Validation of Stroke-Specific Protocols to Enhance the Clinical Utility of the 10-Metre and 6-Minute Walk Tests in People with Acute, Subacute, and Chronic Stroke

by

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A thesis submitted in conformity with the requirements for the degree of Master of Science
Rehabilitation Sciences Institute
University of Toronto

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Abstract

Background: Standardized stroke-specific 10-metre walk test (10mWT) and 6-minute walk test (6MWT) protocols have been developed, but reliability, measurement error, and validity have yet to be evaluated. Objectives: To estimate the 1) test-retest reliability, 2) measurement error, and 3) construct validity of stroke-specific protocols for the 10mWT and 6MWT using 15 and 30-metre walkway lengths in people post-stroke. Methods: A quantitative, cross-sectional study was conducted. Results: 17 individuals participated. Two evaluations, 2-3 days apart, were completed. Estimates of test-retest reliability for all tests were high (ICC$_{2,1}$=0.75-0.97). Minimal detectable change (MDC$_{95}$) values were similar to the literature for the 6MWT, but larger for the 10mWT. Correlations were high between walk tests (r=0.70-0.93, p<0.01) and low between each walk test and limb strength measured using the Stroke Impact Scale strength subscale (r=0.17-0.39, p>0.05). Conclusions: The 10mWT, and 6MWT on both 15-metre and 30-metre walkways, are reliable, while validity was partially supported.

Keywords: Stroke; Walk test; Gait speed; Walking capacity; Reliability; Measurement error; Validity
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List of Abbreviations

10mWT: 10-metre Walk Test

6MWT: 6-minute Walk Test

ADL: Activities of daily living

BP: Blood Pressure

CI: Confidence Interval

CMSA: Chedoke-McMaster Stroke Assessment

COSMIN: Consensus-based Standards for the Selection of Health Measurement Instruments

ERS/ATS: European Respiratory Society/American Thoracic Society

FIM: Functional independence measure

HR: Heart Rate

HRQL: Health-related quality of life

ICC: Intraclass Correlation Coefficient

ICF: International Classification of Functioning, Disability and Health

MDC: Minimal Detectable Change

PT: Physical Therapist

RPE: Rating of Perceived Exertion

SEM: Standard Error of Measurement

SIS: Stroke Impact Scale
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Appendix A: Completed Consensus-based Standards for the Selection of Health Measurement Instruments Checklists

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Chapter 1
Introduction
1 Introduction

Globally, stroke affects approximately 15 million people each year, resulting in five million deaths and five million people with permanent disability.\textsuperscript{1} Two thirds of people with stroke have limited walking ability, and half are unable to walk even with physical assistance.\textsuperscript{2} As a result, assessing and improving walking is a key objective in stroke rehabilitation\textsuperscript{3,4} especially in the first several weeks post-stroke.\textsuperscript{2,5-7} Following acute care, many people undergo inpatient and outpatient rehabilitation, meaning they receive treatment while in the early phases of stroke recovery,\textsuperscript{8} defined as the acute (<1 month post-stroke) and subacute (1-6 months post-stroke) phases, followed by the later chronic phase (>6 months post-stroke).\textsuperscript{9} A standardized assessment tool is used to assess a person’s current ability and track changes in health status and performance\textsuperscript{10} and use of these tools in stroke rehabilitation is considered a best practice\textsuperscript{11} as they allow comparison of scores within patients, and between patients across settings. The Canadian Stroke Best Practice Recommendations suggest the use of standardized assessment tools that are valid and reliable in assessing patient’s stroke-related impairments and functional status.\textsuperscript{11} As well, the reliability and validity of walk tests has been found to influence their selection by physical therapists (PTs).\textsuperscript{12} International post-stroke physical therapy guidelines recommend the use of several assessment tools for assessing post-stroke deficits.\textsuperscript{13-15} These standardized assessment tools allow clinicians to detect improvement in response to treatment interventions,\textsuperscript{16} better inform family members and patients on their health status,\textsuperscript{13} and determine when patients are ready for discharge and the type of rehabilitation setting that is most appropriate.\textsuperscript{11}

In particular, the 10-metre walk test\textsuperscript{17} (10mWT) and 6-minute walk test\textsuperscript{18} (6MWT) are measures of walking speed and walking capacity, respectively, and have been recommended for assessing gait in post-stroke rehabilitation.\textsuperscript{13-15} Task-oriented, treadmill, and aerobic training are recommended rehabilitation interventions in Canada\textsuperscript{19} and these tests have also been shown to capture change resulting from these treatments.\textsuperscript{20-23}

Support for the use of these tests has been investigated, with reliability and validity of the 6MWT and 10mWT being evaluated repeatedly in the current literature. Studies evaluating test-retest reliability of the 10mWT and 6MWT have reported intraclass correlation coefficients (ICC) ranging from 0.94 to 0.96,\textsuperscript{24,25} and 0.97 to 0.99,\textsuperscript{24,26-28} respectively. Measurement error has
been reported in the literature as minimal detectable change at the 95% confidence level (MDC\textsubscript{95}) with values ranging from 0.18m/s to 0.19m/s\textsuperscript{25,29} and 33.0m to 64.3m\textsuperscript{26,28,30} for the 10mWT and 6MWT, respectively. Construct validity of the 6MWT examined with gait speed tests, including the 10mWT, has found correlation values ranging from 0.84 to 0.91\textsuperscript{24,26,31,32} The 10mWT has been examined with direct measures of strength and have found correlation values ranging from 0.31 to 0.75\textsuperscript{33-37} while the 6MWT has been examined with the Stroke Impact Scale strength subscale (SIS strength)\textsuperscript{38} and found a correlation value 0.52\textsuperscript{39} No studies have looked at correlations between the 10mWT and the SIS strength, but dynamometry constructs match onto lower limb items of the SIS strength.

Despite the importance of walking function and support for using the 10mWT and 6MWT, these tests are not widely used in assessing people with stroke\textsuperscript{40} Several factors that limit the use of these recommended tests have been identified, including; insufficient research on reliability and validity of tests in relevant populations\textsuperscript{41} variation in test protocols\textsuperscript{41-43} which affect performance;\textsuperscript{44,45} lack of aphasia instructions or provision of physical assistance;\textsuperscript{46} and difficulty in administering the 6MWT when using the recommended 30-metre (m) walkway\textsuperscript{46} in settings that do not have access to the physical space needed to accommodate this walkway length\textsuperscript{41}.

To address some of these limitations, research has yielded standardized protocols that permit assistance from one person to walk during these walk tests and include pictorial instructions for use in people with aphasia\textsuperscript{47} but measurement properties have yet to be evaluated. There is a need to investigate test-retest reliability to describe consistency of repeated use of the tests; measurement error to gauge the difference between measured values and true values; and construct validity to measure the extent to which the walk tests truly measure walking ability. The Consensus-based Standards for the Selection of Health Measurement Instruments \textsuperscript{48} (COSMIN) provides guidance for the investigation of these measurement properties (see Appendix A for checklists).

This thesis is comprised of four chapters including the introduction, a literature review, a manuscript presenting the results of a quantitative study, and a summary and conclusion. The purpose of the literature review is to provide an overview and critical synthesis of the literature pertaining to the epidemiology of stroke, impairments, activity limitations and participation.
restrictions resulting from stroke, post-stroke rehabilitation in Canada, standardized assessment tools in clinical practice, best practice recommendations, measurement properties of the 10mWT and 6MWT used in stroke, and issues with their implementation. The recently developed protocols\textsuperscript{47} are the first stroke-specific standardized guidelines for the 10mWT and 6MWT but have yet to be tested for reliability, measurement error, and validity. Thus, the objectives of the quantitative study were to estimate the test-retest reliability, measurement error, and construct validity of stroke-specific protocols for the 10mWT and 6MWT, with the latter conducted twice using 15m and 30m walkway lengths, in ambulatory people with acute, subacute, and chronic stroke. The purpose of the final chapter was to provide a summary and conclusion of the thesis, including key considerations for future research.
Chapter 2
Literature Review
2 Literature Review

2.1 The Epidemiology of Stroke

A stroke, or cerebrovascular accident, is a sudden loss of brain function caused by interruption of blood flow (ischemic stroke) or the rupture of blood vessels in the brain (hemorrhagic stroke).\(^9\) Annually, approximately 15 million people worldwide experience a stroke, of which five million do not survive and five million are left with permanent disability.\(^1\) Five percent of all deaths in Canada are due to stroke\(^50\) and it remains the third leading cause of death\(^51\) and a leading cause of adult neurological disability.\(^52\) In Canada, approximately 62 000 people experience a stroke each year, resulting in an annual cost of approximately $3.6 billion in healthcare costs and lost economic output.\(^53\) In Canada, approximately 60% of people with stroke are left with some disability of which more than 40% experience moderate to severe disability that requires rehabilitation and community support.\(^54\) Furthermore, after the age of 55, an individual’s risk of stroke doubles every 10 years,\(^55,56\) and women are more likely than men to die and experience poorer outcomes from stroke.\(^57\) An estimated 405 000 Canadians were living with the effects of stroke in 2013, a number that is projected to almost double in the next 25 years.\(^58\)

2.2 The Impact of Stroke

2.2.1 The ICF Framework

The International Classification of Functioning, Disability and Health (ICF) is a unified and standard scientific framework for describing, organizing, and documenting health and health-related status.\(^59\) The ICF describes functioning and disability as multi-dimensional concepts reflecting the interactions between health condition and contextual factors of the individual or groups of people. The components related to functioning and disability are classified as body functions and structures, activities, and participation, which interact with contextual environmental factors (physical, social, and attitudinal setting in which people conduct their lives) and personal factors (characteristics of the individual).\(^50\)

In classifying functioning and disability, the ICF model and conceptual framework shifts the focus from health condition to the impact of the health condition on the individual or group.
Furthermore, the framework provides a platform for a common language in classifying functioning and disability and allows for specific description and quantification across settings.60

2.2.2 Describing the Impact of Stroke using the ICF Framework

Individuals can experience a wide range of impairments, activity limitations, and participation restrictions post-stroke. The internationally-accepted and evidence-based ICF Core Sets for stroke includes components that are often impacted by stroke and help in effectively describing and classifying stroke profiles.61

Stroke can affect many functions and structures of the body. Perceptual functions such as vision, and hearing, as well as mental functions such as memory, attention, and cognition can be affected.62 Similarly, language impairments can result in difficulties with reception and/or expression of spoken, written, or other forms of language.63 Cardiovascular health and fitness is also often affected after stroke and associated with muscle deconditioning.64 Control over voluntary movement functions can be affected, and can include changes in coordination, supportive functions, and eye-foot coordination.65 Furthermore, gait pattern functions may also be affected, resulting in spastic gait, hemiplegic gait, asymmetric gait, limping or stiff gait pattern, and impaired sensation.66 These stroke-related impairments described by the ICF subsequently affect performance of a range of everyday activities post-stroke that are required for participation.

Many activities and modes of participation can also be affected by stroke. Communication is an important activity that can often be limited post-stroke in the form of aphasia, a functional communication impairment that affects over 100 000 Canadians54 and restricts an individual’s ability to participate. Among other activities affected by stroke, walking is commonly limited, and has been identified as one of the most important components of the ICF for rehabilitation post-stroke.67 The ability to walk independently allows individuals to carry out activities of daily living (ADL) around the home and in the community, but the literature reports that 40% of people post-stroke need assistance with ADLs.68 Relatedly, certain walking distances and speeds reflect an individual’s ability to move about and participate in the community. To illustrate, a mean distance of approximately 90m is required to visit a physician’s office, and 330m is required to navigate the drugstore, while a mean walking speed of 0.49m/second (s) is required to cross the average US crosswalk.69 Walking limitation post-stroke
also decreases people’s level of physical activity and restricts the means to maintaining health in neurological populations. Given that walking deficit frequently contributes to activity limitations and participation restrictions, it is therefore an important target for treatment.

2.3 Post-stroke Rehabilitation in Canada

Rehabilitation is an individualized process that aims to enable each patient to reach their full functioning potential. Given the importance of walking ability, assessing and improving it are key objectives in stroke rehabilitation to allow people to better participate in everyday activities and tasks. The 2016 Ontario Stroke Evaluation Report indicated that from April 2014 to March 2015, 14,287 individuals with stroke were admitted to acute care hospitals for stroke, of which 30.2% were discharged to inpatient rehabilitation, 28.5% discharged home without services, 18.9% discharged home with services like outpatient rehabilitation, and 8.7% discharged to other acute care. According to Health Quality Ontario and Ministry of Health and Long-Term Care and the Ontario Stroke Report, no standardized process or outcome data are reported in Ontario on the total number of people with stroke seen in outpatient settings.

The first several weeks post-stroke have been shown to be a critical period for gait rehabilitation, which is the rationale for rehabilitation in the early phase of stroke recovery. In 2014/2015, the median number of days between stroke onset and admission to stroke inpatient rehabilitation in Ontario was 9 days and the overall median active length of stay in inpatient rehabilitation was 26 days. Furthermore, a study done at a large urban rehabilitation hospital in Toronto, Ontario recruited inpatients with stroke over the span of two years and reported time of admission to be at a mean of 17.3 days post-stroke with standard deviation of 16.7 days. These reports indicate that many patients are receiving stroke rehabilitation from inpatient and outpatient settings while in the early phases of stroke.

2.3.1 Walking recovery and health-related quality of life

Walking deficit post-stroke is a key target for rehabilitation, especially in the early phases of recovery. Two thirds of people with stroke have limited walking ability, and half of which are unable to walk even with physical assistance. A study also reported that one third of patients experience disability 5 years after stroke. Furthermore, the first 11 weeks post-stroke are critical for motor recovery, where 95% of patients report recovery in walking ability, after
which no significant changes in recovery occur for initially mild, moderate, severe, and very severe stroke after 8.5, 13, 17, and 20 weeks, respectively.\textsuperscript{6} Given that motor recovery post-stroke varies in time course based on severity, it is important to investigate walking ability based on the acute, subacute, and chronic phases, defined as 1 month, 1-6 months, and more than 6 months post-stroke, respectively.\textsuperscript{9}

The deficits and limitations as a result of stroke, particularly in walking ability, can contribute significantly to people’s overall well-being. Health-related quality of life (HRQL) is a subjective and multi-dimensional concept that can be defined as the effect of a medical condition or its treatment on an individual\textsuperscript{77} and is a concept that can be affected by various outcomes post-stroke. Findings show that many people living with stroke experience reduced HRQL when compared to individuals that did not experience stroke.\textsuperscript{68,78} Furthermore, those with limited walking ability and functional capacity have been found to experience decreased level of meaningful activity and health-related quality of life.\textsuperscript{4,39} Substantial improvement in HRQL has been found during post-stroke inpatient rehabilitation, but an equal decline occurred 6 months after discharge\textsuperscript{79} and similar long-term reductions in HRQL have also been observed in non-Canadian stroke populations.\textsuperscript{80} Given the associations between walking ability and HRQL, rehabilitation interventions early on in recovery is critical in improving outcomes and there are efficacious treatment interventions\textsuperscript{11} that can improve walking post-stroke.

2.4 Standardized assessment tools and use in clinical practice

2.4.1 Standardized assessment tools

A standardized assessment tool is a standardized evaluation used to assess an individual’s ability, generate scores, and track changes in health or performance.\textsuperscript{10} Use of standardized assessment tools in stroke rehabilitation is considered a best practice\textsuperscript{11} as their use allows comparison of scores between patients, and within patients across settings. Clinicians are able to detect improvement in response to treatment interventions,\textsuperscript{16} better inform relevant parties on patients’ health status,\textsuperscript{13} and determine when patients are ready for discharge and the type of rehabilitation setting that is most appropriate.\textsuperscript{11} Furthermore, standardized assessment tools can be classified using the ICF according to the constructs that they measure,\textsuperscript{81} allowing for effective description and classification of patient profiles.
2.4.2 Best Practice Recommendations for Standardized Outcomes

The Canadian Stroke Best Practices recommends the use of standardized assessment tools that are valid and reliable in assessing patient’s stroke-related impairments and functional status. In clinical practice, selection of standardized assessment tools by physical therapists has been found to be influenced by the reliability and validity of tools, relevance to the patient population, and feasibility of administering the tools. The Canadian best practice recommendations provides suggested measurement tools for post-stroke. The Functional Independence Measure (FIM), Alpha Functional Independence Measure, Chedoke-McMaster Stroke Assessment (CMSA), and 6-minute walk test are recommended for assessing gait in rehabilitation care. Other international guidelines also recommend assessment tools for the evaluation of walking post-stroke. The Dutch clinical guidelines for physiotherapy post-stroke recommend the use of the Functional Ambulation Categories, and the 10-metre walk test (10mWT) for assessing walking. The American Physical Therapy Association Neurology Section StrokEDGE Task Force highly recommends the use of the 10mWT, 6MWT, Fugl-Meyer Assessment of Motor Performance, and Dynamic Gait Index in all practice settings and during all phases of stroke recovery. The American Department of Veterans Affairs Clinical Practice Guideline for the Management of Stroke Rehabilitation, The National Clinical Guideline for Stroke from the United Kingdom, and the Australian Clinical Guidelines for Stroke Management recommend the assessment of walking post-stroke with standardized tools to improve quality of care and rehabilitation, but do not specify which tools should be used.

2.5 The 10-metre walk test and 6-minute walk test

The 10mWT and 6MWT are measures of comfortable walking speed and walking capacity, respectively, and have both been recommended for the assessment of people post-stroke.

The 10mWT is used as a measure of comfortable walking speed, and is administered using a 14 metre walkway length where the time taken to walk the middle 10m portion is recorded. The original version of the test was described by Collen et al. (1990) for use in people with stroke and has since been updated. The 6MWT is a self-paced measure of walking capacity, and evaluates the distance walked over a pre-determined walkway in 6 minutes. The protocol for this test was first introduced by Butland et al. (1982) for use in people with
respiratory disease, and a technical standard has since been developed by the European Respiratory Society/American Thoracic Society (ERS/ATS). The current standard recommends the use of a 30-metre walkway length, includes standardized instructions and encouragement, and the evaluator does not provide physical assistance to walk. The ERS/ATS standard for the 6MWT is recommended by multiple post-stroke guidelines despite not being intended for use in people without chronic respiratory disease, as a widely used standard for assessing walking capacity in people post-stroke does not currently exist. Furthermore, both the 10mWT and 6MWT have been shown to be responsive to improvement from treatment interventions recommended in Canada for post-stroke rehabilitation. Recommendations of the use of the 10mWT and 6MWT are based on literature that shows these tests to be clinically useful in stroke.

2.5.1 Test-retest reliability, measurement error, and construct validity

Reliability, measurement error, and construct validity of the 6MWT and 10mWT have been evaluated repeatedly in the current stroke literature and provide support for the use of these tests. Test-retest reliability is a way of estimating how well a tool can consistently measure something over time and is often reported with the intraclass correlation coefficient (ICC), where higher ICC values representing higher test-retest reliability. The ICC is preferred for evaluating reliability over Pearson correlations primarily due to the limitation of detecting systematic error with Pearson. Measurement error is commonly reported in the form of minimal detectable change (MDC), which reflects the value beyond which true change occurs and is not accounted for by variation in measurement. Construct validity is the degree to which a measure appropriately assesses a concept, or construct and is evaluated by assessing the correlation between related variables.

Currently, three studies have examined the test-retest reliability of the 10mWT walked at a comfortable pace in people post-stroke (Table 2.1). Two of these studies used the most current test protocols and reported excellent ICC values with narrow 95% confidence intervals (95% CI): 0.94 (0.90-0.97), 0.96 (0.92-0.98). Retest interval for these studies ranged from 5 to 10 days and both tests included 2m acceleration and 2m deceleration distances and measured walking speed on the middle 10m distance. However, both studies only evaluated people in the chronic phase of stroke and neither included people with aphasia nor provision of physical
assistance to walk during the test. One study evaluated the 10mWT using the original protocol where the test was completed on a 5m walkway walked twice with no acceleration or deceleration distances. This study reported an excellent ICC value of 0.87, but a wider 95% CI of 0.72-0.95, and also did not include people with aphasia or assistance. Two other studies that used the 5-metre and 6-metre walk tests have evaluated people in the acute and subacute phases of stroke recovery. These two tests are similar to the 10mWT as they also measure walking speed, but over shorter test distances and still with 2m acceleration and deceleration distances. The study that evaluated the 5-metre walk test allowed for provision of physical assistance and reported a high ICC value of 0.86 and a 95% CI of 0.68-0.94, while the study using the 6-metre walk test did not provide assistance and reported a high ICC values of 0.97 but did not report 95% CI. No studies on the 10mWT or similar gait speed tests included people with aphasia and retest interval ranged from 1 day to 17 days.

Measurement error of the 10mWT in the form of MDC at the 95% confidence level (MDC95) has been estimated in the same two studies that reported test-retest reliability, and values ranged from 0.18m/s to 0.19m/s. Again, these studies only evaluated people with chronic stroke and did not include people with aphasia or provision of physical assistance to walk. The study on the original 10mWT protocol did not report on measurement error. The study that used the 5-metre walk test reported a MDC95 of 0.31m/s, while the study using the 6-metre walk test reported MDC95 of 0.11m/s, both evaluating people with acute and subacute stroke and the former including provision of physical assistance.

Table 2.1 Test-retest reliability and measurement error of the 10mWT and similar gait speed tests

<table>
<thead>
<tr>
<th>First Author, Year</th>
<th>Phase of Stroke Recovery</th>
<th>Walk Test and Protocol</th>
<th>Retest Interval (days)</th>
<th>N</th>
<th>ICC (95% CI)</th>
<th>MDC95 (m/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flansbjer, 2005</td>
<td>Chronic</td>
<td>10mWT</td>
<td>14, 2, 2</td>
<td>7</td>
<td>0.94 (0.90-0.97)</td>
<td>0.19a</td>
</tr>
<tr>
<td>Hiengkaew, 2012</td>
<td>Chronic</td>
<td>10mWT</td>
<td>14, 2, 2</td>
<td>5-10</td>
<td>0.96 (0.92-0.98)</td>
<td>0.18</td>
</tr>
<tr>
<td>Green, 2002</td>
<td>Chronic</td>
<td>10mWT</td>
<td>10, 0, 0</td>
<td>7-17</td>
<td>0.87 (0.72-0.95)</td>
<td>NR</td>
</tr>
<tr>
<td>Fulk, 2008</td>
<td>Acute/Subacute</td>
<td>5mWT</td>
<td>9, 2, 2</td>
<td>Yes</td>
<td>1-3</td>
<td>0.86 (0.68-0.94)</td>
</tr>
<tr>
<td>Stephens, 1999</td>
<td>Subacute</td>
<td>6mWT</td>
<td>10, 2, 2</td>
<td>1</td>
<td>24</td>
<td>0.97 (NR)</td>
</tr>
</tbody>
</table>

Abbreviations: MDC95 = minimal detectable change at the 95% confidence level; TD = total distance; AD = acceleration distance; DD = deceleration distance; Assist = provision of physical assistance during test; N = sample size; ICC (95% CI) = Intra-class correlation coefficient (95% confidence interval); NR = not reported; 10mWT = 10m Walk Test.
Seven studies on the test-retest reliability of the 6MWT have reported ICC values (Table 2.2). All ICC values were excellent and ranged from 0.97 to 0.99, with 95% CI values ranging from 0.92 to 1.00. Only two studies included people in the acute and subacute phases of stroke recovery while the other five focused on chronic stroke. However, neither study that evaluated earlier phases of stroke used the recommended encouragement instructions or walk test length. Only two studies used the recommended straight 30m walkway length indoors, while others used different walkway length, shape, and location. Two studies reported the provision of physical assistance but one was conducted on oval tracks that were 46m or 76m long, which is unlikely to be available in many hospital settings, and the other conducted the test outdoors on the 30m walkway and in people with chronic stroke. Furthermore, only two studies used the standardized encouragement recommended in the ERS/ATS standard, but one was conducted on a rectangular walkway that measured 42m long and did not report retest interval or 95% CI, while the other did not report on the provision of physical assistance. No studies included people with aphasia, and retest interval ranged from 30 minutes to 7 days.

The seven studies also evaluated measurement error in the 6MWT and MDC values ranged from 33.0m to 64.3m. However, the same issues mentioned apply; varied adherence to recommended test instructions or walkway shape, length, and location, largely evaluating people with chronic stroke, no provision of physical assistance to walk, and not including instructions for people with aphasia.

**Table 2.2 Test-retest reliability and measurement error of the 6MWT**

<table>
<thead>
<tr>
<th>First Author, Year</th>
<th>Phase of Stroke Recovery</th>
<th>Walk Test and Protocol</th>
<th>Retest Interval (days)</th>
<th>N</th>
<th>ICC (95% CI)</th>
<th>MDC&lt;sub&gt;95&lt;/sub&gt; (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulk, 2009&lt;sup&gt;26&lt;/sup&gt;</td>
<td>Acute/Subacute</td>
<td>46/76, oval, indoor</td>
<td>No, Yes</td>
<td>1-3</td>
<td>37</td>
<td>0.97 (0.92-0.99)</td>
</tr>
<tr>
<td>Liu, 2008&lt;sup&gt;27&lt;/sup&gt;</td>
<td>Subacute/Chronic</td>
<td>20, straight, indoor</td>
<td>Yes (30s), No&lt;sup&gt;a&lt;/sup&gt;</td>
<td>30min</td>
<td>83</td>
<td>0.98 (0.97-0.99)</td>
</tr>
<tr>
<td>Eng, 2004&lt;sup&gt;99&lt;/sup&gt;</td>
<td>Chronic</td>
<td>42, rectangle, indoor</td>
<td>Yes (ATS), No&lt;sup&gt;a&lt;/sup&gt;</td>
<td>NR</td>
<td>12</td>
<td>0.90 (NR)</td>
</tr>
<tr>
<td>Flansbjer, 2005&lt;sup&gt;24&lt;/sup&gt;</td>
<td>Chronic</td>
<td>30, straight, indoor</td>
<td>No (3min), No&lt;sup&gt;a&lt;/sup&gt;</td>
<td>7</td>
<td>50</td>
<td>0.99 (0.98-0.99)</td>
</tr>
</tbody>
</table>
Performance on the 10mWT and 6MWT have been shown to correlate with several measures of functioning and activity post-stroke. Comfortable gait speed on the 10mWT has been shown to correlate with constructs including mobility, balance, balance self-efficacy, lower limb strength, participation, physical activity, aerobic capacity, and walking speed and walking distance. Walk distance from the 6MWT has also been shown to correlate with several constructs such as mobility, balance, balance self-efficacy, aerobic capacity, lower limb motor function, lower limb strength, participation, physical activity, self-report extremity strength, health-related quality of life, walking ability, and walking speed and walking distance.

Three studies in the literature have evaluated construct validity using both the 10mWT and 6MWT (Table 2.3). Correlation values were high and ranged from 0.84 to 0.91 and evaluated people with acute, subacute, and chronic stroke. However, one study did not use the recommended encouragement timing, one study allowed the provision of physical assistance but only for the 6MWT and used a 20m walkway length, and none included people with aphasia.

Table 2.3 Construct validity – correlations between 10mWT with 6MWT

<table>
<thead>
<tr>
<th>First Author, Year</th>
<th>Phase of Stroke Recovery</th>
<th>6MWT Protocol</th>
<th>N</th>
<th>Pearson’s r (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Length (m), Shape, Location</strong></td>
<td><strong>Encouragement (timing)</strong></td>
<td><strong>Assist (10mWT, 6MWT)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kelly, 2003(^{32})</td>
<td>Acute/Subacute</td>
<td>20, straight, indoor</td>
<td>Yes (ATS)</td>
<td>No, Yes</td>
</tr>
<tr>
<td>Flansbjer, 2005(^{24})</td>
<td>Subacute/Chronic</td>
<td>30, straight, indoor</td>
<td>Yes (3min)</td>
<td>No, No</td>
</tr>
</tbody>
</table>
Lower limb strength is required for walking ability and has been evaluated as a construct for construct validity with the 10mWT and 6MWT. Five studies using dynamometry, a measure of force produced by a muscle or group of muscles, found correlations with performance on the 10mWT (Table 2.4). These values ranged from 0.31 to 0.75,\(^{33-37}\) reflecting moderate correlations.\(^{119}\) One study evaluated performance on the 6MWT with scores on the strength subscale of the Stroke Impact Scale (SIS)\(^ {38}\) (SIS strength), a self-report measure of upper and lower extremity strength, and reported a correlation value of 0.52 (p<0.01),\(^ {39}\) reflecting a moderate relationship.\(^ {119}\)

### Table 2.4 Construct validity – correlations between 10mWT and dynamometer strength

<table>
<thead>
<tr>
<th>First Author, Year</th>
<th>Phase of Stroke Recovery</th>
<th>N</th>
<th>Construct (strength)</th>
<th>Pearson’s r (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severinsen, 2011(^ {33})</td>
<td>Subacute</td>
<td>48</td>
<td>Knee extension</td>
<td>0.31 (p&lt;0.05)</td>
</tr>
<tr>
<td>Eng, 2002(^ {34})</td>
<td>Chronic</td>
<td>25</td>
<td>Plantarflexion</td>
<td>0.54 (p&lt;0.01)</td>
</tr>
<tr>
<td>Flansbjer, 2006(^ {35})</td>
<td>Chronic</td>
<td>50</td>
<td>Knee flexion</td>
<td>0.61 (p&lt;0.01)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Knee extension</td>
<td>0.61 (p&lt;0.01)</td>
</tr>
<tr>
<td>Liu-Ambrose, 2011(^ {36})</td>
<td>Chronic</td>
<td>63</td>
<td>Quadriceps</td>
<td>0.35 (p&lt;0.01)</td>
</tr>
<tr>
<td>Nasciutti-Prudente, 2009(^ {37})</td>
<td>Chronic</td>
<td>12</td>
<td>Knee flexion</td>
<td>0.8 (p&lt;0.05)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Knee extension</td>
<td>0.34 (NR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hip flexors</td>
<td>0.75 (p&lt;0.05)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hip extensors</td>
<td>0.53 (NR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ankle dorsiflexors</td>
<td>0.5 (NR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ankle plantarflexors</td>
<td>0.58 (p&lt;0.05)</td>
</tr>
</tbody>
</table>

Abbreviations: N = sample size; NR = not reported.

Overall, there is some evidence of test-retest reliability, measurement error, and construct validity for both the 10mWT and 6MWT, but various factors limit their current use.

### 2.6 Rationale

Despite the importance of walking function and support for using the 10mWT and 6MWT in rehabilitation, these tests are not widely used in assessing people with stroke. One Canadian study has found that only an estimated 11% and 32% of physical therapists use the 6MWT and a measure of gait speed, respectively, in people after stroke,\(^ {40}\) while another conducted in the Netherlands reported that 44% of PTs use the 10mWT.\(^ {120}\) Relatedly, a
systematic review has reported that self-paced gait speed tests (such as the 10mWT) were the most frequently used clinical outcome measure of walking ability in stroke research. Several reasons may explain the limited use of these tests in clinical practice, including 1) insufficient research on reliability and validity in populations at different phases of stroke recovery, 2) variation in test protocols, 3) lack of aphasia instructions, and limited provision of assistance to walk, and 4) limited accessibility of the recommended 6MWT walkway distance.

First, given how reliability and validity of tests influence their selection by PTs, one major factor limiting use of the 10mWT and 6MWT is the insufficient research supporting their reliability and validity in the acute and subacute stroke population. As discussed, the majority of studies evaluating the test-reliability and construct validity of both the 10mWT and 6MWT studied people in the chronic phase of stroke (Tables 2.1, 2.2). It is important to thoroughly evaluate these tests across all phases of stroke recovery as walking ability is known to change over time and as mentioned, many people undergo rehabilitation and therefore require useful assessment tools of walking ability during the early phases of stroke. Furthermore, important factors that influence mobility such as fatigue have also been found to vary across the time course of stroke recovery.

Second, current protocols for the 10mWT and 6MWT vary, making it difficult for clinicians to know which protocol to choose for use in people post-stroke. Only two studies on test-retest reliability assessed the 10mWT protocol recommended by the Dutch clinical guidelines, and another used the original protocol, which required participants to walk along a 5m twice. Only three test-retest reliability studies for the 6MWT used the recommended straight 30m walkway with one conducted outdoors, while all others used different walkway lengths (varying from 20m to 200m), different walkway shapes (oval, rectangle, and an unreported shape of a 200m track), and only two studies used the standardized encouragement outlined by the ERS/ATS. These variations affect the ability to select these tests as it has been found that different walkway lengths and instructions are known to affect 6MWT performance. Walkway shape has not been investigated but can be expected to also affect walk performance as the number and tightness of turns will differ from those in the standard protocol. The varying test protocols of the 10mWT and 6MWT also limits the ability of researchers and clinicians to compare walk performance across settings. These variations further illustrate how currently used protocols are not meeting the needs of the people that use them.
Third, validated protocols for administering both tests are limited by the fact that they lack instructions for use in patients with aphasia and do not allow for physical assistance from the evaluator during walking. These limitations affect the applicability to many people with stroke, including those with communication deficits and more severe walking difficulties. It is particularly important to accommodate these two subgroups of people with stroke as rates of aphasia post-stroke have been reported to range from 18% to 38%, and half of people with limited walking ability post-stroke are unable to walk even with physical assistance. In particular, the Canadian Best Practice Recommendations highlight the need to adapt instructions for standardized assessment tools for use with people with aphasia. The provision of physical assistance during tests was not included in any test-retest reliability studies of the 10mWT and only two studies of the 6MWT, though other issues were present in those studies. One study investigating the construct validity of the 10mWT and 6MWT included assistance for the 6MWT, but not the 10mWT, while no study evaluating validity of the 10mWT with dynamometer strength or 6MWT with SIS strength provided physical assistance. None of the studies on reliability or validity mention any use of instructions for walk tests for patients with aphasia.

Lastly, clinical use of the 6MWT has been limited by the recommended 30-metre walkway as many hospital settings do not have access to the physical space needed to accommodate this walkway length. The wide variations in 6MWT walkway length and shape in studies on test-retest reliability helps illustrate how current standards are not feasible to conduct in many settings. One study has previously used a 15m walkway length to conduct the 6MWT, though validity and reliability has not been evaluated in the test using this length. A systematic review of varying 6MWT protocols found that many studies reduced the recommended 30m walkway length, but there was no significant difference in distance walked between the 30m walkway and shorter walkway lengths.

Given the limitations of the use of the 10mWT and 6MWT, research has yielded standardized protocols that permit assistance from one person to walk during these walk tests, and include pictorial instructions for use in people with aphasia, but measurement properties have yet to be evaluated. As well, current validated walk test protocols are not feasible to use in many hospitals as they require long walkway lengths, and support for use of the two walk tests is needed in the acute and subacute phase of stroke recovery. There is a need to investigate test-
retest reliability to describe consistency of repeated use of the tests; measurement error to gauge the difference between measured values and true values; and construct validity to describe the accuracy of the walk tests. Therefore, the objectives of this research are to estimate the:

1. Test-retest reliability;

2. Measurement error; and

3. Construct validity of stroke-specific protocols for the 10-metre walk test (10mWT), 6-minute walk test conducted using a 15-metre walkway (6MWT\textsubscript{15m}), and a 30-metre walkway (6MWT\textsubscript{30m}) in ambulatory people with acute, subacute, and chronic stroke.

The COSMIN\textsuperscript{48} is an accepted standard in measurement research and was used to guide planning of investigating these measurement properties. The COSMIN checklist manual\textsuperscript{135} was used in the selection of the test-retest interval, testing location and time, reporting of ICC and MDC, and formulation of specific hypotheses of expected correlation values (see Appendix A).

By addressing the limitations in the current literature, this study will facilitate its use in clinical settings and improve patient education about their current walking ability.
Chapter 3
Validation of stroke-specific protocols to enhance the clinical utility of the 10-metre walk test and 6-minute walk tests in people with acute, subacute, and chronic stroke

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Note: This manuscript is in British English. Detailed descriptions of the methods used in the scoping review are presented beyond what would be expected in a manuscript submitted for publication
3 Validation of stroke-specific protocols to enhance the clinical utility of the 10-metre and 6-minute walk tests in people with acute, subacute, and chronic stroke

**Background:** Standardized stroke-specific walk test protocols have been developed and include aphasia instructions and allow provision of assistance to walk, but test-retest reliability, measurement error, and construct validity have yet to be evaluated. Current protocols also require long walkway lengths that are inaccessible in many settings.

**Objectives:** To estimate the 1) test-retest reliability, 2) measurement error, and 3) construct validity of stroke-specific protocols for the 10-metre walk test (10mWT), and 6-minute walk test conducted using a 15-metre walkway (6MWT$_{15m}$) and a 30-metre walkway (6MWT$_{30m}$), in ambulatory people with acute, subacute, and chronic stroke.

**Methods:** A quantitative, cross-sectional study of people post-stroke was conducted.

**Results:** Data from 17 participants were collected. Median age was 61 years, 88% experienced an ischemic stroke, and median time post-stroke was 134 days. Performance on the 10mWT, 6MWT$_{15m}$, and 6MWT$_{30m}$ during two sessions, yielded intraclass correlation coefficient (ICC$_{2,1}$) values of 0.75, 0.97, 0.94, respectively, and minimal detectable change (MDC$_{95}$) values of 0.45 m/s, 43.1 m, and 58.8 m, respectively. Pearson correlation coefficients ranged from 0.70 to 0.93 \((p<0.005)\) between the three walk tests and ranged from 0.17 to 0.39 \((p>0.05)\) between each test and limb strength measured using the Stroke Impact Scale strength subscale (SIS strength).

**Conclusions:** Findings showed excellent test-retest reliability for all three test protocols, measurement error values similar to current literature, and partial support for construct validity. Future studies are required to investigate a larger sample of people with a broader range of post-stroke deficits, and possible practice effects in the 6MWT$_{30m}$.

**Keywords (7):** Stroke; Walk test; Gait speed; Walking capacity; Reliability; Measurement error; Validity
3.1 Introduction

Annually, stroke affects approximately 15 million people worldwide, resulting in five million deaths and five million people with permanent disability. Two thirds of people with stroke have limited walking ability, and half are unable to walk even with physical assistance. As a result, assessing and improving walking is a key objective in stroke rehabilitation especially in the first several weeks post-stroke. Following acute care, more than 30% of individuals are discharged into inpatient rehabilitation, and nearly 19% are discharged home with services like outpatient rehabilitation. Given these data, many people undergo rehabilitation while in the early phases of stroke recovery which are of the acute (<1 month post-stroke) and subacute (1-6 months post-stroke) phases. Use of standardized assessment tools in stroke rehabilitation is considered a best practice as their use allows comparison of scores within patients, and between patients across settings. A standardized assessment tool is used to assess a person’s current ability and track changes in health status and performance. The opportunity to compare scores allows clinicians to detect changes in performance, allowing them to determine when patients are ready for discharge and the type of rehabilitation setting that is most appropriate. The Canadian Stroke Best Practice Recommendations are to use standardized assessment tools that are valid and reliable in assessing patient’s stroke-related impairments and functional status. International post-stroke physical therapy guidelines recommend the use of the 6MWT and 10mWT for assessing gait in post-stroke rehabilitation. These tests have been shown to capture change resulting from treatment interventions recommended in stroke rehabilitation, such as task-oriented, treadmill, and aerobic training.

Reliability and validity of the 6MWT and 10mWT have been evaluated repeatedly in the current literature. The test-retest reliability of the 10mWT has been evaluated in people in the chronic phase of stroke recovery (>6 months post-stroke) and has reported ICC values ranging from 0.94 to 0.96, but did not allow for physical assistance. Literature on the test-retest reliability of the 6MWT reported slightly higher ICC values, testing acute, subacute, and chronic phases of stroke, and ranged from 0.97 to 0.99. Test-retest intervals used in studies that evaluated test-retest reliability of gait speed tests and the 6MWT in subacute and acute stroke ranged from 1-3 days. Measurement error has been reported in the literature as MDC and ranged from 0.18m/s - 0.36m/s and 39m-50.2m for the 10mWT and 6MWT, respectively. Performance on the 10mWT and 6MWT have been shown to correlate with each
other in people with subacute stroke as well as other measures of body functions post-stroke. Construct validity of the 6MWT has been examined with gait speed tests as constructs and correlation values ranged from 0.84 to 0.91.\textsuperscript{24,26,31,32} Limb strength measured using dynamometry has found to correlate with performance on the 10mWT, with values ranging from 0.31 to 0.75,\textsuperscript{33-37} though no studies have looked at correlations between the 10mWT and the strength subscale of the Stroke Impact Scale.\textsuperscript{38} Distance walked on the 6MWT has been correlated with several constructs including aerobic capacity, mobility, balance self-efficacy, motor function, physical activity, strength of lower extremity, and health-related quality of life (both comfortable and fast).\textsuperscript{41} In particular, performance on the 6MWT has been correlated with scores on the SIS strength with a value of 0.52.\textsuperscript{39}

Despite the importance of walking function and support for using the 10mWT and 6MWT, these tests are not widely used in assessing people after stroke. Only an estimated 11% and 32% of physical therapists (PT) use the 6MWT and a measure of gait speed, respectively, in people with stroke.\textsuperscript{40} Several factors limit the use of these recommended tests. First, reliability and validity of tests influence their selection by PTs,\textsuperscript{12} and there is insufficient research supporting their reliability and validity in the acute and subacute stroke populations.\textsuperscript{41} Second, current protocols for the 10mWT and 6MWT vary in walkway length, shape, location, and instructions.\textsuperscript{41-43} Variations in protocols make it difficult for clinicians to know which protocol to use with people post-stroke and studies have shown that differences in walkway length\textsuperscript{44} and instructions\textsuperscript{45} affect performance on the 6MWT. Third, validated protocols for administering both tests are of limited use in the stroke population as they do not allow for physical assistance from the evaluator during walking and do not include instructions for use in patients with aphasia.\textsuperscript{46} Lastly, clinical use of the 6MWT has been limited by the recommended 30-metre (m) walkway, as many hospital settings do not have access to the physical space needed to accommodate this length\textsuperscript{46} and use is affected by feasibility of administration.\textsuperscript{41} One study has previously used a 15-m walkway length to conduct the 6MWT,\textsuperscript{134} though validity and reliability has not been evaluated in the test using this length.

To address some of these limitations, research has yielded standardized protocols for these walk tests that permit assistance from one person to walk and include pictorial instructions for use in people with aphasia,\textsuperscript{47} but measurement properties have yet to be evaluated. There is a need to investigate test-retest reliability to describe consistency of repeated use of the tests;
measurement error to gauge the difference between measured values and true values; and construct validity to describe the accuracy of the walk tests. The Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) provides guidance for the investigation of these measurement properties.

There is a lack of standardized protocols in the current literature, which has led to the use of varied walk test protocols untested for reliability and validity. Current validated walk test protocols are not feasible to use in many hospitals as they require long walkway lengths, do not allow the evaluator to provide physical assistance to walk, and lack instructions for patients with aphasia. Evidence of reliability and validity of stroke-specific protocols for the 10mWT and the 6MWT has primarily been found in people with chronic stroke and is needed in early phases of recovery post-stroke. The recently developed protocols are the first stroke-specific standardized guidelines for the 10mWT and 6MWT. By addressing these limitations in the current literature, this study will facilitate use of these walk tests in clinical settings.

Thus, the objectives of this study were to estimate the test-retest reliability, measurement error, and construct validity of stroke-specific protocols for the 10mWT, 6MWT conducted using a 15m walkway length (6MWT_{15m}), and 6MWT conducted using a 30m walkway length (6MWT_{30m}), in ambulatory people with acute, subacute, and chronic stroke.

For construct validity, a priori hypotheses were that:

- performance on the 10mWT will correlate highly \((r>0.75)^{119}\) with distance walked on the 6MWT_{15m} and 6MWT_{30m};
- performance on the 6MWT_{15m} and 6MWT_{30m} will correlate highly \((r>0.75)^{119}\) with each other;
- 10mWT, 6MWT_{30m}, and 6MWT_{15m} performance will correlate moderately \((r=0.50-0.75)^{119}\) with upper and lower extremity strength measured by the strength subscale of the Stroke Impact Scale.\(^{119}\)
3.2 Methods

3.2.1 Study design

A quantitative cross-sectional study was conducted. The COSMIN\(^{48}\) was used to guide planning of study methodology (see Appendix A for completed COSMIN checklists). The Mount Sinai Health System Research Ethics Board, Joint West Park Healthcare Centre/Toronto Central CCAC/Toronto Grace Health Centre Research Ethics Board, and the University of Toronto, Office of Research Ethics approved the study protocol.

3.2.2 Participants and sampling

The target population was ambulatory people with stroke-related gait deficits in the acute, subacute, and chronic phases of recovery.

Inclusion criteria were: 1) diagnosis of stroke (either ischemic or hemorrhagic) as confirmed by the referring PT; 2) age $\geq$ 18 years; 3) stroke-related gait deficits (e.g. coordination deficits) in the judgment of the referring PT; 4) ability to walk 14 metres, with or without ambulatory aids and orthoses, independently or with no more than minimal physical assistance of one person in the judgment of the referring PT; 5) expected length of stay of at least two weeks in the judgment of the referring PT in order to feasibly complete screening, consent, and assessment (for inpatients); and 6) ability to understand English. For inclusion criterion 4, physical assistance included providing manual support at the waist, but not advancing the lower limb or supporting the lower limb in stance phase to avoid knee buckling.

Exclusion criteria were: 1) diagnosis of any absolute contraindications to 6MWT administration that increase risk of negative health events during the 6MWT, as documented in the health record and confirmed by the referring PT; 2) cognitive deficits or severe receptive aphasia limiting ability to provide informed consent and understand test instructions in judgment of the referring PT; and 3) lower limb amputation. Absolute contraindications to 6MWT administration included: myocardial infarction within 3-5 days; unstable angina; uncontrolled arrhythmias causing symptoms or haemodynamic compromise; syncope; active endocarditis; acute myocarditis or pericarditis; symptomatic severe aortic stenosis; uncontrolled heart failure; acute pulmonary embolus or pulmonary infarction; thrombosis of lower extremities; suspected dissecting aneurysm; uncontrolled asthma; pulmonary edema; oxygen saturation $\leq$85% on room
air at rest; acute respiratory failure; acute non-cardiopulmonary disorder that may affect exercise performance or be aggravated by exercise (i.e. infection, renal failure, thyrotoxicosis); mental impairment leading to inability to cooperate.46

3.2.2.1 Recruitment

Study participants were recruited from two rehabilitation hospitals with inpatient and outpatient services. PTs working in inpatient and outpatient programs identified potentially eligible participants, introduced them to the study, and provided them with a study brochure. PTs obtained written or verbal permission to be contacted by the graduate student (author DKC) from patients who were interested in the study and recorded relevant contact information. Patients were contacted and screened for eligibility. Eligible patients were provided with a consent form and written informed consent was obtained at first visit. Two evaluations were scheduled at times that were convenient for the participant. If the participant had conditions that were relative contraindications to conducting the 6MWT (adapted from Holland et.al.46), approval to conduct the 6MWT would be obtained from the patient’s physician or physical therapist prior to the evaluations.

3.2.3 Data collection

3.2.3.1 Evaluations

Two evaluations were conducted, time 1 and time 2, each lasting approximately 1 hour and scheduled 2-3 days apart in the same testing location. To minimize sources of random error, evaluations were scheduled at a similar time of day for both evaluations to maintain comparable levels of fatigue. The location was an uncluttered hospital corridor that accommodated a 30m straight walkway. Participants were instructed to wear comfortable clothes, supportive footwear, and usual eyewear, and to use the same assistive device and/or orthotics at both evaluations. The evaluator was trained by a physical therapist to conduct the 10mWT and 6MWT and was first aid and CPR certified. At each evaluation, participants performed 3 walk tests: the 10mWT, 6MWT15m, and 6MWT30m. The walk tests were conducted in a random order determined by drawing lots at the first assessment and maintaining the same order at the time 2. Test order was randomized to mitigate systematic effects of fatigue on tests performed last. Heart rate (HR) and blood pressure (BP) were measured before the 6MWT to ensure there were no relative contraindications to completing the test. A physician or PT was consulted if the participant
exhibited relative contraindications to completing the 6MWT, including tachycardia (resting HR > 120 bpm), bradycardia (resting HR < 60 bpm), or stage 2 hypertension (resting systolic BP ≥ 160 mmHg or resting diastolic BP ≥ 100 mm Hg). Participants rested for a minimum of 15 minutes after each 6MWT or until HR returned to baseline. A rest period of 5 minutes was provided after the 10mWT. At time 1, the participant provided information on socio-demographic and stroke characteristics (age, sex, level of education, setting (i.e., inpatient or outpatient), time post-stroke, type and side of stroke, comorbidities, usual use of assistive devices and orthotics) and completed the 4-item SIS strength scale during one of the 15-minute rest periods. Physical assistance required, type of walking device or orthosis used, and type of shoes worn were also recorded at both evaluations.

3.2.3.2 Measurement

The 10mWT was used to measure comfortable walking speed over 10m. Tape was placed on the floor at 0m, 2m, 12m, and 14m, to mark the start point, 2m acceleration distance, 10m test distance, 2m deceleration distance, and end point. A bright orange pylon was placed at the end of the walkway. Instructions to walk at a comfortable speed was given. Walking was timed using a digital stopwatch (Sportline 480 Tough Timer WV4413RE, Sportline Inc.) when the participant’s first foot crossed the 2-m mark and stopped when the first foot crossed the 12-m mark, though the participant continued to walk to the pylon at the 14-m mark. No encouragement was given during the test. Comfortable walking speed (m/s) was calculated by dividing 10m by the time in seconds taken to walk 10m (see Appendix B, Supplemental File 3.1 for the detailed 10mWT protocol including set-up and test instructions).

The 6MWT<sub>15m</sub> and 6MWT<sub>30m</sub> were used to measure functional walking ability. HR and BP were measured before conducting the tests to screen for relative contraindications. Tape was placed on the wall of the hallway to mark every metre along the walkway. Bright orange pylons were placed just inside the two end points. Participants were instructed to walk between the pylons for 6 minutes and to cover the maximum distance possible. The test was timed using a digital stopwatch (Sportline 480 Tough Timer WV4413RE, Sportline Inc.) and a mechanical lap counter used to count number of lengths walked. Standardized phrases of encouragement were provided at each minute. The spot where the participant stopped at the end of 6 minutes was marked with a bean bag or piece of tape and the final partial distance was measured (rounded to
the nearest centimetre) using a measuring tape. The total 6MWT distance was calculated by multiplying the number of lengths walked by the walkway length (15m or 30m) and adding the partial distance (see Appendix B, Supplemental File 3.2 for the detailed 6MWT protocol including set-up and test instructions).

**Methods applicable to 10mWT and 6MWTs:** Pictorial versions of 10mWT and 6MWT instructions were developed for use with people with aphasia (Supplemental Files 3.1 and 3.2). The evaluator walked on the affected side of the participant and slightly behind so as not to pace the participant during the test. Physical assistance was provided if necessary for participants that could not walk independently. Participants wore a transfer belt if the referring PT felt that there was a risk for falls. Each test was completed once at each evaluation. Use of walking aids and orthoses, footwear, and usual eyewear at time 1 was recorded, and participants were asked to use them again at time 2.

The **SIS strength** is a 4-item subscale in the self-report Stroke Impact Scale\(^{38}\) which has been validated in the stroke population.\(^{136}\) Items ask about strength of the upper and lower limb most effected by stroke in the past week. Item A, B, C, and D score the strength of the arm, hand grip, leg, and foot/ankle, respectively. Each item is scored on a scale from 1 to 5 where 1 indicates no strength at all and 5 indicates a lot of strength. Scores were summed and transformed to a score out of 100, where a higher score indicates greater strength.\(^{38}\)

The **Physical Assistance Rating** was taken using the FIM locomotion scale.\(^{137}\) This scale measures level of physical assistance needed by participants based primarily on amount of help given by evaluator or use of walking aids. A score of 1 indicates total dependence and an inability to complete the walk tests, and 7 indicates total walking independence without a need for walking aids.

**3.2.4 Sample Size**

An estimated sample size of 32 participants was required for this study. For test-retest reliability, to obtain an expected ICC point estimate of 0.85 for each test, with a width of the lower 95% confidence interval (95% CI) of 0.10, and two measurements per participant,\(^{138}\) 32 participants are required. For construct validity, to detect a correlation of ≥0.50 for estimating
relationships between constructs at a 2-sided Type I error of 0.05 and Type II error level of 0.20, 29 participants are required.

3.2.5 Statistical analysis

Analyses were completed using SPSS statistical software package (Version 21, IBM Corp). Descriptive statistics (i.e., frequency and percentages for categorical data; mean, standard deviation, and range for normally distributed continuous data; and median and interquartile range for non-normally distributed continuous data) were used to describe participant socio-demographic and clinical characteristics, walk test performance, and SIS strength scores. To estimate test-retest reliability of the 10mWT, 6MWT_{15m}, and 6MWT_{30m}, ICC: type 2:1^{138} (ICC_{2, 1}) estimates and their 95% CI were calculated based on an absolute-agreement, 2-way random model. The 95% CI is interpreted as the interval that will capture the true ICC value of the population 95% of the time when repeated random samples are drawn from the population. Estimates were interpreted as: perfect reliability (ICC=1), excellent reliability (ICC≥0.75); adequate reliability (ICC 0.4 to 0.74); and poor reliability (ICC<0.4).^{95} Measurement error was estimated using minimal detectable change at the 95% confidence level (MDC_{95}), interpreted as the amount of change beyond which 95% of true change values will be found, and was computed using the standard error of measurement (SEM) from the ICC value (see Appendix C for equations).^{139} A Bland-Altman plot of the difference (y-axis) vs the mean (x-axis) of the test and re-test performances with limits of agreement were constructed for the 10mWT, 6MWT_{30m}, and 6MWT_{15m} to examine whether the extent of agreement between test and retest performance for each of the three walk tests varied by severity of walking deficit.^{140} Individual change lying beyond the limits of agreement were considered extreme. Pearson correlations were used to test the hypotheses for construct validity if normality of the data was established; otherwise Spearman correlations were used. Correlations were examined between walk test performance (on the 10mWT and two 6MWTs) and SIS strength scores at a two-sided alpha value of 0.05. Correlations was interpreted as poor (r<0.25), fair (0.25≤r<0.5), moderately (r=0.50-0.75), or high (r>0.75).^{119}

3.3 Results

Of the 34 patients referred to the study, 25 (74%) were eligible and of these, 17 (68%) agreed to participate, 7 (41%) from inpatient and 10 (59%) from outpatient programs. Of the 17
study participants, 1 (6%) did not complete the retest evaluation so their data was only included in participant characteristics and correlation analyses. Sociodemographic and clinical characteristics of the study participants are presented in Table 3.1. No participants required the use of ankle-foot orthoses, no relative contraindications to completing the 6MWT were present, and all evaluations were completed 2-3 days apart. Descriptive statistics on walk test performance are presented in Table 3.2. A time 1, 3 participants exhibited difficulty in following instructions (i.e. talking during the test, veering off track) during the 6MWT_{30m} and 6MWT_{15m}. In contrast, no participants demonstrated these behaviours during retest. At time 1, 7 participants voluntarily reported that they had never performed any of the 3 tests before.

3.3.1 Test-retest reliability and measurement error

The magnitudes of test-retest reliability for the 10mWT, 6MWT_{15m}, and 6MWT_{30m} estimated using the ICC_{2,1} (95% CI) were 0.75 (0.42-0.91), 0.97 (0.91-0.99), and 0.94 (0.85-0.98), respectively (Table 3.2). SEM and MDC_{95} values are also presented in Table 3.2. Bland-Altman plots for the 10mWT, 6mWT_{15m}, and 6mWT_{30m} (Figure 1a-c) showed no apparent pattern between performance means and differences at the individual level and did not support agreement based on severity of walking deficit. There were 2, 0, and 1 extreme change scores lying beyond the limits of agreement for the 10mWT, 6mWT_{15m}, and 6mWT_{30m}, respectively. Additionally, it was noted that 12, 10, and 13 participants increased their performance on the 10mWT, 6MWT_{15m}, and 6MWT_{30m}, respectively, from time 1 to time 2, indicating the possible presence of a practice effect in these individuals. Thus, post hoc analyses were completed, with Pearson correlations computed for data collected at time 2 when all participants would have become familiar with the tests (Table 3.3), and overall walk speed on the 6MWTs calculated for both time 1 and time 2 to further aid in comparisons between performance from time 1 to time 2 (Table 3.2).

3.3.2 Construct validity

Based on data from time 1, significant correlations were found between the 10mWT and 6MWT_{15m} (r=0.70, p=0.002), 10mWT and 6MWT_{30m} (r=0.72, p=0.001), and 6MWT_{15m} and 6MWT_{30m} (r=0.925, p=0.000), while correlations between the 10mWT, 6MWT_{15m}, and 6MWT_{30m} and the SIS strength were not significant (r=0.17, p=0.516; r=0.28, p=0.274; and r=0.39, p=0.120, respectively) (Table 3.3).
3.4 Discussion

This study evaluated the test-reliability, measurement error, and construct validity of novel stroke-specific protocols for the 10mWT, 6MWT\textsubscript{15m}, and 6MWT\textsubscript{30m} in adults with acute, subacute, and chronic stroke. Point estimates of test-retest reliability for all walk tests demonstrated excellent reliability while the lower limits of the 95% CIs for point estimates of test-retest reliability were adequate for the 10mWT, and excellent for the 6MWT\textsubscript{15m} and 6MWT\textsubscript{30m}.\textsuperscript{95} The MDC\textsubscript{95} values for the 10mWT, 6MWT\textsubscript{15m}, and 6MWT\textsubscript{30m} indicated that a person with stroke must exhibit a change of 0.45m/s, 43.1m, and 58.8m, respectively, for the change to be considered true change and beyond the limits of measurement error. Support for construct validity was limited as correlation values were lower than hypothesized and only supported the hypothesis of excellent correlation between the 6MWT\textsubscript{15m} and 6MWT\textsubscript{30m}. A sample size of 16 was obtained and allowed the detection of a Pearson correlation of 0.65 at a 2-sided type I error of 0.05 and type II error level of 0.20. The limited evidence supporting the validity of these tests means further investigation is required.

The magnitude of the test-retest reliability estimates for the 10mWT were lower than those found in two previous studies, which reported ICC\textsubscript{2, 1} (95% CI) of 0.94 (0.90-0.97)\textsuperscript{24} and 0.96 (0.92-0.98).\textsuperscript{25} Only individuals with chronic stroke were previously evaluated and later phases of stroke recovery are associated with more stable walking ability compared to earlier phases.\textsuperscript{123,124} Thus the lower reliability estimates for the 10mWT may be explained by the variability of walking in earlier phases of stroke recovery included in this study. The findings from the 6MWT\textsubscript{15m} were similar to a previous study that conducted the 6MWT on a 20m walkway, which found ICC\textsubscript{2, 1} (95% CI) to be 0.98 (0.97-0.99),\textsuperscript{27} while estimates for the 6MWT\textsubscript{30m} were similar to studies that conducted the test on the recommended 30m walkway indoors, with estimates of 0.98 (0.94-0.99)\textsuperscript{98} and 0.99 (0.98-0.99).\textsuperscript{24} The similarity of estimates for the 6MWT to the current literature may have been due to the test duration requiring participants to walk for 6-minutes, a duration in which walk speed is likely to plateau\textsuperscript{18} which may help to minimize variability between test and retest. The Bland-Altman plots showed that agreement did not appear to vary by severity of walking deficit for any of the walk tests. The plots also presented 2 and 1 extreme values for the 10mWT and 6MWT\textsubscript{30m}, respectively, which may have contributed to the lower value of the lower limit of the 95% CI when compared to previous studies.
The MDC$_{95}$ for the 10mWT was larger than the values of 0.18$^{25}$ and 0.19$^{24}$ reported in the previous studies on the 10mWT, and also larger than values found from other similar gait speed tests that ranged from 0.11m/s$^{97}$ to 0.31m/s$^{29}$. Values for the 6mWT$_{15m}$ and 6mWT$_{30m}$ fell within the range of values found previously, ranging from 33.0m to 64.3m$^{24,26-28,30,98,99}$. The MDC$_{95}$ was calculated from the ICC$_{2,1}$ point-estimate of a small sample size, which has limited accuracy and may have contributed to the relatively large MDC values for the 10mWT. When comparing individual change scores to MDC$_{95}$ values of 0.31m/s for the 10mWT and 64.3m for the 6MWT, 2, 0, and 2 participants exhibited change beyond the level of measurement error for the 10mWT, 6MWT$_{15m}$, and 6MWT$_{30m}$, respectively. Since few individual change scores exceeded current MDC$_{95}$ values, it is likely that change in performance for most participants was due to random error or variability between tests 1 and 2.

For construct validity, correlation values based on walk test protocols with no practice trial varied. The 6MWT$_{15m}$ and 6MWT$_{30m}$ correlated highly with each other, moderately with the 10mWT, and fairly with SIS strength, while the 10mWT did not correlate with SIS strength.$^{119}$ Since one hypothesis for the 6MWTs and none for the 10mWT were supported, the construct validity for the three walk tests was partially supported. Correlation values between the 6MWTs and 10mWT were lower than those found previously in people with acute, subacute, and chronic stroke, which ranged from 0.84 to 0.91$^{31,32,35}$. A high correlation between the 6MWT$_{15m}$ and 6MWT$_{30m}$ was expected as both tests evaluate walking capacity based on distance walked in six minutes. The correlation value between the 10mWT and SIS strength was much lower than the values found in previous studies that evaluated correlation of the 10mWT with direct measures of lower limb strength, ranging from 0.31 to 0.8$^{33-37}$ while correlations of 6MWTs and SIS strength were lower than the value of 0.52 found in a previous study.$^{39}$ The most likely contributor to the low correlation values between walk tests and the SIS strength was the low variability of the SIS strength observed in this study, with larger mean and smaller standard deviation than the values previously reported.$^{39}$ Additionally, mean values for the 10mWT speed were higher than those in previous studies, which ranged from 0.89m/s$^{24}$ to 0.51m/s$^{25}$. These findings indicated that the participants in this study were largely high-level walkers, which may have had an impact on correlation values. Furthermore, there were no previous studies correlating the 10mWT to SIS strength and only direct measures of dynamometry were used. This may have contributed to the differences in correlations found in this study as direct
measures may result in more accurate measures of limb strength compared to a self-report measure. The correlation values may also have been affected by the possible presence of practice effects.

Participants may have paced their walking more heavily at time 1 due to their unfamiliarity with the tests. Seven participants that voluntarily reported that they had not previously performed any of the walk tests. Based on post hoc analyses showing higher correlations between walk test performance on all three tests at time 2 compared to time 1, it is possible that there are practice effects when conducting these tests. These potential effects are also supported by gait speed values calculated for 6MWT performance at time 1 and 2, which showed that the mean 6MWT 30m speed and minimum and maximum values appeared to have shifted more than the value for the 6MWT 15m, though both were higher at time 2. This may suggest that the 6MWT 15m has less of a practice effect than the 6MWT 30m, which may be due in part to the increased number of turns required on the shorter walkway that may mitigate differences in pacing from time 1 to time 2. One previous study found no presence of a practice effect for the 6MWT conducted on a 20m walkway, while no studies have specifically looked at the presence of an effect in the 10mWT and 6MWT on a 15m or 30m walkway. It is also important to note that the previous study investigating the presence of a practice effect in the 6MWT only included individuals with chronic stroke, a phase during which patients are more likely to have learned how to effectively pace their walking over longer periods of time compared to people in the earlier phases who also tend to have lower levels of functioning. These findings indicate a need for further investigation into the possibility of practice effects, particularly in the 6MWT with shorter and longer walkway lengths and in people in the earlier phases of stroke recovery.

Other factors may have also influenced the differences in results of this study compared to the current literature. In particular, patients with acute, subacute, and chronic stroke were evaluated in this study when no past studies included participants from all three phases, with the majority focusing only on the chronic phase. It is important to thoroughly evaluate these tests across all phases of stroke recovery as walking ability is known to change, and important factors that influence mobility, such as fatigue, have also been found to vary across the time course of stroke recovery. No studies that evaluated the 10mWT allowed provision of physical assistance, while only two studies of the 6MWT did, though one was conducted outdoors and
the other used oval tracks. As well, no studies have included instructions for people with aphasia and none evaluated reliability or validity of the 6MWT on a 15m walkway. These differences in protocols and lack of people with aphasia or those requiring assistance to walk may have also affected results of this study.

3.4.1 Strengths and Limitations

In this study, possibly sources of error were minimized by controlling for several variables between the two evaluations including: time of day (within 1-hour difference), location, order of tests, type of clothing, type of footwear, use of glasses or contacts, type of walking aid used during tests, use of aphasia instructions, use of a transfer belt, and amount of physical assistance given. The short retest interval of 2-3 days was selected as it is similar to studies that evaluated walking speed and walking capacity in people with acute and subacute stroke (1-3 days) and is a period within which participants were unlikely to have improved. Furthermore, participants were recruited from settings in which the 10mWT and 6MWT would be most useful, supporting the application of study findings in clinical practice settings.

The desired sample size was not achieved due to challenges with recruitment. Due to the small sample size, it was inappropriate to divide participants into subgroups for further analysis, and the precision of the ICC estimates and MDC values for the 10mWT may have been affected. The lack of participants with aphasia and those walking at lower levels of functioning limits the ability to generalize these results to the broader population of people with stroke. Only 1 participant (6%) required a transfer belt and assistance to walk and 1 individual (6%) required use of pictorial aphasia instructions, and so the applicability to patients with aphasia after stroke and need for physical assistance was not thoroughly investigated. Possible sources of error that were not controlled for included participant distraction as tests were completed in hospital corridors with some foot traffic. No cognitive measures were used in this study and so the degree to which participants were able to understand and follow test instructions is unknown. Though not systematically collected, at time 1, some participants showed difficulty in following instructions (i.e. talking during the test, veering off track) but did not show these difficulties at time 2. It is possible that differences in understanding of test instructions may have contributed to improved walk test performance at time 2.
3.5 Conclusion

This study found evidence of excellent test-retest reliability of the 10mWT, 6MWT$_{15m}$, and 6MWT$_{30m}$, values of measurement error, and partial support for construct validity. This research was novel in that it evaluated reliability, measurement error, and validity of the first stroke-specific standardized protocols for the 10mWT and 6MWT in people with acute, subacute, and chronic stroke. As clinicians report using evidence of reliability and validity to support their selection of standardized assessment tools,$^{12}$ evidence supporting reliability and validity has the potential to influence clinicians’ decisions to utilise these recommended tests in a broader proportion of people with stroke and in more settings. Use of these tests allows detection of improvement and deterioration of walking ability during stroke rehabilitation and enable therapists to respond appropriately by maintaining or changing treatment.$^{20-23}$ Use of these tests can also help improve patient education about current walking ability, as walking speed relates to ability to walk in the community.$^{59}$

In future research, a larger sample size of individuals with a broader spectrum of stroke-related deficits, including people with aphasia and lower levels of walking that require physical assistance, is recommended to increase the generalizability of study findings. Future studies should also examine the need for a practice trial and evaluate construct validity using direct measures of lower limb function and balance.$^{34,104}$ The inclusion of cognitive measures would also provide more insight into how the degree of understanding may affect 10mWT and 6MWT performance.
**Table 3.1 Sociodemographic and Clinical Characteristics (n=17)**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age(^a) (years), median (P(<em>{25}) - P(</em>{75}))</td>
<td>61 (50- 73)</td>
</tr>
<tr>
<td>Time post-stroke (days), median (P(<em>{25}) - P(</em>{75}))</td>
<td>134 (44-243)</td>
</tr>
<tr>
<td>Height(^a) (m), mean ± SD (range)</td>
<td>1.68 ± 0.09 (1.48-1.83)</td>
</tr>
<tr>
<td>Body weight(^a) (kg), mean ± SD (range)</td>
<td>65.2 ± 8.2 (51.0-88.5)</td>
</tr>
<tr>
<td>Men, n (%)</td>
<td>10 (59)</td>
</tr>
<tr>
<td>Type of stroke(^a), n (%)</td>
<td></td>
</tr>
<tr>
<td>Ischemic</td>
<td>15 (88)</td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>2 (12)</td>
</tr>
<tr>
<td>Side of cerebral lesion(^a), n (%)</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>6 (35)</td>
</tr>
<tr>
<td>Right</td>
<td>8 (47)</td>
</tr>
<tr>
<td>Bilateral</td>
<td>3 (18)</td>
</tr>
<tr>
<td>Side of paresis(^a), n (%)</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>9 (53)</td>
</tr>
<tr>
<td>Right</td>
<td>6 (41)</td>
</tr>
<tr>
<td>Bilateral</td>
<td>1 (6)</td>
</tr>
<tr>
<td>Stroke acuity, n (%)</td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>6 (35)</td>
</tr>
<tr>
<td>Subacute</td>
<td>6 (35)</td>
</tr>
<tr>
<td>Chronic</td>
<td>5 (29)</td>
</tr>
<tr>
<td>Use of assistive device, n (%)</td>
<td></td>
</tr>
<tr>
<td>Walker (four-wheeled)</td>
<td>4 (23)</td>
</tr>
<tr>
<td>Cane (single-point)</td>
<td>3 (18)</td>
</tr>
<tr>
<td>None</td>
<td>10 (59)</td>
</tr>
<tr>
<td>Physical Assistance Rating(^b), n (%)</td>
<td></td>
</tr>
<tr>
<td>4 (Minimal contact assistance)</td>
<td>1 (6)</td>
</tr>
<tr>
<td>6 (Independent with device)</td>
<td>6 (35)</td>
</tr>
<tr>
<td>7 (Independent without device)</td>
<td>10 (59)</td>
</tr>
<tr>
<td>SIS strength, n (%)</td>
<td></td>
</tr>
<tr>
<td>Item a (arm, 1-5), median (P(<em>{25}) - P(</em>{75}))</td>
<td>3 (3-3.5)</td>
</tr>
<tr>
<td>Item b (hand grip, 1-5), mean ± SD (range)</td>
<td>3.27 ± 0.97 (1.5-5)</td>
</tr>
<tr>
<td>Item c (leg, 1-5), mean ± SD (range)</td>
<td>3.53 ± 0.717 (2-5)</td>
</tr>
<tr>
<td>Item d (foot/ankle, 1-5), mean ± SD (range)</td>
<td>3.59 ± 0.712 (2-5)</td>
</tr>
<tr>
<td>Total, mean ± SD (range)</td>
<td>67.79 ± 12.18 (45-90)</td>
</tr>
</tbody>
</table>

Abbreviations: P\(_{25}\)-P\(_{75}\) = 25\(^{th}\) and 75\(^{th}\) percentiles; SD = standard deviation, SIS = self-report Stroke Impact Scale strength subscale.

\(^a\)Self-reported values.

\(^b\)No participants were given ratings of 1, 2, 3, or 5.
Table 3.2 Performance, test-retest reliability, and measurement error (n=16)

<table>
<thead>
<tr>
<th>Test</th>
<th>Mean ± SD (Range)</th>
<th>ICC&lt;sub&gt;2, 1&lt;/sub&gt; (95% CI)</th>
<th>SEM</th>
<th>MDC&lt;sub&gt;95&lt;/sub&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>10mWT (m)</td>
<td>0.99 ± 0.32 (0.50-1.57)</td>
<td>1.02 ± 0.32 (0.54-1.63)</td>
<td>0.75 (0.42-0.91)</td>
<td>0.16</td>
</tr>
<tr>
<td>6MWT&lt;sub&gt;15m&lt;/sub&gt; (m)</td>
<td>291.2 ± 85.7 (125.2-429.1)</td>
<td>304.0 ± 84.4 (165.1-407.2)</td>
<td>0.97 (0.91-0.99)</td>
<td>15.6</td>
</tr>
<tr>
<td>6MWT&lt;sub&gt;30m&lt;/sub&gt; (m)</td>
<td>312.0 ± 89.7 (125.2-444.7)</td>
<td>339.6 ± 101.3 (169.7-493.8)</td>
<td>0.94 (0.85-0.98)</td>
<td>21.2</td>
</tr>
<tr>
<td>6MWS&lt;sub&gt;15m&lt;/sub&gt; (m/s)&lt;sup&gt;*&lt;/sup&gt;</td>
<td>0.81 ± 0.24 (0.44-1.19)</td>
<td>0.85 ± 0.24 (0.46-1.13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6MWS&lt;sub&gt;30m&lt;/sub&gt; (m/s)&lt;sup&gt;*&lt;/sup&gt;</td>
<td>0.87 ± 0.25 (0.35-1.24)</td>
<td>0.94 ± 0.28 (0.47-1.37)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: ICC<sub>2, 1</sub> = intraclass correlation coefficient, single measures; CI = confidence interval; SEM = standard error of measurement; MDC<sub>95</sub> = minimal clinically detectable change at the 95% confidence level; 6MWS<sub>15m</sub> = 6-minute walk speed on 15m walkway; 6MWS<sub>30m</sub> = 6-minute walk speed on 30m walkway.

* 6MWS, calculated as: total distance (m)/360 (s)
Table 3.3 Construct validity (n=17)

<table>
<thead>
<tr>
<th>Tests</th>
<th>Time 1</th>
<th>Time 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10mWT</td>
<td>6MWT&lt;sub&gt;15m&lt;/sub&gt;</td>
</tr>
<tr>
<td>6MWT&lt;sub&gt;15m&lt;/sub&gt;</td>
<td>r=0.70, p=0.002*</td>
<td>r=0.91, p=0.000*</td>
</tr>
<tr>
<td>6MWT&lt;sub&gt;30m&lt;/sub&gt;</td>
<td>r=0.72, p=0.001*</td>
<td>r=0.93, p=0.000*</td>
</tr>
<tr>
<td>SIS strength</td>
<td>r=0.17, p=0.516</td>
<td>r=0.28, p=0.274</td>
</tr>
</tbody>
</table>

Abbreviations: r = Pearson correlation, SIS strength = self-report Stroke Impact Scale strength subscale. *significant.
Figure 3.1 Bland-Altman Plots for the a. 10mWT, b. 6MWT<sub>15m</sub>, and c. 6MWT<sub>30m</sub> (n=16)
Chapter 4
Summary and Conclusion
4 Summary and Conclusion

4.1 Summary and Conclusion

The objectives of this thesis were to summarize limitations of current standards for the use of walk tests in people with stroke and to evaluate the test-retest reliability, measurement error, and construct validity of novel stroke-specific protocols for the 10mWT and 6MWT in ambulatory people with acute, subacute, and chronic stroke. The quantitative study provided strong evidence that protocols for the 10mWT and 6MWT, conducted on both 15m and 30m walkway lengths, are highly reliable, and produced MDC\(_{95}\) values for the three walk tests. Findings provided limited evidence, however, of construct validity based on relationships between measures of walking capacity and strength.

Strengths of this study include 1) the inclusion of participants in all phases of stroke recovery, 2) the inclusion of aphasia instructions and provision of physical assistance, 3) the minimization of potential sources of error, and 4) the investigation of the 6MWT using a shorter and more accessible walkway. First, many findings from this study were similar to those found in the current literature, however no previous study has included people with acute, subacute, and chronic stroke. As mentioned, it is important to evaluate these protocols in relevant populations and establish support for their use in early phases of stroke recovery. Second, unlike previous literature, this study included pictorial instructions for people with aphasia post-stroke and allowed for the provision of physical assistance during the 10mWT and 6MWT. The inclusion of these accommodations would allow the use of these protocols in a larger proportion of people with stroke and stroke-related deficits. Third, several aspects of the study design minimized potential sources of error. Evaluations were scheduled for the same time of day (within 1-hour of each other) at the same test location and order of tests were maintained, while clothing, type of footwear, use of glasses or contacts, type of walking aid, use of aphasia instructions, use of a transfer belt, and amount of physical assistance given were also kept consistent at both evaluations. The short retest interval of 2-3 days chosen was similar to studies that evaluated walking speed and capacity in people with acute and subacute stroke and was selected to minimize the chance of improvement in walking between tests and effects of recall bias. Last, this is the first study to investigate the test-retest reliability, measurement error, and
construct validity of the 6MWT conducted on a 15m walkway and there is some evidence that it has less of a practice effect than the 6MWT_{30m}.

Expanding upon the limitations outlined in Chapter 3, limitations of this study include those that 1) affected the precision of results, 2) influenced correlation values for construct validity, and 3) limit the generalizability of findings. First, the precision of findings from this study may have been affected by the small size and participant characteristics that were not evaluated. A small sample size was achieved due to limited recruitment from a low volume of referred patients at study sites and time constraints. The sample size achieved was lower than desired. This likely reduced the precision of ICC_{2,1} estimates resulting in larger MDC_{95} values than expected for the 10mWT. However, efforts were made to maximize recruitment including; the minimization of tasks required of PTs in order to refer participants, giving regular reminders to PTs about the ongoing study, and the inclusion of two study recruitment sites. Furthermore, during time 1, some participants exhibited difficulty in following instructions (i.e. talking during the test, veering off track). It is possible that differences in understanding of test instructions contributed to seemingly improved walk test performance at time 2 and thereby influenced the precision of reliability analyses. Second, the support for construct validity of walk tests was limited, and various factors may have contributed to this. Findings from previous literature correlating the 6MWT to the SIS strength was limited to one study that directly investigated the relationship, while no studies examined the 10mWT and SIS strength. Developing hypotheses based on validity studies evaluating the 10mWT and direct measures of limb strength likely caused the hypotheses made in this study to be higher than appropriate. Other measures more directly related to walking ability and with less limitations should have been included. For example, a measure of balance may have provided a more highly correlated construct for the 6MWTs as balance would affect individuals’ ability to navigate turns. As described in Chapter 3, it also appeared that many participants in this study were high-level walkers. Most participants walked independently and did not require an assistive device to walk (59%) and can be considered high-level walkers, while 1 individual (6%) used a transfer belt and required assistance to walk. The limited variation in walking ability likely affected the ability to detect higher correlation values. Third, the opportunity to generalize findings from this study was limited by the individuals that took part in this study. As mentioned, it appeared that most participants in this study walked at higher levels of functioning, which limits the applicability of
study findings to people walking at lower levels. Overall SIS strength values were high, again reflecting high levels of functioning in this sample and likely contributed to the lower correlation values. PTs that referred patients to the study may have been somewhat cautious about approaching people walking at lower levels. The small number of participants walking at lower levels of functioning limits the opportunity to generalize these results to the broader population of people with stroke. As well, only 1 individual (6%) required use of pictorial aphasia instructions, and so the applicability to patients with aphasia after stroke was not thoroughly investigated. Additionally, although people with cognitive deficits or severe receptive aphasia were excluded, no standardized measures of cognition were conducted in this study. The lack of such a measure thereby limits the generalizability of results to people post-stroke with cognitive impairments, which make up approximately 20% of the post-stroke population.\textsuperscript{141} Overall, some limitations may have affected study findings and more research should be done to provide further support for the use of the 10mWT and 6MWT.

The findings of the quantitative study support the reliability of these novel 10mWT and 6MWT protocols and address some the gaps identified in the literature review, including the lack of studies in early stroke populations, limitations and variations of current protocols, and feasibility of conducting the 6MWT in smaller spaces. Evidence of reliability and validity of these protocols, which are applicable to a larger proportion of people with stroke and in smaller settings, is important in promoting the use of the protocols by clinicians and researchers.

The potential clinical implications of evidence supporting the use of these 10mWT and 6MWT walk test protocols include: broader applicability of these protocols to people post-stroke, effective evaluation of response to rehabilitation interventions, and increased ability to educate people on current walking ability. Clinicians report using evidence of reliability and validity to support their selection of standardized assessment tools,\textsuperscript{12} evidence supporting reliability of these three tests has the potential to influence clinicians’ decisions to utilise these tests when evaluating people in the acute, subacute, and chronic phases of stroke, people with aphasia, people requiring assistance to walk, and in settings that cannot accommodate a 30m walkway for the 6MWT. Furthermore, the 10mWT and 6MWT have been found to be responsive to recommended treatment interventions such as treadmill, task-oriented, and aerobic training.\textsuperscript{20-23} Thus, the use of these tests will allow detection of improvement and deterioration of walking ability during stroke rehabilitation and thereby enable therapists to respond appropriately by
maintaining or changing treatment. Use of these tests can also help improve the education and inform the expectations of patients, families, and clinicians on patients’ current walking ability, as walking speed and distance have been related to ability to walk in the community.\textsuperscript{69}

### 4.2 Future Research

Building upon the results of this study, several possible future directions are possible. The most important next step is to evaluate test-retest reliability, measurement error, and construct validity with a larger sample size that includes a wider spectrum of stroke-related deficits from all phases of stroke recovery. The study sample was composed of primarily high-level walkers and was therefore limited in how representative it is of people with more severe walking deficits. More participants with aphasia are also required in order to appropriately evaluate the reliability, measurement error, and validity of the pictorial instructions. Similarly, more participants who require physical assistance are necessary to investigate the reliability and validity when assistance is provided. Another important next step is to next investigate the potential presence of practice effects and the effects of including practice trials before each test. This is particularly important for the 6MWT, as findings from this study suggest that practice effects may be stronger when the test is conducted on the 30m walkway compared to the 15m length. Future studies should consider explicitly collecting information on previous experience with performing these walk tests as this may have impacted pacing when performing the 6MWT for the first time. Future research on these tests should continue to include participants from all phases of stroke recovery and maintain the retest interval of 2-3 days in order to limit the effects of improvement and recall bias on walking ability.

Other future studies should also investigate the reliability and validity of these tests among those with impaired and normal cognition, as there appeared to be varying degrees of understanding of test instructions in this study. The use of direct measures of strength should also be investigated instead of the self-reported SIS strength, as they will be more accurate in assessing strength. Direct measures would also be more effective for assessing people with limited cognitive function. Furthermore, future studies should investigate the relationship between balance on walk performance using these protocols, particularly in comparing performance on the 6MWT\textsubscript{15m} and 6MWT\textsubscript{30m} as more turns are required to complete the 6MWT\textsubscript{15m}.\textsuperscript{69}
References


51. Statistics Canada. Table 102-0561 Leading causes of death, total population, by age group and sex, Canada (table). In: CANSIM (database).

52. Statistics Canada. Table 13-10-0467-01 Neurological conditions in household population.


110. Ovando AC, Michaelsen SM, de Carvalho T, Herber V. *Evaluation of Cardiopulmonary Fitness in Individuals with Hemiparesis after Cerebrovascular Accident.* Vol 962011.


Appendices
Appendix A. Completed COSMIN Checklists\textsuperscript{135}

Reliability Checklist - Test-retest Reliability

<table>
<thead>
<tr>
<th>Box B. Reliability: relative measures (including test-retest reliability, inter-rater reliability and intra-rater reliability)</th>
<th>yes</th>
<th>no</th>
<th>?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design requirements</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Was the percentage of missing items given?</td>
<td>✓</td>
<td>□</td>
<td></td>
</tr>
<tr>
<td>2 Was there a description of how missing items were handled?</td>
<td>✓</td>
<td>□</td>
<td></td>
</tr>
<tr>
<td>3 Was the sample size included in the analysis adequate?</td>
<td>□</td>
<td>✓</td>
<td>□</td>
</tr>
<tr>
<td>4 Were at least two measurements available?</td>
<td>✓</td>
<td>□</td>
<td></td>
</tr>
<tr>
<td>5 Were the administrations independent?</td>
<td>✓</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>6 Was the time interval stated?</td>
<td>✓</td>
<td>□</td>
<td></td>
</tr>
<tr>
<td>7 Were patients stable in the interim period on the construct to be measured?</td>
<td>✓</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>8 Was the time interval appropriate?</td>
<td>✓</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>9 Were the test conditions similar for both measurements? e.g. type of administration, environment, instructions</td>
<td>✓</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>10 Were there any important flaws in the design or methods of the study?</td>
<td>□</td>
<td>✓</td>
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</tr>
<tr>
<td><strong>Statistical methods</strong></td>
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<td>no</td>
<td>NA</td>
</tr>
<tr>
<td>11 for continuous scores: Was an intraclass correlation coefficient (ICC) calculated?</td>
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<td>□</td>
<td>□</td>
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<tr>
<td>12 for dichotomous/nominal/ordinal scores: Was kappa calculated?</td>
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<td>□</td>
<td>✓</td>
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<tr>
<td>13 for ordinal scores: Was a weighted kappa calculated?</td>
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<tr>
<td>14 for ordinal scores: Was the weighting scheme described? e.g. linear, quadratic</td>
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<td>□</td>
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</table>
### Measurement Error Checklist

<table>
<thead>
<tr>
<th>Box C. Measurement error: absolute measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design requirements</strong></td>
</tr>
<tr>
<td>1. Was the percentage of missing items given?</td>
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<tr>
<td>2. Was there a description of how missing items were handled?</td>
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<tr>
<td>3. Was the sample size included in the analysis adequate?</td>
</tr>
<tr>
<td>4. Were at least two measurements available?</td>
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<tr>
<td>5. Were the administrations independent?</td>
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<tr>
<td>6. Was the time interval stated?</td>
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<tr>
<td>7. Were patients stable in the interim period on the construct to be measured?</td>
</tr>
<tr>
<td>8. Was the time interval appropriate?</td>
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<tr>
<td>9. Were the test conditions similar for both measurements? e.g. type of administration, environment, instructions</td>
</tr>
<tr>
<td>10. Were there any important flaws in the design or methods of the study?</td>
</tr>
<tr>
<td><strong>Statistical methods</strong></td>
</tr>
<tr>
<td>11. for CTT: Was the Standard Error of Measurement (SEM), Smallest Detectable Change (SDC) or Limits of Agreement (LoA) calculated?</td>
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</table>
Construct Validity Checklist – Hypothesis Testing

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<th>Box F. Hypotheses testing</th>
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<tbody>
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<td></td>
<td></td>
</tr>
<tr>
<td>1  Was the percentage of missing items given?</td>
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<td>☐</td>
<td></td>
</tr>
<tr>
<td>2  Was there a description of how missing items were handled?</td>
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<td>☐</td>
<td></td>
</tr>
<tr>
<td>3  Was the sample size included in the analysis adequate?</td>
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<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>4  Were hypotheses regarding correlations or mean differences formulated a priori (i.e. before data collection)?</td>
<td>☑</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td><strong>Statistical methods</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5  Was the expected direction of correlations or mean differences included in the hypotheses?</td>
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<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>6  Was the expected absolute or relative magnitude of correlations or mean differences included in the hypotheses?</td>
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<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>7  for convergent validity: Was an adequate description provided of the comparator instrument(s)?</td>
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<td></td>
</tr>
<tr>
<td>8  for convergent validity: Were the measurement properties of the comparator instrument(s) adequately described?</td>
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<td>☐</td>
<td></td>
</tr>
<tr>
<td>9  Were there any important flaws in the design or methods of the study?</td>
<td>☑</td>
<td>☒</td>
<td></td>
</tr>
<tr>
<td>10 Were design and statistical methods adequate for the hypotheses to be tested?</td>
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<td>☑</td>
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</table>
Appendix B. Walk Test Protocols

Supplemental File 3.1. 10-metre Walk Test Protocol

*Equipment Needed:*

- Stopwatch
- Masking tape
- Measuring tape
- 2 chairs
- 1 pylon

*Test Set-up:*

Place 15cm long pieces of tape on the floor along the test walkway at 0m, 2m, 12m, and 14m to mark the zones shown in the diagram below. Place chairs near the beginning and end of the walkway, and a pylon at the 14m mark. Wear the stopwatch around the neck to allow for use of the hands during test.

*Instructions:*

Begin with the participant in a seated position at the start of the walkway. Give the instruction, “I am going to measure your comfortable walking speed. I will say “Ready, set, go”. When I say “go”, walk in a straight line at a pace that is safe and comfortable for you, until you reach the pylon. Now I’m going to show you. Do you have any questions?” before demonstrating the test. Ask the participant to stand behind the start line and say “Ready, set, go.” Begin timing with the stopwatch when the participant’s first foot fully crosses the 2-m mark at the end of the acceleration zone. Stop timing when the participant’s first foot fully crosses the 12-m mark at the beginning of the deceleration zone and end of the test distance. Record time taken to walk 10m.
**Instructions for patients with mild to moderate aphasia:**

1. **Walk**
   - Show slide 1, say: “Walk here to here” as you point from the start mark to the pylon.

2. **Comfortable speed**
   - Show slide 2, say: “Walk at a comfortable speed.”

3. **Questions?**
   - Show slide 3 and say: “Questions?”

4. **Go!**
   - Show slide 4 and say: “Ready? Go!” Patient performs the test.
Supplemental File 3.2. 6-minute walk test protocol

*Note: these protocols apply to tests performed on both the 15m and 30m walkway lengths

Equipment Needed:

- Stopwatch
- Lap counter
- Masking tape
- Permanent marker
- Measuring tape
- 3-4 chairs
- 2 pylons
- Bean bag

Test Set-up:

Mark each metre of the walkway with pieces of tape on the wall. Place chairs near each end of the walkway and one or two chairs along the walkway for the 15m or 30m walkway tests, respectively. Place pylons just inside the ends of the walkway as shown in the diagram below. Wear the stopwatch and lap counter around the neck to allow for use of the hands during test.

![Diagram of walk test setup]

Instructions:

Begin with participant seated at the start end of the walkway and given the instructions, “*The aim of this test is to walk as far as possible for 6 minutes. You will walk along this hallway between the pylons as many times as you can in 6 minutes. I will let you know as each minute goes past, and then at 6 minutes I will ask you to stop where you are. 6 minutes is a long time to walk, so you will be exerting yourself. You are permitted to slow down, to stop, and to rest as*
necessary, but please start walking again as soon as you are able. Please do not talk during the
test unless you have a problem, are feeling unwell or need to tell me you need a rest. You must
let me know if you have any chest pain or dizziness. Now I’m going to show you,” before
demonstrating walking the full walkway length and back.

Ask participant to stand at the starting point and give the instruction, “Remember that the
objective is to walk AS FAR AS POSSIBLE for 6 minutes, but don’t run or jog. Do you have any
questions? When you are ready, please begin.”

Begin timing as soon as the participant begins to walk and use the lap counter for every
length walked. Give standardized encouragement in even tones at each minute; 1 minute, “You
are doing well. You have 5 minutes to go,” at 2 minutes, “Keep up the good work. You have 4
minutes to go,” at 3 minutes, “You are doing well. You are halfway,” at 4 minutes, “Keep up the
good work. You have only 2 minutes left,” and at 5 minutes, “You are doing well. You have only
1 minute to go.” If the participant stops to rest by sitting or leaning against the wall, continue
timing and give the following instructions every 30 seconds, “Please start walking again
whenever you feel able.” Record the time at which the participant stops and starts. When 6
minutes have passed, tell the participant, “Please stop where you are,” and mark the exact spot
where the participant stopped with a bean bag or piece of tape. Assisted to the nearest chair.

Stop test immediately if the participant exhibits any of the following: chest pain, severe
dyspnea (shortness of breath), leg cramps, staggering, diaphoresis (excessive perspiration or
sweating), pale or ashen appearance, light-headedness, confusion, cyanosis (blue or grey skin
colour), nausea, excessive fatigue, or facial expression signifying distress. Hospital code will be
called immediately for emergency response personnel. If the participant stops before 6 minutes
and is unable to continue or it is decided they should not continue, mark the spot at which they
stopped, assist to the nearest chair, and record time stopped and reason for stopping.

Record number of lengths walked, and any residual distance between whole metre
markings with a measuring tape.
Instructions for patients with mild to moderate aphasia:

1. **Walk around**
   - Show slide 1. Trace the walking path to the end and back 3 times with your finger saying “Walk around and around”.

2. **Walk for 6 minutes**
   - Show slide 2 and say: “Walk for 6 minutes”.

3. **No talking**
   - Show slide 3 and say: “No talking”.

4. **Feel bad, take a break**
   - Show slide 4 and use your finger to trace from the symptom to the action and say: “If you feel bad, sit down”.

5. **Walk again**
   - Show slide 5. Trace the walking path to the end and back with your finger pointing and say: “Walk again”.

6. **Pain**
   - Show slide 6. Point to each point of pain, then to the stop sign and say “Pain (point to heart) or pain (point to calf), then stop”.

**Note:**
- Instructions may vary depending on the specific needs and abilities of the patient.
Show slide 7 and say: “After 6 minutes, stop walking”.

Show slide 9 and say “Ready? Go!”. Patient performs the task.

**Standardized Encouragement**
Each minute provide the following standardized encouragement:
- At 1 minute: *Good work, 5 minutes more.*
- At 2 minutes: *Good work, 4 minutes more.*
- At 3 minutes: *Good work, 3 minutes more.*
- At 4 minutes: *Good work, 2 minutes more.*
- At 5 minutes: *Good work, 1 minute more.*
- At 6 minutes: *STOP*

As you say 5, 4, 3, 2, or 1 minute more, hold up the corresponding number of fingers.

**When a patient takes a rest**
If the patient takes a rest, every 30 seconds ask:
*“Can you walk now?”*
If the patient indicates “yes”, then say:
*“Please walk”*

Follow instructions on slide.
Appendix C: Measurement Error Equations

\[ MDC = z\text{-score}_{level\ of\ confidence} \times \sqrt{2} \times SEM \]

\[ SEM = SD_{baseline} \times \sqrt{1 - r_{test-retest}} \]

\[ r_{test-retest} = \text{coefficient for test-retest reliability, estimated using ICC}_{2, 1} \]