400	.000	.056
21.000	.000	.000

a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

```
ROC TUG_MAN_TIME BY Faller_nonfaller (1)
 /PLOT=CURVE(REFERENCE)
 /PRINT=SE COORDINATES
 /CRITERIA=CUTOFF(INCLUDE) TESTPOS(LARGE) DISTRIBUTION(FREE) CI(95)
 /MISSING=EXCLUDE.
```

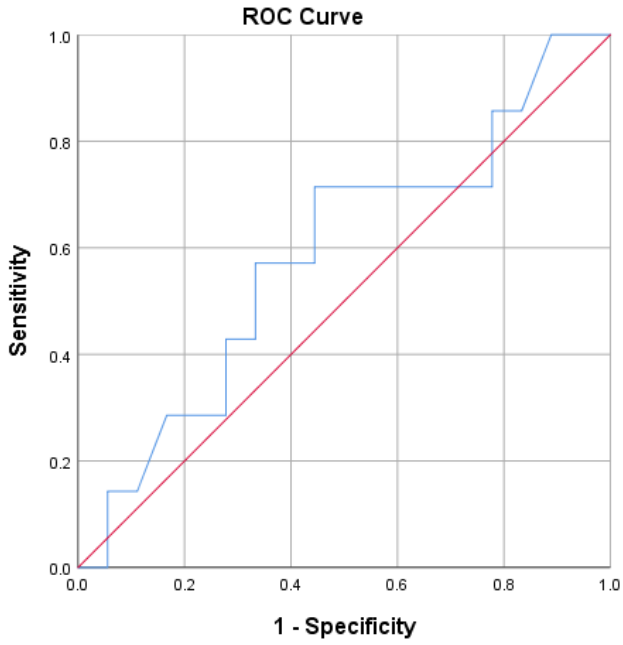
ROC Curve

Case Processing Summary

Falls categories	Valid N (listwise)
Positive[a]	7
Negative	18

Larger values of the test result variable(s) indicate stronger evidence for a positive actual state.

a. The positive actual state is 1.



Diagonal segments are produced by ties.

Area Under the Curve

Test Result Variable(s): TUG_MAN_TIME

Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound

.587	.130	.506	.333	.841

The test result variable(s): TUG_MAN_TIME has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

Coordinates of the Curve

Test Result Variable(s): TUG_MAN_TIME

Positive if Greater Than or Equal To[a]	Sensitivity	1 - Specificity
5.600	1.000	1.000
6.850	1.000	.944
7.400	1.000	.889
8.100	.857	.833
8.550	.857	.778
8.700	.714	.778
8.850	.714	.722
8.950	.714	.667
9.100	.714	.556
9.350	.714	.500
9.550	.714	.444
9.700	.571	.444
9.950	.571	.389
10.350	.571	.333
10.750	.429	.333
11.000	.429	.278

11.150	.286	.278
11.550	.286	.222
12.350	.286	.167
15.450	.143	.111
19.250	.143	.056
23.800	.000	.056
28.200	.000	.000

The test result variable(s): TUG_MAN_TIME has at least one tie between the positive actual state group and the negative actual state group.

a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

```
ROC TUG_COG_TIME BY Faller_nonfaller (1)
 /PLOT=CURVE(REFERENCE)
 /PRINT=SE COORDINATES
 /CRITERIA=CUTOFF(INCLUDE) TESTPOS(LARGE) DISTRIBUTION(FREE) CI(95)
 /MISSING=EXCLUDE.
```

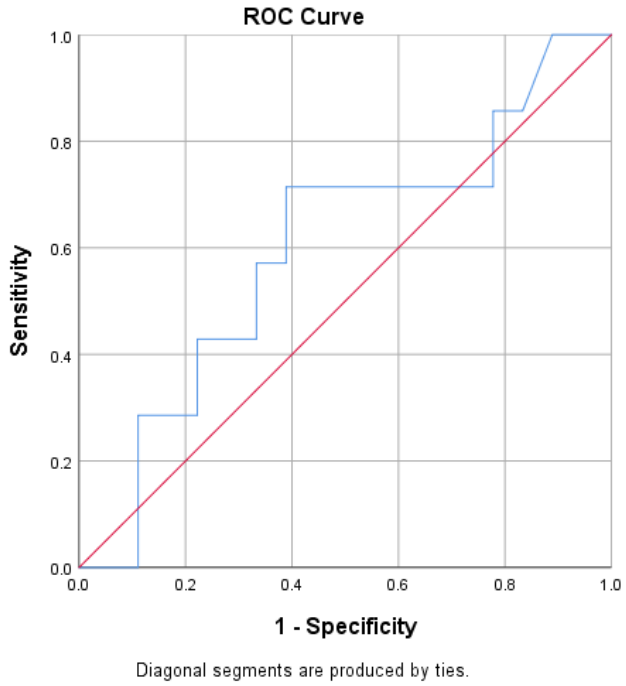
ROC Curve

Case Processing Summary

Falls categories	Valid N (listwise)
Positive[a]	7
Negative	18

Larger values of the test result variable(s) indicate stronger evidence for a positive actual state.

a. The positive actual state is 1.



Area Under the Curve

Test Result Variable(s): TUG_COG_TIME

Area	Std. Error[a]	Asymptotic Sig.[b]	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound

.599	.130	.449	.345	.853

The test result variable(s): TUG_COG_TIME has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.

a. Under the nonparametric assumption

b. Null hypothesis: true area = 0.5

Coordinates of the Curve

Test Result Variable(s): TUG_COG_TIME

Positive if Greater Than or Equal To[a]	Sensitivity	1 - Specificity
5.900	1.000	1.000
6.950	1.000	.944
7.500	1.000	.889
8.200	.857	.833
8.500	.857	.778
8.650	.714	.778
8.850	.714	.722
9.050	.714	.667
9.150	.714	.611
9.300	.714	.556
9.700	.714	.500
10.100	.714	.389
10.350	.571	.389
11.200	.571	.333
12.100	.429	.333
12.750	.429	.278

13.300	.429	.222
13.750	.286	.222
14.500	.286	.167
15.150	.286	.111
19.900	.143	.111
26.700	.000	.111
29.650	.000	.056
31.300	.000	.000

The test result variable(s): TUG_COG_TIME has at least one tie between the positive actual state group and the negative actual state group.

a. The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

```
GET
  FILE='E:\n=25 final sample 15th March.sav'.
DATASET NAME DataSet1 WINDOW=FRONT.
```