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# Evaluating a Concern for Falling Among People with a Lower Extremity Amputation

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# 1. Abstract

The purpose of these studies was to evaluate a concern for falling (CFF) among people with a lower extremity amputation (PLEA). Study 1 evaluated relative and absolute test-retest reliability of five standardized scales which have not been previously evaluated among PLEA. Twenty-two participants completed Study 1, an online survey that was administered twice. Study 2 assessed the inter-relationship of the multiple dimensions in a CFF using nine standardized scales of measurement and open-ended questions, and the association on quality of life (QOL). Forty-eight participants completed Study 2, a onetime online survey. Study 1 provided support for the reliable use of four CFF standardized scales among PLEA. Study 2 demonstrated statistically significant correlations between subdomains of fear of falling, falls efficacy, and mobility efficacy and an independent association on overall QOL. Open-ended responses demonstrated numerous activities that elicited a CFF. A CFF negatively influences QOL in PLEA after successful prosthetic rehabilitation.

**Keywords*:*** *lower extremity amputation, lower limb loss, concern for falling, falls prevention, lived experience, quality of life*

## Summary for Lay Audience

Half of all people with lower limb loss will fall at least once each year. The consequences of falling can lead to injuries and a concern for falling. Frequently, a concern for falling can trigger a reduction in activity and overall quality of life. Existing questionnaires that assess a concern for falling were not developed for people with lower limb loss and may not tell us the unique mobility challenges they experienced. There are a few concern for falling questionnaire that are used among people with lower limb loss. However, they are only focused on one area of falling. This leaves much unknown about how a concern for falling impacts people with lower limb loss. The goal of this research project was divided into two studies. The first measured the reliability (if scores are repeatable on two different occasions) for five concern for falling questionnaires in people with lower limb loss through an online survey. The second study evaluated five different areas that make up a concern for falling and the relationship between these different areas. Four of the five scales we evaluated for reliability showed consistent results when assessed on two separate occasions among people with lower limb loss. Study 2 found a fear of falling, confidence of not falling, and confidence in mobility were each associated with quality of life. This research project allowed us to establish four reliable concern for falling measures for people with lower limb loss and that different areas of a concern for falling affect quality of life.

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# List of Abbreviations

ABC: Activities-specific Balance Confidence Scale

CFF: Concern for Falling

CI: Confidence Interval

CLI: Critical Limb Ischemia

COF: Consequences of Falling Scale

DASS: Depression Anxiety Stress Scale

FES-I: Falls Efficacy Scale-International

FOF-VAS: Fear of Falling-Visual Analogue Scale

ICC: Intraclass Correlation Coefficient

IQR: Interquartile Range

LCI: Locomotor Capabilities Index

LEA: Lower Extremity Amputation

LOA: Limits of Agreement

MDC: Minimal Detectable Change

mSAFFE: Modified-Survey of Activities and Fear of Falling in the Elderly

PAD: Peripheral Arterial Disease

PAMF: Perceived Ability to Manage Falls Scale

PCOF: Perceived Control Over Falling Scale

PLEA: People with a major Lower Extremity Amputation

PLUS-M: Prosthetic Limb Users Survey – Mobility

PPA-LCI: Prosthetic Profile of Amputee – Locomotor Capabilities Index

QOL: Quality of Life

SD: Standard Deviation

SEM: Standard Error of Measurement

TF: Transfemoral

TT: Transtibial

VAS: Visual Analogue Scale

WHOQOL: World Health Organization Quality of Life Questionnaire

# Chapter 1

## 1.1 Introduction

People with a major (transtibial or transfemoral) lower extremity amputation (PLEA) are at a high risk for falling. More than 52.4% of PLEA aged 18 years and older who ambulate with a prosthesis in their community fall at least once each year.[1, 2] The occurrence of falls in PLEA is twice that of community-dwelling older adults, a group for whom their level of falls have been recognized as a significant public health issue.[3–7] When compared to PLEA, only 32.0% of older adults who ambulate in the community fall each year.[8]

After amputation, prosthetic rehabilitation programs cover fitting with a prosthesis and training on how to maneuver with it for return to normal daily activities.[9] Skills learned during this program include, but are not limited to, ambulating in the home, ascending and descending stairs, and donning and doffing a prosthesis safely.[9] However, the prevalence of falls at 52.4% is among PLEA who have successfully completed a rehabilitation program and falls remains elevated compared to that of community-dwelling older adults.[1]

Consequences of falls such as fractures, lacerations, and head injuries can be devastating to an individuals' health and functional independence.[10–12] Specifically, the physical consequences of falls can interfere with progression in prosthetic rehabilitation and in the use of a prosthetic device throughout the life span of PLEA after rehabilitation.[8,13] Additionally, falls can lead to psychological consequences, such as a fear of falling.[1,10,11] The psychological consequences of falling can be multidimensional, and therefore, we have termed this overarching paradigm: concern for falling (CFF). A CFF may not be as apparent as the physical injuries that result from a fall but can have similar adverse functional consequences. A CFF can result in a reduction in prosthesis use and physical activities,[14] social isolation,[16] and decreased overall quality of life (QOL).[17] Our paradigm for a CFF includes five subdomains: fear of falling, falls efficacy, mobility efficacy, consequences of falling, and perceptions of falling.[14,15] Existing standardized scales to measure each subdomain were developed for community-dwelling older adults and their experience of falls. The literature for PLEA has focused mostly on falls efficacy to the exclusion of evaluating the other subdomains of CFF. Thus, there is still much to understand about the

psychological consequences of falls within each of the subdomains of a CFF in PLEA. This enhanced knowledge has the potential to improve rehabilitation through targeted interventions.

The objectives of this research project were divided into two phases; the first will evaluate the relative test-retest and absolute reliability of standardized scales within the CFF model that have not been previously evaluated in PLEA. The second phase will evaluate the multiple subdomains of a CFF and their inter-relationship using nine standardized scales of measurement and open-ended questions in PLEA. Additionally, the second phase will evaluate the association between each of the different CFF scales on QOL in PLEA.

## 1.1 Surgical Procedure of a Lower Extremity Amputation

A lower extremity amputation (LEA) is a significant surgical procedure removing a portion of a limb that can take place at various levels.[20] Several factors contribute to the decision of the level of amputation performed, including tissue viability if infected or diseased, prosthetic options, cosmesis, and biomechanics of the residual limb.[20]

Transtibial (TT) level amputation is the surgical procedure occurring through the tibia bone.[20] A transfemoral (TF) level amputation occurs above the knee through the femur, but below the hip joint.[20] Both the TT and TF are considered a major LEA. Amputations below the TT level will not be included in this paper.

## 1.2 Epidemiology of an LEA

### 1.2.1 Prevalence and Incidence of LEAs

An estimated 1.6 million people are living with limb loss in the United States, 1.02 million (65%) of whom have a major LEA.[21] Unfortunately, prevalence estimates are not available for Canada. Yet, the cumulative incidence of LEAs in Canada between 2006 and 2009 was 44,430 for an estimated 7,405 new LEAs each year.[22] By 2050, it is predicted that 3.6 million people will be living with limb loss in the United States.[23]

The majority of new LEA procedures are the result of dysvascular causes, including peripheral arterial disease (PAD) and diabetes.[22] LEAs as a result of dysvascular etiology account for up to 91.0% of amputation-related hospital admissions.[23,24] An increase in dysvascular conditions

among older adults and longer overall life expectancy are the driving factors of a projected increased prevalence of LEAs in North America.[22,23]Alternative etiologies for an LEA include congenital defects, trauma, and cancer.[17]

In Canada, TT level amputations are more commonly performed compared to TF.[22] Between 2012 and 2016, 73.0% of new LEAs performed in Canada were of the TT level.[22] The trend of more distal amputations being performed (i.e., TT level) aligns with more effective clinical care management strategies of dysvascular-related conditions, such as a diabetic foot, from extending to more proximal level of limbs.[22, 23]

## 1.2.2 Underlying Disease Leading to an LEA

Dysvascular disease is the term used throughout this paper to refer to a collection of vascular-related diseases, including PAD and diabetes.

### 1.2.2.1 Peripheral Arterial Disease

PAD describes disorders of the non-coronary arteries, including but not limited to, atherosclerosis, abnormal vascular reactivity, and thrombus formation leading to restricted blood flow.[27, 28] The estimated global prevalence of PAD in 2010 was 202 million people, indicating an increase from previous estimates in 2000 (164 million).[29] Globally, PAD prevalence is similar in men and women.[30]

A symptomatic PAD condition may include reports of stabbing, stinging, and paresthesia of limbs while ambulating and at rest.[31] These symptoms can cause a claudication effect, the impairment of ambulation due to fatigue and pain in the limb.[32] PAD can also be asymptomatic or present intermittently, in which case the diagnosis of PAD is denoted with a low ankle brachial index (the ratio of blood pressure at the ankle compared to the upper arm).[30]

Persistent restriction of blood flow to the lower extremities can lead to critical limb ischemia (CLI).[27, 30] Additionally, the presence of a nonhealing tissue injury, such as ulcers or gangrene, can result in CLI.[27, 30] Symptoms of CLI include pain, paresthesia, a non-palpable pulse, and cold to the touch extremities, all of which do not subside with rest.[27,30] The risk of developing CLI increases with age; 1-2% of individuals with PAD at 50 years old will develop CLI, while people

aged 70-years an older have a 29.0% risk of developing CLI.[33] Risk factors associated with an increased likelihood of developing lower extremity PAD-related complications (e.g., CLI) include a pre-existing diabetic condition,[34, 35] history of tobacco use,[27, 34] dyslipidemia, and hypertension.[37]

The prognosis of CLI improvement is poor, and subsequently increases the likelihood of an LEA to salvage the limb.[27, 30] The probability of undergoing an LEA will occur for 10.0% to 40.0% of individuals with CLI.[34] Severe PAD conditions may benefit from an LEA, as it can be an opportunity to increase functional mobility with a prosthetic device and drastically improve a person's QOL.[20]

#### 1.2.2.2 Diabetes Mellitus

Diabetes mellitus is a chronic metabolic disorder affecting the ability to maintain blood sugar and insulin homeostasis within the body.[38] In 2015, an estimated 3.4 million Canadians were living with diabetes.[39] By 2025, the prevalence of diabetes is expected to rise to 12.1% (5 million) of the Canadian population.[39] The primary driving factors of this growth is attributed to the increased number of diabetic conditions among adolescents and young adults (50 years old and younger).[40]

Diabetic mortality rates have reduced 25.0% from 1995 to 2005,[41] indicating people are living longer with diabetes.[40] However, the overall prevalence of various secondary conditions as a result of diabetes, including skin conditions, visual impairment, nerve damage, and kidney complications is estimated to increase.[40]

A poorly managed diabetic condition can cause severe consequences.[42] Diabetic neuropathy is the damage of peripheral nerves in the foot causing weakness, numbness, and pain.[25] Diabetic neuropathy can lead to an abnormal gait, restriction of mobility, and an atypical distribution of weight on the foot.[25] The altered weight distribution can lead to a breakdown of the skin resulting in infection, ulceration, or gangrene development.[25]

Diabetic foot conditions are a major contributor to dysvascular-related LEAs performed each year.[43] In Canada, between 2011 and 2012, one-third of all LEA performed had a pre-existing diabetic foot wound.[43]

#### 1.2.2.3 Other Underlying Diseases Causing an LEA

Cancer- and tumour-related LEAs are relatively uncommon compared to the other etiologies.[24] A total of 5,342 cancer- and tumour-related LEAs (3.0%) occurred in Canada between 2006 to 2009.[24] Adolescents and young adults had the highest incidence of these LEAs.[22,44] Finally, congenital deficiencies accounted for 0.6% of LEAs in Canada between 2006 and 2011.[22]

### 1.2.3 Traumatic Etiologies for an LEA

In Canada, an LEA secondary to a traumatic incident is the second leading cause of an LEA.[22] Between 2006 and 2011, a total of 2,679 (6.0%) LEAs performed in Canada had a traumatic etiology.[22] Eighty-seven percent of trauma-related amputations were reported by males under the age of 40 years old.[45] Traumatic LEAs are typically the result of work-related accidents or motor vehicle crashes.[46] Incidence rates of trauma-related LEAs have decreased in recent years, some of these gains have been attributed to improvements in occupational safety standards in the workplace when using heavy machinery.[21]

Work-related and motor-vehicle LEA rates were highest among males aged 20 to 24 and 20 to 29 years old, respectively. [21, 46] Male and female older adults, aged 70 to 79 years old have reported an increased incidence of trauma-related LEAs, primarily due to injuries resulting from a fall without pre-existing dysvascular conditions.[21, 47]

### 1.2.4 General Risk Factors for an LEA

LEAs are primarily performed on older adults. In Canada, the average age for PLEA is 65.7 years old, and 85.9% of new LEAs performed were on individuals 50 years and older.[22] This is not surprising as the predominant cause of an LEA is dysvascular-related conditions, which commonly affect this age group.[22]

The number of comorbidities a person has typically increases with age.[48] Dysvascular-related comorbidities are the most common within this age group, as well as increased the likelihood of secondary dysvascular-related complications.[22]

Males are at higher risk for an LEA at all ages compared to females.[22] Males have consistently made up the majority of LEA cases; between 2006 to 2011, 68.8% of LEAs occurred on males.[22]

Males are also more likely to undergo both traumatic and non-traumatic related-LEAs compared to females.[22]

### 1.2.5 LEA Demographic and Clinical Characteristic Summary

In summary, the majority of Canadians living with an LEA are older males with an average of five comorbid conditions.[22] The majority of a new LEAs have a primary cause of dysvascular-related complications.[22] The next section of this literature review will focus on the mobility with an LEA and the risk of falling while ambulating with a prosthetic device for PLEA.

## 1.3 Falls in PLEA

Falls and risk factors for falls have been comprehensively researched among older adults over the past several decades.[5,7,8,49,50] However, one limitation in falls research is there is no universal operational definition of falls. Falls are not defined similarly as an event nor outcome in previous literature. A consensus definition of falls was created based on the expertise of Lamb and colleagues to best quantify falls.[51] For this thesis project, a fall will be defined as, "an unexpected event in which the participants come to rest on the ground, floor or lower level".[51] Moving forward, falls research should use one consistent definition of falls.

A fall at home can require emergency services, a hospital stay, a referral to therapy, and potentially admission to a long term care institution.[52,53] Falls also generate a significant financial cost, which threaten a healthcare systems' resources.[52,53] As such, falls among older adults are frequently cited as a significant public health concern.[8] However, falls are also prevalent among PLEA.[1] Fifty-two percent of PLEA aged 18 years and older will fall at least once each year, which is 30.0% more than the occurrence of falls among community-dwelling older adults.[2,54,55] Further, falls are common among PLEA from the amputation through to prosthetic rehabilitation and remain prevalent throughout the remaining life span of PLEA.[56,57] Falls are important to understand as they can result in severe physical consequences, including head injuries, lacerations, and fractures.[12] Falls can also result in psychological consequences, such as a fear of falling, reduced prosthetic use, and social withdrawal.[13,58]

Among PLEA, the most commonly reported activity performed at the time of a fall was walking on a level terrain while wearing their prosthesis, accounting for 41 of 90 falls recorded (45.6%).[59]

Intrinsic factors, such as a missed step or poor foot clearance, are more commonly attributed as the cause of a fall (58.0%), compared to extrinsic factors, including slippery floors or uneven terrain.[59] For individuals with a dysvascular-related amputation, the most common activity resulting in a fall was during transfers or sit to stand motions (29.3%), followed by reaching and stationary activities (19.5%), and walking on a level terrain (14.6%).[56] The majority of falls also occurred in the home (65.8%), compared to in the community.[59]

Falls are the result of an interplay between intrinsic factors (e.g., features of the person that may be consequences of comorbid diseases and functional abilities) and extrinsic factors (e.g., environment).[60] There are numerous fall risk factors that are shared between PLEA and community-dwelling older adults.[13] However, PLEA have unique mobility challenges while navigating life with a prosthesis, which increase the risk of falling.[14] There are numerous possible mechanisms through which falls risk is increased among PLEA. The following section will summarize the literature on factors related to falls in PLEA.

### 1.3.1 Movement Strategies

Movement strategies to avoid postural instability include using the ankle as a pendulum to allow sway, using the hip to create a torque to quickly move the center of mass back over the base of support, or taking a step to recover.[61] A person with a major LEA (TT or TF) does not have an ankle joint, preventing the use of this movement strategy. Using the hip to create a torque is challenging for PLEA at the TF level, as the most widely used knee-prosthetics have a weight-activated stance feature controlling the knee.[20, 21] As such, a more proximal of level amputation is associated with an increased risk of falls.[1,64] This ultimately leaves taking a recovery step to maintain postural stability as the most frequent movement strategy employed by PLEA.[59]

Ambulating with an LEA prosthesis requires an additional amount of metabolic energy compared to ambulating without.[65,66] Among the different levels of LEAs, TF level amputations require the greatest amount of additional energy.[65,66] The increased energy requirement is spent on maintaining an upright posture, and regulating pace and rhythm of walking with a prosthesis.[67] Importantly, increased energy expenditure has also been suggested to reduce enthusiasm and participation in activities of daily living.[67] This can lead to a reduction of muscle strength and endurance, perpetuating a vicious cycle of downward loss of function.[68] Interestingly, a TT level

amputation is associated with a higher risk of recurrent falls (≥ 2 falls per 1000-patient days) among PLEA.[64] This may be the result of greater mobility with a TT level prosthetic and increased exposure to environmental situations that may result in a fall, when compared to individuals with TF level amputations.[64]

### 1.3.2 Sensory Strategies

Visual, somatosensory, and vestibular systems also inform postural stability.[61] For PLEA, sensory strategies for maintaining postural stability are not the same as for individuals without limb loss.[69] The sense of touch and pressure from the ground to the bottom of the foot provides somatosensory information about the surrounding environment.[70] An LEA reduces the somatosensory input and redistributes that to vision and vestibular inputs to maintain postural stability.[20,69,70] Reorganization of lost sensory somatosensory inputs from lower extremities can be achieved by increased sensory contributions of the contralateral limb or through visual feedback, such as looking down while walking with a prosthesis.[70,71] However, looking down is not always possible during activities of daily living and may lead to colliding with obstacles resulting in instability and increased risk of falling.[31,32]

Somatosensory deficits specific to dysvascular-related complications can include reduced somatosensation of the non-amputated leg due to limb ischemia affecting a person bilaterally.[33,69] Even with re-distribution of somatosensory information to the non-amputated leg, pre-existing dysvascular conditions could already compromise the functioning of those systems.

### 1.3.3 Orientation in Space

Orientating the body in relation to structures in the environment is essential for maintaining postural stability.[61] Visual and internal references will provide information to the nervous system on how to adapt ambulation to maintain an upright position.[61] An LEA will cause an uneven weight distribution between the amputated and non-amputated limb, inaccurately orientating the body in space and increasing the risk of falling.[18,27]

The type and state of the surface can also influence the internal postural verticality when spatially orientating oneself.[61] Walking on slippery floors with a prosthesis has been cited anecdotally by PLEA as a challenging task causing postural alignment to feel shifted.[10,35,36]

In Canada, 5.7% of adults reported a visual impairment, primarily due to dysvascular-related consequences, including glaucoma, retinopathy, cataracts, and macular degeneration.[77,78] The average person with an LEA is 66 years old who may have pre-existing or developing visual impairments related to age associated changes.[22] Visual impairment due to old age or comorbid disease increases the risk of falling among PLEA.[39,40]

A dimly lit environment can also reduce available visual strategies to orientate oneself in space.[61] If a person does not feel confident in the environment due to limited visual acuity, they will avoid activities, again creating the vicious cycle of downward decline of functioning.[18, 41]

Finally, assessing the environment for potential falls risks is an integral part of preventative falls training.[81] In order to effectively assess the risks in a person's surrounding, rehabilitation programs need to proactively train individuals to critically assess their environment.[8,79,82,83]

### 1.3.4 Control of Dynamics

Falling as a result of muscle weakness has been consistently reported in the literature as a falls risk factor for PLEA.[8,86] Sources of muscle weakness can result from sarcopenia, which is an age-related changes in muscle function independent of the amputation surgery.[85] Therefore muscle weaknesses in the lower extremity are an important consideration as the average age of PLEA in Canada is 66 years old.[22] A reduction in muscle mass may compromise the dynamic control of postural stability, ultimately increasing the risk of falling.[86–88]

Individuals with an LEA as a result of dysvascular etiology demonstrate an increased postural sway, indicating worse balance, compared to an amputation as a result of trauma.[64,89,90] Additionally, dysvascular-related extremity complications including infection, peripheral neuropathy, foot ulcers, claudication, and ischemia, can affect balance and mobility on the stump or the non-amputated leg.[27,42,91] Pain due to these conditions can alter gait dynamics, putting stress on uncommon areas of the foot or prosthesis.[27,92,93] Altering ambulation to compensate for pain will negatively influence gait variability (e.g., pace, step-length, postural asymmetry) which is associated with an increase the risk of falling.[27,92,93]

### 1.3.5 Cognitive Processing

Cognition is an important resource in postural stability.[61] As the complexity of a task and required postural stability increases, performance declines and reaction time to perturbations increase in length.[61] The cognitive processes required to react to perturbations are shared with the cognitive resources required to maintain postural stability, increasing the cognitive demand when negotiating complex tasks.[61] Cognitive impairment is prevalent among PLEA. Among a group of PLEA admitted to a prosthetic rehabilitation program in Canada between 2011 through 2014, 26.1% had a physicians diagnosis of some degree of cognitive impairment at admission.[94] The double burden of cognitive impairment and an LEA is a predictor of poorer walking ability and can increase the risk of falling.[60, 61]

## 1.4 Falls Prevention in PLEA

### 1.4.1 Knowledge of Falls

Knowledge of the risks of falling is essential in order to learn strategies to prevent falls.[81] However, limited literature exists within this area among PLEA. To date, one study has been published examining the knowledge of falls risk factors and falls prevention strategies among PLEA.[81] Among a group of adult PLEA, falls and falls prevention were rated 7.6 out of 10 on overall importance to their health.[81] Further, the sample of PLEA understood the wide range of physical consequences that may result from a fall (e.g. injury), but did not perceive the personal consequences that falls would affect.[81] Additionally, knowledge of falls risk factors and falls prevention strategies did not change between inpatient prosthetic rehabilitation discharge and a four-month follow up; demonstrating that the four-month lived experience at home for PLEA did not affect knowledge of falls risk factors.[81] This highlights a divide between PLEA knowledge of falls and how that knowledge is incorporated into their lives.[81]

## 1.5 Concern for Falling

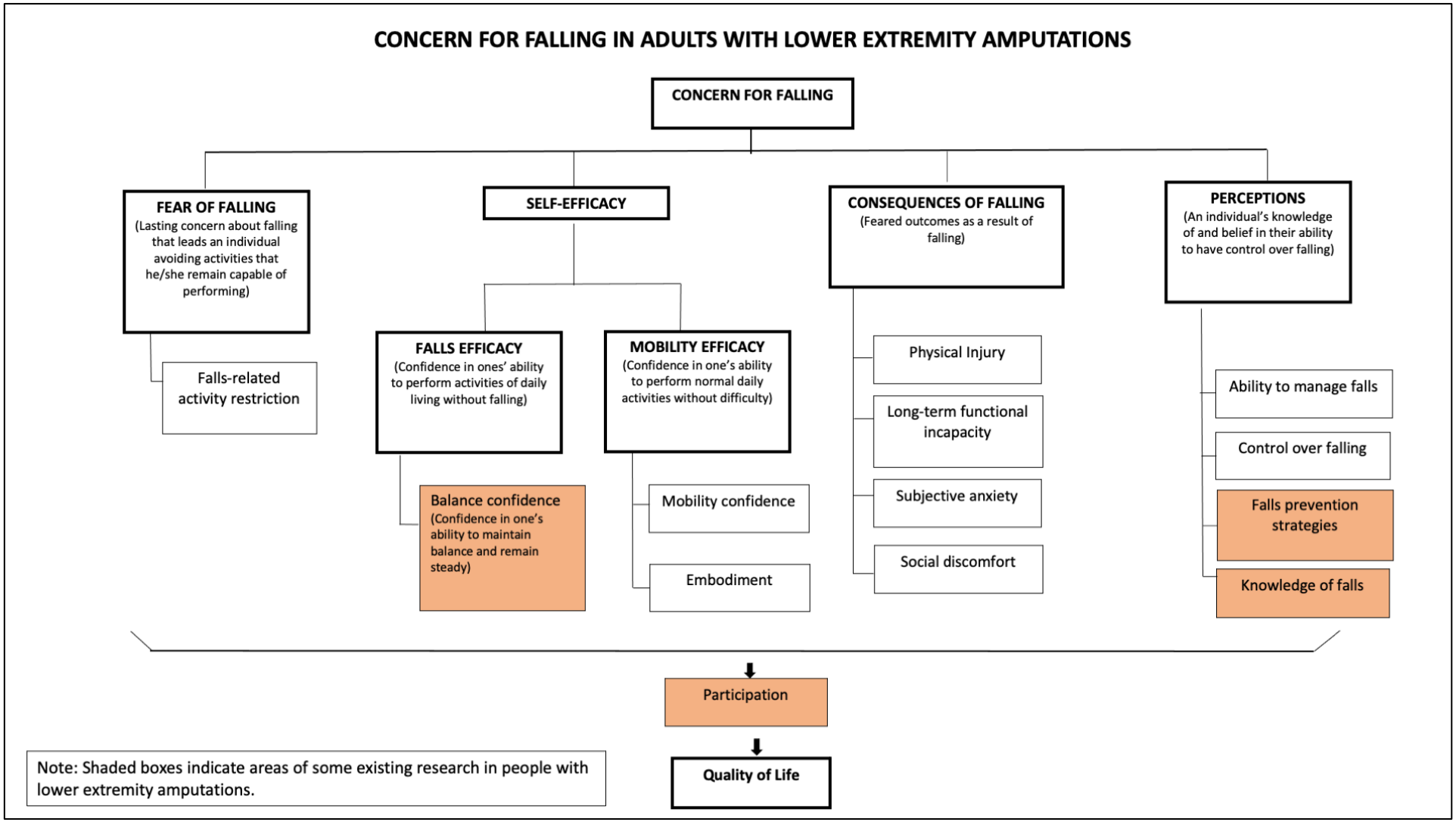
The psychological consequences of falling can influence future participation in the community and overall QOL.[17,18] Therefore, psychological indicators of falling should be addressed in rehabilitation alongside functional assessments.[97] A CFF is the overarching term used to describe the negative multifaceted psychological influences of falling. Falling is the result of numerous

physical and psychological factors. Therefore, to comprehensively understand and address a CFF in PLEA, a multidimensional approach should be used.[4]

The CFF conceptual model (Figure 1.1) has five subdomains including fear of falling, falls efficacy, mobility efficacy, consequences of falls, and perceptions of falls. The rationale for the CFF conceptual model was developed based on a comprehensive and expansive overview of the psychological aspects of falling among older adults by Moore and Ellis.[98] To encompass the unique and specific mobility challenges of PLEA, we adapted the psychological aspects of falling proposed by Moore and Ellis to include an additional subdomain specific to PLEA.

The majority of falls research across multiple clinical populations has focused primarily on falls efficacy. It is important to note that within this body of literature, the subdomain terms of fear of falling, falls efficacy, and balance confidence are used interchangeably, resulting in inaccuracy when classifying the psychological consequences of falling.[99] However, each subdomain addresses a fundamentally different component of a CFF and should be measured independently of other constructs in falls prevention programs. Each subdomain within the CFF model is associated with at least one existing standardized scale that evaluates that particular area. The majority of the standardized scales within the CFF model were not developed for PLEA. Only the mobility efficacy subdomain has scales that were specifically developed for this population.[100,101] The next sections will highlight each of the subdomains of the CFF paradigm as pertains to PLEA.

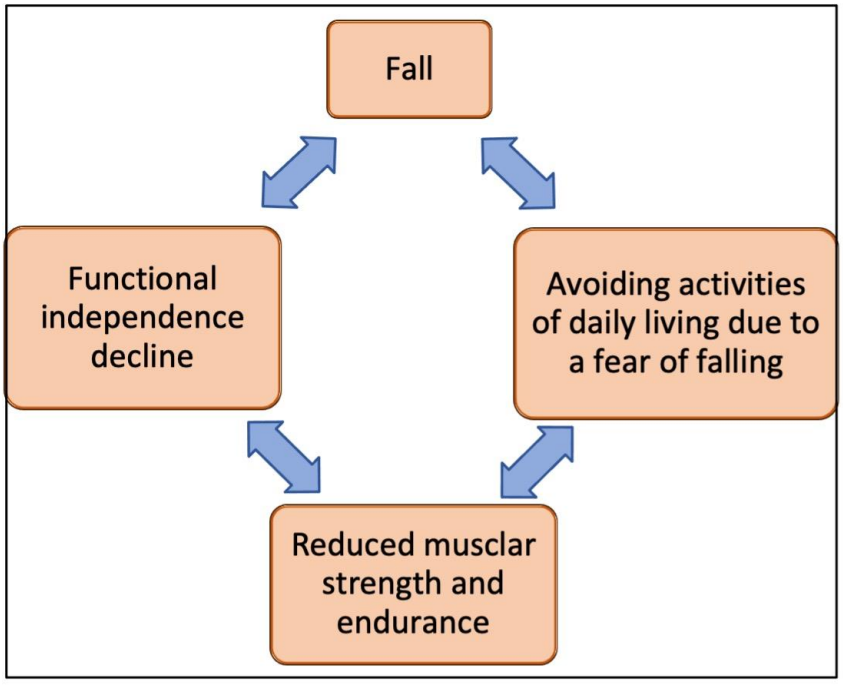
Figure 1.1 Concern for falling conceptual model for adults with a major lower extremity amputation.



### 1.5.1 Fear of Falling

Fear is an emotional trait important for survival.[102] Specific antecedents or unfamiliar settings may activate fear.[102] This conditioning process is advantageous to avoid harmful situations.[102] A fear of falling is the avoidance of activities that a person is physically capable of performing due to a lasting concern that a fall will occur.[103] However a fear of falling as the accurate evaluation of one's capabilities may provide a protective layer for future falls by stopping a person from engaging in risky activities.[102] Fear as a response to non-harmful or adaptable situations may negatively condition a person to avoid activities in the future.[102] A fall can be that aforementioned antecedent, evoking fear for individuals who are at risk of falling.[104–106] A self-imposed restriction of activities due to a fear of falling can lead to a functional decline from reduced muscular strength and endurance,[1,107] contributing to a vicious multidirectional cycle of physical and psychological consequences of falling and reduced overall quality of life. (Figure 1.2)

Figure 1.2 Multidirectional cycle of negative physical and psychological consequences of falling.




A person may have a fear of falling and restrict participation in activities of daily living because they believe they are unable to execute a task, but have no history of falling.[3,4,102,104,106]

Importantly, fear of falling is highly prevalent among older adults ambulating in the community, regardless of current functional capacity or falls history.[108]

Past literature which addresses fear of falling in PLEA is limited. Specifically, literature in this area is populated with studies using falls efficacy measurement tools to measure fear of falling outcome measures, which is not equivalent as per our CFF paradigm. The preliminary work by Miller and colleagues identified the importance of evaluating fear of falling for falls prevention among PLEA.[1,13,109] Prevalence of a fear of falling among PLEA was evaluated with a single-item question, *"Are you afraid of falling?"* with a dichotomized yes/no answer.[1] In a large sample of PLEA, 49.2% expressed a fear of falling, but only half of these individuals had a history of falling, meaning that many PLEA had manifested the concern without an antecedent event.[1] Miller and colleagues also found that those with a fear of falling avoided activities of daily living.[1] Understanding how fear of falling relates to falling and participation in normal activities among PLEA needs further research.[1]

In the literature, two types of measurement tools have been used to evaluate fear of falling among older adults – single-item questions and multi-item scales. Single-item questions for fear of falling consist of asking a version of the question, "*Do you have a fear of falling*?" with dichotomized yes/no answers or scoring on a Likert scale.[4,5,58,107,110] Measuring fear of falling through a single question can determine whether fear is present, but is problematic if used solely as it lacks quantification of the magnitude of concern and specificity to rank antecedents eliciting fear.[1, 111]

The Visual Analogue Scale (VAS) is a single-item question widely accepted as a valid measure of psychology and medical constructs in the literature.[58,112–114] Specifically, the Fear of Falling-Visual Analogue Scale (FOF-VAS) asks individuals to indicate their level of fear of falling on a 10 centimeter line with lower and upper anchors being 'no concern' and 'greatest concern'. The FOF-VAS has been investigated in community-dwelling older adults with demonstrated acceptable reliability and validity, but has not been used in PLEA.[115] The FOF-VAS allows the respondent to indicate whether a fear of falling is present and the intensity at which they feel that emotion.

Multi-item scales to evaluate fear of falling include the Mobility Efficacy Scale,[116] Modified Survey of Activities and Fear of Falling in the Elderly (mSAFFE),[107] and University of Illinois at Chicago Fear of Falling Measure.[117] Among these commonly used scales in older adults, the

mSAFFE demonstrated the most acceptable validity among older adults in a recent systematic review.[18] The mSAFFE evaluates level of avoidance in activities of daily living due to a fear of falling.[107] Items on the mSAFFE specifically target fear of falling in relation to the restricting or avoidance of activities in the community or social life.[75]

Interventions to address fear of falling among older adults are limited to falls prevention exercise programs and have reported low to moderate success among community-dwelling older adults.[118] However, based on the theoretical framework and operational definition for fear of falling as a psychological construct,[58,102,108,111,118] purely exercise-based interventions may lack depth for addressing this issue in falls prevention.

Fear of falling among PLEA has not been delineated from other CFF-related subdomains in previous falls literature. Terms such as balance confidence, falls efficacy, and anxiety have been used interchangeably to define fear of falling.[18]

## 1.5.2 Self-Efficacy Theoretical Framework

Perceived self-efficacy is the confidence a person has within themselves to perform and execute a specific task.[19] A person with high self-efficacy will have confidence to execute a physical or mental task, leading to a sense of mastery.[119, 120] Alternatively, a person with low self-efficacy will avoid activities that appear threatening to their perceived abilities,[19] reducing their exposure those activities and self-affirming a reduced functional capacity.[119] Repeated exposure and engagement in activities of daily living are essential to build strong self-efficacy, perception of safety, and confidence.[120] Overtime, low self-efficacy can create an unconscious self-regulation of behaviours.[19] Self-efficacy has been the basic framework for initiation and maintenance of behaviour change and is recognized in various areas of healthcare literature, such as post-stroke rehabilitation,[121] to improve QOL, perceived health status, and engagement in the community.[122]

There are two subdomains within the CFF model that are informed by the theoretical framework of self-efficacy – falls efficacy and mobility efficacy.[19, 119]

### 1.5.2.1 Falls Efficacy

Falls efficacy is the perceived confidence a person has within themselves to avoid a fall during essential, nonhazardous activities.[7, 25] Falls prevention research among older adults has identified a relationship between low falls efficacy and an increased risk of falls, resulting in a decline in functional mobility.[3,123–125] Further, there is a statistically significant difference between perceived falls efficacy among individuals with a history of falls and individuals without; individuals with no history of falling have a higher rated perceived falls efficacy.[111]

Not all individuals who report a fear of falling also perceive low falls efficacy. In the large, pivotal study conducted by Tinetti et al., 43.0% of older adults reported a fear of falling while the same group reported a very high level of perceived falls efficacy.[111] This demonstrates that falls efficacy can be relatively high even when a fear of falling is present. Therefore, the two constructs are not equitable.[111] Measuring falls efficacy can provide clinicians and researchers a rich story of how the individual perceives their ability to execute activities of daily living compared to identifying if fear is present.[111]

Enhancing falls efficacy is an important component in falls prevention intervention and overall QOL. Therefore, falls efficacy should be assessed for individuals who are at risk for falling to intervene and prevent functional decline.[4,126] Previous literature among older adults have demonstrated that falls efficacy is a mediator for fear of falling.[127] Through enhancing falls efficacy, the risk of falling can be reduced.[127] There is a lack of falls efficacy research using reliable measures among PLEA.

Two of the most commonly used standardized scales in falls research among older adults are the Falls Efficacy Scale-International (FES-I)[80] and the Activities-specific Balance Confidence (ABC) scale.[98,128] Both were developed among community-dwelling older adults, but differ on the complement of tasks. Additionally, the FES-I uses a 4-point Likert scale, ranging from ‘Not at all concerned’ (1) to ‘Very concerned’ (4) and the ABC uses a sliding scale from 0 (no confidence) to 100 (completely confident). A low score on the FES-I and a high score on the ABC indicate high falls efficacy. The ABC includes more complex and challenging tasks, reducing the possibility of ceiling effects by respondents.[27, 32]

Previous literature which evaluated the ABC scale found PLEA demonstrated lower falls efficacy when compared to other clinical populations.[109,128] Specifically, ABC scores among PLEA are low in the range of 54.1 to 74.7 while other cohorts averaged 88.0.[109,128] Further, a low score on the ABC scale was strongly correlated to reduced prosthetic mobility and a reduction in participation of social activities.[109] Therefore, the subdomain falls efficacy is valuable to understand for PLEA.

To the best of our knowledge, the FES-I has limited use in existing literature for measuring falls efficacy among PLEA.[126,130,131] However, there is no available data on reliability of the FES-I among PLEA which can limit the interpretation and usability of study data for future clinical care. Therefore, reliability of the FES-I among PLEA is needed. The ABC is the most commonly used outcome measure in research and clinical practice among PLEA and has shown excellent relative reliability and good internal consistency within this group.[132]

Scales that assess falls efficacy should fully capture community reintegration at different points in PLEA's life span.[16] The FES-I scale has demonstrated floor effects among older adults, indicating the scale may be skewed to assess people who have greater concerns about falling.[133] Therefore, the activities within these scales must be applicable to a person with lower limb loss but also inquire about relevant activities on a continuum of basic to more advanced skills.[16] Previous researchers have raised concerns regarding the validity of existing falls efficacy scales when used among PLEA as scores on these scales may not improve alongside functional mobility gains after rehabilitation.[134] ABC scores have not changed even with statistically and clinically significant changes in objective physical function.[135] Among a large group of PLEA who had been ambulating with a prosthetic at home for at least 6-months with a mean time since amputation of 17.2 years, ABC score surprisingly did not change over the course of a 2-year follow up period.[135] This finding may indicate that falls efficacy is not a modifiable factor for PLEA at stable points in their care trajectory, or, and more likely, that the ABC scale is not sensitive to change and cannot capture the unique falls efficacy concerns among this population.

The FES-I and ABC scales explicitly instruct respondents to speculate on their confidence in doing any activities listed within the scales if they do not perform them.[29,34] Moreover, people completing the scales are not instructed to identify to the assessor which activities they are making guesses on. A consequence of this result in clinicians being not able to identify the activities which are

contributing to the individual's lower falls efficacy score without identifying activities that are not performed. This limitation of the ABC and FES-I scale may contribute to falls efficacy scores remaining the same while physical function improves.[135]

#### 1.5.2.2 Mobility Efficacy

Mobility efficacy is the confidence a person has in themselves to execute physical daily activities. Poor perceived mobility efficacy can have negative effects that are similar to low falls efficacy including activity avoidance, reduced confidence and safety, and social withdrawal.[13,17,136]

Self-report questionnaires of mobility efficacy provide different information than that obtained with physical performance tests (e.g., physical function tests or timed assessments) by providing clinicians and researchers a comprehensive understanding of how a condition has impacted an individual's life.[137] Previous research in PLEA and mobility demonstrate a moderate to strong correlation between physical performance and perceived mobility capability scores.[138] In a study among adults with an LEA who ambulate in the community, researchers identified a strong relationship between scores on the Amputee Mobility Predictor with Prosthesis Scale and the Timed-Up-and-Go physical assessment.[138] However, without a perfect correlation, these measures should not be substituted for each other and should be considered together to provide clinicians and researchers a more comprehensive understanding of mobility for PLEA.

The Locomotor Capabilities Index (LCI) is a self-report subscale of the larger Prosthetic Profile of the Amputee Locomotor Capabilities Index (PPA-LCI).[139,140] The PPA-LCI was developed to quantify mobility efficacy for PLEA using a prosthesis for a range of activities of transferring and ambulation. The LCI includes 14 items, seven focusing on basic skills and seven relating to more advanced motor skills, rated on a 5-point Likert scale ranging from 0 (no) to 4 (yes, alone, without ambulation aids). A higher score on the LCI indicates more mobility capability. This scale used a theoretical framework in development to delineate factors potentially related to prosthetic use.[9] The LCI demonstrates superior psychometric properties compared to other mobility capability self-report scales developed specifically for PLEA.[141] Additionally, the LCI has been reported to have a high ceiling effect, which is beneficial when assessing perceived mobility efficacy among a heterogenous group of PLEA.[141]

The Prosthetic Limb Users Survey of Mobility (PLUS-M) was developed specifically to measure mobility efficacy in PLEA.[100, 142] The PLUS-M includes 12 questions that evaluate the level of difficulty a participant has performing an activity while wearing their prosthesis.[137] In a recent large cross-sectional study of PLEA who used a prosthesis, greater cognitive concerns were independently associated with poorer perceived mobility measured using the ABC scale and the PLUS-M, respectively.[143] This relationship remained statistically significant even when adjusted for demographic and amputation-related factors. The relationship between cognition and mobility in PLEA have been previously demonstrated,[95,96] but there is less evidence of completing complex tasks and negotiating complex environments in the literature. Further, a statistically significant relationship between two different subdomains within our CFF model, falls efficacy measured through the ABC and mobility efficacy measured through the PLUS-M.[143] This warrants the investigation to identify inter-relationships between the other CFF subdomains.

Miller and colleagues evaluated the relationship between balance confidence and perceived mobility capability among PLEA who had fallen in the past 12 months and determined that balance confidence accounted for 70.0% of the variance in mobility capability.[13] Perceived mobility has also been correlated to QOL and general satisfaction, highlighting the influence that perceived mobility has on QOL.[144]

To address the growing evidence demonstrating the significant impact concerns of mobility has on physical performance, evaluating mobility efficacy alongside other CFF subdomains and overall QOL is needed to understand the unique mobility challenges of this group.

### 1.5.3 Consequences of Falling

The feared consequences of falling can negatively regulate participation in activities, similar to a fear of falling.[5] However, feared consequences of falling contextualizes the long-term anticipated and feared consequences that may be the result of a fall. The consequences of falling subdomain includes topics of physical injury, long-term functional incapacity, subjective anxiety, and social discomfort. (Figure 1) There is substantial evidence describing the physical injuries of falling among PLEA and long-term functional incapacity,[12,131,145–147] but minimal information regarding the psychological consequences resulting from a fall.

Past research among older adults have contextualized the social discomforts and incident anxieties as a result of falling. A loss of independence resulting from a fall, such as admission to long-term care, is commonly feared among older adults.[49] Further, there is a moderate statistically significant relationship between anxiety and fall-related psychological concerns within the literature of falls prevention among older adults,[148] but no evidence of quantitative data on this topic among PLEA.

The Consequences of Falling (COF) scale was developed among community-dwelling older adults to identify the long-term damage to identity and functional capacity that perceived consequences of falls could stimulate.[5] Previous literature has demonstrated that lower perceived consequences of falling have been associated with higher level of mobility among healthy older adults.[127,149]

The COF scale has not been studied among PLEA. The only study which mentions evaluation of the construct consequences of falling among PLEA does so with the use of one dichotomized (yes/no) question, *"Did you experience any physical problems after falling?"*, with 82.0% of PLEA indicating they did not have any physical problems after falling and no interpretation of this result.[84] Additionally, there is evidence in PLEA literature which highlight the physical consequences of falling, including prevalence of physical injury and seeking medical attention,[1,55] but no available research on the psychological components of consequences of falling.

## 1.5.4 Perception of Falling

This subdomain focuses on people's agency to have the knowledge of and belief in their ability to have control over falling. Areas that can be evaluated within this domain include ability to manage falls, control over falling, falls prevention strategies, and knowledge of falls. (Figure 1) Within PLEA literature, perceptions of falling is limited to falls prevention strategies and knowledge of falls.[81] In the recent study conducted by Hunter and colleagues evaluating the knowledge of falls risk and falls prevention strategies among PLEA, there was no change in knowledge of risk factors or falls prevention strategies among participants from rehabilitation discharge to a 4-month follow-up period.[81] There was a general perception among respondents that falls could be prevented and were an important health concern compared to other health issues.[81] Additionally, at discharge 77.8% of individuals anticipated they would fall in the next 12 months, but at the 4-month follow up period, only 37.0% anticipated a fall.[81] This study demonstrated that individuals were not able to effectively anticipate their risk of falling based on past fall occurrences among this group. The

gap between knowledge of falls among PLEA and how falls are addressed and prevented in clinical settings may be the result of a lack of research on perceptions of falling among PLEA.[81]

To increase our knowledge of perceptions of falling among PLEA, understanding how PLEA perceive falls is an initial step. The perceived ability to manage and control falls is a unique area within falls literature, as such has limited measuring tools available. Two scales were developed by Lawrence et al.[114], Perceived Control Over Falling (PCOF) and Perceived Ability to Manage Falls (PAMF).[107,114] Lawrence and colleagues stated that a person can believe they do not have control over falling, yet still hold the belief that they can get up from a fall or protect oneself during a fall.[114] Neither of these scales have been investigated for PLEA.

## 1.6 Concern for Falling Influencing QOL for PLEA

Functional mobility is a strong predictor of participation in the community and overall QOL.[150,151] A greater perceived overall QOL was correlated to more advanced levels of mobility among 65.0% of PLEA.[136] A higher level of mobility was also the second best predictor, next to depressive symptoms, of greater QOL.[17] PLEA who had robust independent mobility engaged in more prosthetic use, community activity, and resulted in a greater overall QOL.[17,141,152] Given the importance of mobility for greater levels of QOL after an amputation, it stands to reason that functional mobility remains a primary goal in prosthetic rehabilitation for PLEA.[13,141,153] However, the independent subdomains of CFF (fear of falling, falls efficacy, mobility efficacy, consequences of falling, and perceptions of falling) and association to QOL have not been studied together among PLEA.

Previous falls literature among PLEA have expanded on living with an amputation through various qualitative research projects, providing clinicians and researchers valuable information to better understand the challenges that this group experiences.[49,79,120,154]

In a recent qualitative study conducted by Anderson and colleagues, a mobility clinic provided PLEA the opportunity to improve their mobility with professional assistance in a safe setting and provided peer learning and support for amputation adaptation.[72] Alternatively, Day and colleagues, conducted focus groups to investigate the everyday experiences of PLEA.[155] Themes of this study identified pain, planning and organization, the embodied experience after amputation, and

interactions with others as critical experiences that help define what constitutes a ‘good’ and ‘bad’ day.[155] Finally, the most recent publication of the lived experience of PLEA investigated experiences associated with fall-related events, including activities preceding a fall, landing of a fall, the result of the fall, and how a memory of a fall persists overtime.[156] Initial exploration of the lived mobility challenges of PLEA has not been done before, which is a limitation of the effectiveness of rehabilitation programs offered to this group.

## 1.7 Summary

There is limited research exploring the different components of a multidimensional CFF among PLEA. Among research conducted on falls efficacy within this group, there are notable limitations. Research on the psychological consequences of a concern for falling have used the terms a fear of falling, avoidance of activities, and falls efficacy have been used interchangeably by researchers and clinicians in the field. However, these constructs are fundamentally different and require full evaluation to provide a greater understanding of this outcome among PLEA. Further, our CFF paradigm suggests that falling is the result of multiple physical and psychological factors, and as such, interventions for falls prevention must align to the same. Evaluating the CFF subdomains independently and in relation to each other is necessary to provide a more comprehensive understanding of the paradigm’s inter-relationships. It is only through a better understanding of the multiple domains of a CFF among PLEA and the lived experiences of this group can effective strategies be implemented to improve rehabilitation outcomes and optimizing overall QOL.

# Chapter 2

# Study 1 – Reliability of five concern for falling scales among people with a lower extremity amputation

## 2.1 Introduction

Currently, there is an estimated 1.02 million people whom have a major LEA in the United States.[21] Unfortunately, prevalence estimates are not available for Canada. Yet, the cumulative incidence of LEAs in Canada is estimated to increase.[22] Among all individuals aged 18 years and older with an LEA, more than 52.4% of PLEA will fall at least once each year.[1] The occurrence of falls in PLEA is twice that of community-dwelling older adults, a group for whom their level of falls have been recognized as a significant public health issue.[3–5,7,157] Although community-dwelling older adults and PLEA share many similar falls risk factors, PLEA have unique mobility challenges due to the LEA and prosthetic device. There are significant movement strategy deficits caused by an amputation, which are also not regained through use of a prosthetic device.[158] Postural instability occurs for PLEA using a prosthesis due to a lack of sensation from the sole of the foot and orientating the body when walking on surfaces that may be uneven or slippery.[61]

The psychological consequences of falling may be less apparent when compared to physical consequences of a fall but can result in detriments that impact the long-term functionality and independence of PLEA. There are numerous psychological consequences of falling such as social withdrawal, a reduction in prosthesis use, and reduced QOL.[1] Moore and Ellis outlined there are many different subdomains to the psychological consequences of falls,[98] that we term a CFF. The subdomains include fear of falling, falls efficacy, mobility efficacy, consequences of falling, and perceptions of falling.[98] Each of the subdomains are conceptually different and operationally defined from previous falls literature.[98] Clear delineation of the numerous psychological consequences of falling have not been effectively done in previous literature.[98] To this end, prior research have used terms such as fear of falling, activity avoidance, falls efficacy, balance confidence, and mobility confidence interchangeably.[99]

Due to limited research in falls among PLEA, the majority of the scales available to evaluate each subdomain have not been assessed within this group. Only three of the standardized scales within

our paradigm have been evaluated for reliability among PLEA; the ABC, PLUS-M, and LCI scales.[101,129,159] The reliability of the mSAFFE, FES-I, COF, PAMF, and PCOF among PLEA needs to be established in the context of an online format, which was further necessitated by research design considerations due to the COVID-19 pandemic. An examination of the reliability of these standardized scales is needed as the first step to comprehensively and effectively evaluate a CFF among PLEA.

### 2.1.1 Purpose

The purpose of this study was to evaluate test-retest relative and absolute reliability, and agreement of the mSAFFE, FES-I, COF, PAMF, and PCOF scales among adults with an LEA.

### 2.1.2 Hypotheses

It was hypothesized that: 1) good to excellent test-retest relative and absolute reliability of the five CFF scales would be found among a sample of PLEA, and 2) agreement between initial and re-test assessments would be seen for all five CFF scales.

## 2.2 Methodology

### 2.2.1 Participants

This was a web-based, cross-sectional test-retest reliability study of standardized questionnaires in PLEA. A convenience sample of PLEA were recruited from the Outpatient Amputee Clinic at Parkwood Institute in London, Canada following a scheduled appointment with their physician. This study was approved by the Health Sciences Research Ethics Board at the University of Western Ontario and by the Clinical Research Impact Committee of Lawson Health Research Institute (REB# 115507). Recruitment for the online survey occurred between July 2020 through December 2020, the survey was closed on December 31, 2020. Participation in the survey was voluntary and consent was implied through questionnaire completion.

### 2.2.2 Inclusion & Exclusion Criteria

Individuals who were stable community ambulators were recruited for this study. To be considered to have stable mobility, individuals must have been using their prosthesis for at least one year.

Individuals were eligible to participate if they had a unilateral or bilateral amputation at either the TF or TT level, the LEA be of any etiology, 18 years of age or older, completed a prosthetic rehabilitation program, have a functional use of the English language and currently using a prosthesis for ambulation beyond transfer level use. Availability of a device (i.e., smartphone, tablet, computer) with internet access and an email address were required to complete the study.

### 2.2.3 Survey Development

The online survey was developed using Qualtrics software, Version 4.02 (Qualtrics, Provo, UT, USA). A maximum time of one month was set to complete both assessments. The survey was assessed for usability and functionality among graduate students at University of Western Ontario, Mobility in Aging Lab from June 2020 through August 2020. The survey allowed individuals to review or go back to questions, provided a progress bar at the top of the survey, and included a reminder if there were unanswered questions. Unique links were sent to each participant for the initial and re-test surveys. Seventy-two hours after completing the initial assessment, the re-test assessment link was emailed to the participant. Reminder emails were sent to participants one and two weeks after the initial and re-test link was sent. The one-month time was chosen for established ambulators as there was no expectation that their function would have changed within this time frame.

### 2.2.4 Outcome Measures

All data collected for both surveys were self-report. Demographic and clinical characteristics collected during the initial survey were age, gender, height (centimeters) and weight (kilograms) to calculate body mass index, years of education, comorbidities, current number of prescription medications, etiology of amputation, level of amputation, time since amputation, duration of prosthesis use, 12-month falls history, and use of any mobility aid devices. A fall was defined as "unintentionally coming to rest on the ground, floor or other lower level".[51]

#### 2.2.4.1 Concern for Falling

##### 2.2.4.1.1 Fear of Falling

Fear of falling was assessed through the mSAFFE, which evaluates avoidance of activities of daily living due to the perceived fear of falling.[5] The mSAFFE scale contains 17 questions of different basic instrumental activities of daily living, such as going out to a store or cleaning one's house.[5] All items are scored on a 3-point Likert scale; "would never avoid" (1), "sometimes avoid" (2), and "always avoid" (3). The final recorded score is the sum of all items (Maximum: 51), with a higher final score indicating a worse fear of falling. The mSAFFE has satisfactory test-retest reliability among community-dwelling older adults.[5]

##### 2.2.4.1.2 Falls Efficacy

Falls efficacy was evaluated through the FES-I; a 16-item scale which measures an individual's level of concern of falling when performing physical and social activities.[160] Items are rated on a 4-point Likert scale, with upper and lower anchors being "not at all concerned" (1) and "very concerned"(4). A higher FES-I score indicates worse falls efficacy (Maximum: 64). The FES-I has demonstrated excellent reliability and discriminate validity in community-dwelling older adults.[6,160]

##### 2.2.4.1.3 Consequences of Falling

The COF scale is a 12-item measure that quantifies perceived concerns regarding consequences that may occur after a fall.[5] Each question on the COF is scored on a 4-point Likert scale, ranging from "disagree strongly" (1) to "agree strongly" (4). The COF scale is divided into two subtopics: damage to identity (6-items) and functional limitations (6-items). The damage to identity items focus on statements that reflect social consequences of falling, including embarrassment and becoming a nuisance to others.[5] The functional limitations subtopic highlights the immediate and future consequences of falling with a concentration on the physical and functional consequences. [5] The final COF score ranges between 12-48, and a lower score indicates a lower perceived negative impact a fall would have on the individual. The COF scale has excellent internal reliability and satisfactory test-retest reliability in community-dwelling older adults.[5]

#### 2.2.4.1.4 Perceptions of Falling

Perceptions of concern for falling was evaluated using the PCOF scale and the PAMF scale.[114] The PCOF scale has 4 items assessing ability to control the environment and mobility, measured on a 5-point Likert scale, which range from "strongly disagree" (1) through "strongly agree" (5).[114] The PAMF scale has 5 items assessing a participant's certainty that they would be able to manage a fall and find a way to get up. The PAMF scale uses a 4-point Likert scale that ranges from "strongly disagree" (1) through "strongly agree" (4).[114] The maximum final score for the PCOF and PAMF scales are both 20. A higher total score on either scale indicates more control and/or ability to manage falls the respondent perceived.

### 2.2.4.2 Statistical Analysis

Demographic and clinical characteristics were summarized using means and standard deviations or frequencies and percentages, as appropriate. Evaluation of normality and outliers for outcome measure scores at the two assessment times were performed using the Shapiro-Wilk tests, histograms, Q-Q plots, and boxplots. Outliers were defined as values greater than 1.5 times outside the interquartile range, while values more than 3.0 times outside were categorized as extreme outliers. All five scales were determined to be normally distributed, and no participant data were removed based on the outlier criteria.

Relative reliability is an assessment of repeated measurement scores of individuals to determine whether individuals maintain their rank position amongst the group.[161] Relative reliability was assessed using the intraclass correlation coefficients (ICC) with 95% confidence intervals (CI).[162, 163] ICC values of greater or equal to 0.90 are considered excellent; values between 0.80 and 0.89 are considered good; values between 0.70 and 0.79 are considered fair; and values <0.70 are considered to be of questionable clinical value.[164]

Absolute reliability refers to the degree to which variation occurs within an individual's scores.[161] This provides clinicians the opportunity to effectively interpret the precision of the scale being evaluated. Two measures of absolute reliability were calculated: standard error of measurement (SEM) and minimal detectible change ($MDC_{95}$) with a 95% CI. The SEM is expressed in the same units as the scale it is measuring.[164, 165] Smaller SEM values represent a smaller tool error,

reflecting a more reliable measurement.[164, 112] The MDC quantifies the difference needed to be observed between initial and re-test assessments that is outside of the error of the tool, and that true change occurs with a 95% certainty.[166] The MDC is also measured in the same units of the measurement scale. For the present study, SEM and $MDC_{95}$ were calculated using the pooled standard deviation of the initial and re-test scale assessments. A pooled standard deviation ($SD_{pooled}$) is the weighted average of standard deviations of two groups. SEM and MDC were calculated using the following formulas:

$$SEM = SD_{pooled} \times \sqrt{1 - ICC}$$

Equation 1: Standard Error of Measurement

$$MDC_{95} = (1.96 \times SEM) \times \sqrt{2}$$

Equation 2: Minimal Detectable Change within a 95% Confidence Interval

Bland-Altman plots evaluated agreement between the two assessments, displaying the difference in initial and re-test assessment scores (y-axis) against the study sample mean difference (x-axis).[167] The $MDC_{95}$ will be used to evaluate the acceptable sizes for the limit of agreement (LOA), such that the LOA should have similar values as the $MDC_{95}$.

An *a priori* sample size calculation indicated 20 participants would be needed for a desired ICC of 0.90 with a lower CI of 0.70 (assuming $\alpha$=0.05, and $\beta$=0.20).[168] A null hypothesis for assessing normality was set at $p<0.05$. All statistical analyses were performed using SPSS version 26.0 (IBM Inc., Chicago, IL, USA).

## 2.3 Results

### 2.3.1 Demographic and Clinical Characteristics

Twenty-five individuals were enrolled in the study, but three individuals did not complete all components. Therefore, the data analyzed for this study consisted of 22 participants. (Table 2.1) The mean age of the study sample was 63.5±12.9 years and most were males (63.6%). Eighteen participants (81.8%) reported having a unilateral below-knee amputation and two participants (9.1%) reported a unilateral, above the knee amputation. Dysvascular-related diseases was the primary cause of amputation for 11 (50.0%) participants. The average time since amputation was

147.0±148.4 months, ranging from 17 to 549 months. Similar scores were reported on the five scales of interest during the initial and re-test surveys. (Table 2.2)

Table 2.1: Demographic and clinical characteristics of a sample of adults with a major lower extremity amputation. (n=22)

| **Demographic and Clinical Characteristics** | **Mean±Standard Deviation or Frequency (%)** |
|---|---|
| Age (years) | 63.5±12.9 |
| Gender (*n*, male %) | 14 (63.6%) |
| Body mass index (kilogram/meter$^2$) | 28.5±6.3 |
| Years of education (years) | 16.1±3.0 |
| Number of prescription medications | 6.0±3.8 |
| Time since most recent amputation (months) | 147.0±148.4 |
| **Level of amputation:** | |
| Unilateral below the knee | 18 (81.8%) |
| Unilateral above the knee | 2 (9.1%) |
| Bilateral above the knee | 1 (4.5%) |
| Other | 1 (4.5%) |
| **Primary amputation etiology:** | |
| Trauma | 8 (36.4%) |
| Diabetes mellitus | 7 (31.8%) |
| Peripheral vascular disease | 4 (18.2%) |
| Congenital Defect | 3 (13.6%) |
| **Comorbidities:** | |
| Average number of comorbidities | 1.6±1.4 |
| Diabetes mellitus (*n*, yes %) | 8 (36.4%) |
| Hypertension (*n*, yes %) | 10 (45.5%) |
| Myocardial infarction (*n*, yes %) | 5 (22.7%) |
| Bypass (*n*, yes %) | 2 (9.1%) |
| Stroke (*n*, yes %) | 1 (4.5%) |

| | |
|---|---|
| Osteoarthritis (*n*, yes %) | 3 (13.6%) |
| Arthroplasty (hip/knee) (*n*, yes %) | 2 (9.1%) |
| Cataracts (*n*, yes %) | 3 (13.6%) |
| **Issues with stump:** | |
| Average number of issues | 2.1±2.2 |
| Pain | 7 (31.8%) |
| Phantom pain | 14 (63.6%) |
| Open wounds | 4 (18.2%) |
| Ulcers | 2 (9.1%) |
| Swelling | 5 (22.7%) |
| Hypertension | 2 (9.1%) |
| Loss of sensation | 2 (9.1%) |
| Contracture | 1 (4.5%) |
| **Issues with non-amputation leg:** | |
| Average number of issues with non-amputation leg | 1.0±0.8 |
| Pain | 7 (31.8%) |
| Open wounds | 1 (4.5%) |
| Swelling | 1 (4.5%) |
| Hypertension | 1 (4.5%) |
| Loss of sensation | 2 (9.1%) |
| Other | 8 (36.4%) |
| **Fall within the last 12 months:** | |
| Number of people who fell | 15 (68.2%) |
| Number of falls among fallers | 2.9±5.0 |
| $\geq$ 2 Falls within the last 12 (*n*, yes %) | 9 (60.0%) |
| Injured in the fall (*n*, yes %) | 7 (46.7%) |
| Did the fall involve a hospital visit (*n*, yes %) | 2 (13.3%) |
| Wearing prosthesis during fall (*n*, yes %) | 15 (100.0%) |
| **Time using a prosthesis:** | |
| Average duration of prosthesis use (months) | 118.8±125.4 |
| Hours of prosthesis wear per day (hours) | 13.0±4.4 |

| | |
|---|---|
| Days of prosthesis wear per week (days) | 6.8±0.7 |
| Reason for prosthesis use (*n*, walking %) | 22 (100.0%) |
| **Mobility aid use (e.g., cane, walker)** | 10 (45.0%) |

## 2.3.2 Relative Reliability

Relative reliability for each scale is presented in Table 2.2. The mSAFFE demonstrated excellent relative reliability (ICC=0.92, 95% CI: 0.82-0.97) and the FES-I demonstrated good relative reliability (ICC=0.87, 95% CI: 0.70-0.94). The COF and PAMF scales demonstrated fair reliability, with ICC values of 0.78 (95% CI: 0.53-0.90) and 0.73 (95% CI: 0.46-0.88), respectively. Due to a lack in variability in total scores for the PCOF scale, the ICC could not be validly calculated and thus this outcome was not further analyzed.

## 2.3.3 Absolute Reliability

Absolute test-retest reliability values are presented in Table 2.2. SEM values for all scales were small in magnitude.

## 2.3.4 Agreement

There was good agreement between initial and re-test scores for the mSAFFE, FES-I, COF, and PAMF scale. (Figure 2.1, Figure 2.2, Figure 2.3, Figure 2.4) There was no evidence of learning effects based on residual trends in the four Bland-Altman plots. The calculated LOAs for mSAFFE, FES-I, and PAMF scale were similar to the calculated $MDC_{95}$ values, while the value for the COF scale was slightly larger. LOA values for each scale were consistent to calculated $MDC_{95}$ values.

Table 2.2: Scores, test-retest reliability, standard error of the measurement, and minimal detectable change for Modified Survey of Activities and Fear of Falling in Elderly, Falls Efficacy Scale-International, Consequences of Falling Scale, and Perceived Ability to Manage Falls Scale in adults with a major lower extremity amputation.

| **Measurement** | **Modified Survey of Activities and Fear of Falling in Elderly (*n*=22)** | **Falls Efficacy Scale – International (*n*=21)** | **Consequences of Falling Scale (*n*=22)** | **Perceived Ability to Manage Falls Scale (*n*=22)** |
|---|---|---|---|---|
| **Initial (Mean±SD)** | 25±6.92 | 27±9.26 | 25±7.44 | 16±2.01 |
| **Re-test (Mean±SD)** | 25±6.44 | 27±8.13 | 25±7.44 | 16±2.63 |
| **ICC (95% CI)** | 0.92 (0.82 – 0.97) | 0.87 (0.70 – 0.94) | 0.78 (0.53 – 0.90) | 0.73 (0.46 – 0.88) |
| **SEM** | 1.89 | 3.14 | 2.38 | 1.22 |
| **$MDC_{95}$** | 5.24 | 8.70 | 6.59 | 3.37 |

SD = Standard Deviation; ICC = Intraclass correlation coefficient; CI = Confidence interval; SEM = Standard error of measurement; $MDC_{95}$ = minimal detectable change, calculated at a 95% confidence interval. 'Perceived Control Over Falling' survey not included in relative and absolute reliability assessment due to lack of variability among scale scores.

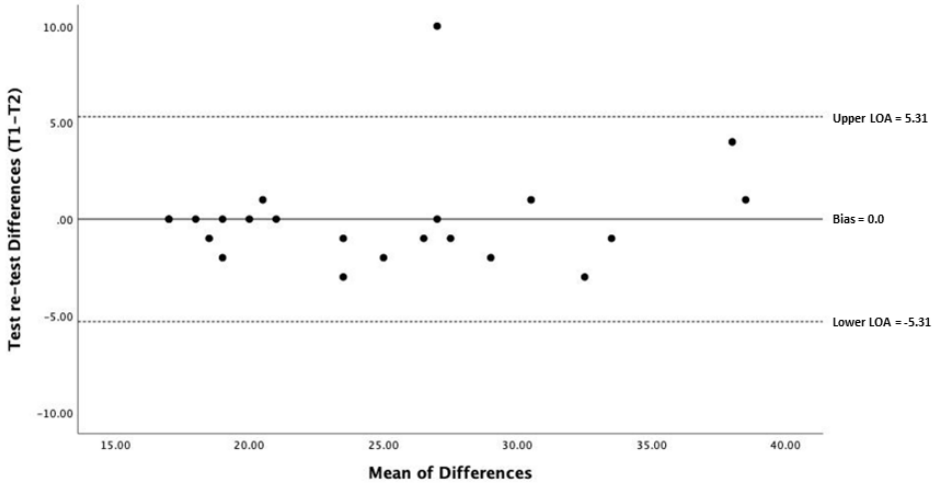



Figure 2.1: Bland-Altman plot for agreement between test re-test of the Modified Survey of Activities and Fear of Falling in the Elderly in a sample of adults with a major lower extremity amputation. (n=22)

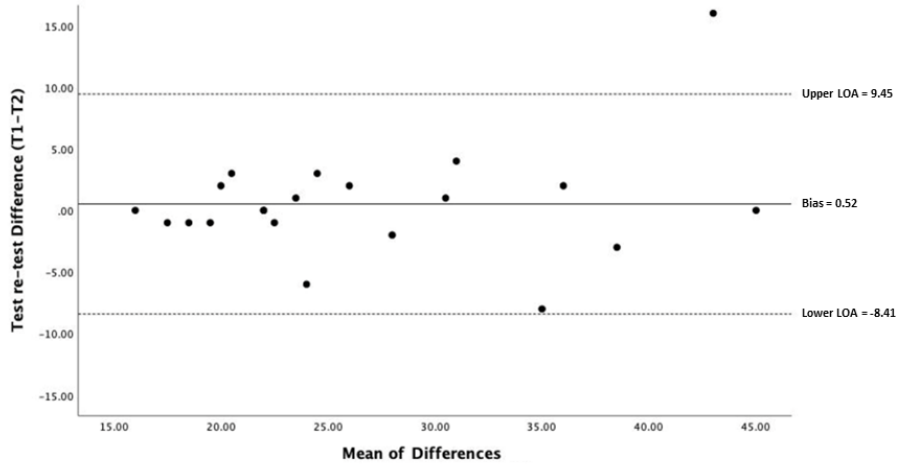



Figure 2.2: Bland-Altman plot for agreement between test re-test of the Falls Efficacy Scale-International in a sample of adults with a major lower extremity amputation. (n=21)

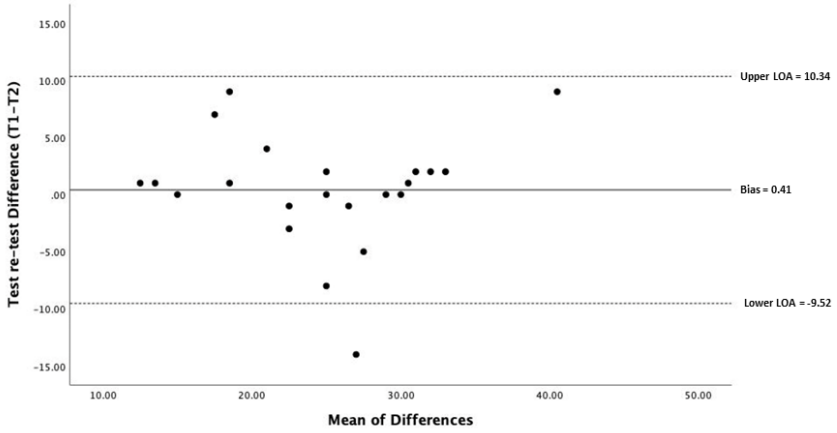



Figure 2.3: Bland-Altman plot for agreement between test re-test of the Consequences of Falling Scale in a sample of adults with a major lower extremity amputation. (n=22)

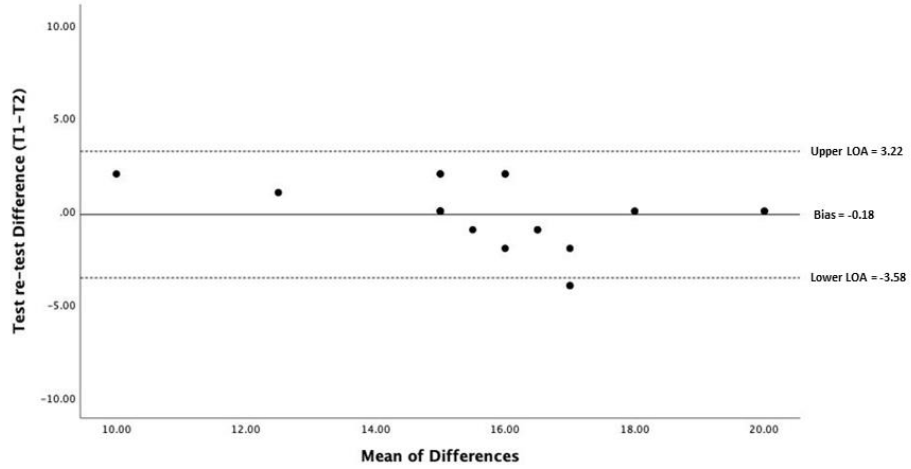



Figure 2.4: Bland-Altman plot for agreement between test re-test of the Perceived Ability to Manage Falls Scale in a sample of adults with a major lower extremity amputation. (n=22)

## 2.4 Discussion

The study has demonstrated the mSAFFE, FES-I, COF, and PAMF scales display acceptable ICC values of fair to excellent test-retest relative reliability. Our research provides clinicians and researchers with values to determine change over time in PLEA. The research has provided support for use of these scales in PLEA which will provide the ability to evaluate a full range of subdomains within a CFF. The establishment of reliability allows researchers and clinicians to differentiate between actual change and random fluctuations among scores, and whether having a specific disease or disorder can influence a person's ability to respond to a self-report measure.[112,165,169]

The PAMF scale that evaluates perceived ability to manage falls demonstrated fair test-retest relative reliability, but agreement demonstrated strong agreement between respondent's initial and re-test assessment scores. The conflicting level of results may be the result of a lack of sufficient variability of initial and re-test scores. There must be some variability within scores when calculating ICC.[170,171] If between-subject scores differ minimally from each other, ICC values may be only fair (e.g., an ICC value less than 0.70) regardless of small variation of initial and re-test scores within-subjects.[170] In the present study, mean initial and re-test scores of the PAMF scale were particularly similar. This problem was more pronounced for the PCOF scale as mean initial and re-test scores were almost identical. As a consequence, it was deemed that the ICC could not be validly calculated. The PCOF has four items measured on a 5-point Likert scale and therefore has a small range of possible score totals.[114] Future research on the reliability of this scale could be enhanced through recruitment of a larger sample. Therefore, the interpretation of small ICC values for measurements which demonstrated similar initial and re-test scores may result in the premature dismissal of a reliable scale.

In the present study, the FES-I scale demonstrated good relative reliability through ICC values and relatively large SEM and $MDC_{95}$ values when compared to raw scores. Similar ICC, SEM, and $MDC_{95}$ values have been previously found among individuals with dizziness and imbalances,[172] and increased risk of falling.[173] These values are useful when using the FES-I to evaluate falls efficacy among PLEA change over time. A unique feature of the FES-I asks respondents if they do not currently do an activity in the list, they are instructed to imagine how confident they would

be if they had to do the activity. This feature of the scale could have implications for consistency of rating on tasks between sessions. Relatively large SEM values may be the result of systemic error of the scales through asking participants to speculate their confidence to successfully complete an activity without falling on tasks they currently do not perform.[160] A person may speculate their performance on these items differently when assessed on two separate occasions because they have no comparison to evaluate their skill level in that specific scenario. Therefore this may indicate a lack of relevance of some items within the FES-I scale.[160]

This is the first study to evaluate the mSAFFE, FES-I, COF, and PAMF scales among PLEA. The average scores on the mSAFFE, FES-I, COF, and PAMF of the present study are comparable to scores of other clinical populations with acquired mobility impairments. Specifically, similarities are seen for individuals with Parkinson's disease, stroke, and mobility disorders due to dysvascular-related complications without an amputation.[174–176] PLEA have unique mobility challenges that may not be entirely comparable to other clinical populations or community-dwelling older adults, for whom the CFF scales were originally developed. Therefore, this study provides novel evidence of average scores for comprehensive range of standardized CFF scale among PLEA yet information obtained from a larger population is warranted.

There were a number of strengths to this study, the sample size of 22 participants ensured that there was appropriate power to evaluate test-retest reliability. Based on the clinical and demographic characteristics, the group who enrolled in the study was a heterogenous sample of PLEA who ambulate with a prosthesis, though is not generalizable to all PLEA. This study contains limitations worth noting. First, a convenience sample of adult PLEA attending a regularly scheduled outpatient clinic appointments with a physiatrist were recruited and may not represent everyone with an LEA who uses a prosthesis. Recruitment was conducted virtually, as the study took place during COVID-19 and this might have impacted accessibility for people to participate. Individuals who were not confident using a telephone or computer or did not have access to an internet device would not be represented within the present study's sample, again affecting generalizability of the findings to all PLEA who use a prosthesis.

## 2.5 Conclusion

The projected increase in the number of new LEAs performed in Canada and the expected growth of PLEA living longer after amputation demand assessment tools that are reliable to this growing population.[22] This study determined that there was fair to excellent test-retest relative and absolute reliability among the mSAFFE, FES-I, COF, and PAMF scales in a sample of PLEA. All four scales demonstrated good agreement between initial and re-test scores. Support and evidence for the reliable use of CFF self-report measures among PLEA in an online format will allow clinicians to comprehensively assess CFF in clinical practice.

# Chapter 3

# Study 2 – A concern for falling influences quality of life among adults with a major lower extremity amputation: an online, cross-sectional study

## 3.1 Introduction

An estimated 7,405 individuals undergo a new LEA in Canada each year.[22] The cumulative incidence of LEAs in Canada is projected to increase in the future.[22] Falling is a major concern for all PLEA, as 52.4% of individuals aged 18 years and older with an LEA will fall at least once each year.[1] The occurrence of falls in PLEA is twice that of community-dwelling older adults, a group for whom their level of falls have been recognized as a significant public health issue.[3–5,7,157] Although community-dwelling older adults and PLEA share many similar falls risk factors, PLEA have unique mobility challenges due to the LEA and prosthetic device. There are significant movement strategy deficits caused by an amputation which are also not regained through use of a prosthetic device.[158] Postural instability occurs for PLEA using a prosthesis due to a lack of sensation from the sole of the foot, orientating the body when walking on surfaces that may be uneven or slippery.[61] Further, the occurrence of falls among PLEA remains elevated after the successful completion of prosthetic rehabilitation.[1]

The consequences of falling for PLEA can be dire. Physical consequences of falling can include musculoskeletal injuries, fractures, lacerations, and head injuries.[10–12] Specifically, the physical consequences of falls can interfere with progression in prosthetic rehabilitation and in the use of a prosthetic device throughout the life span of PLEA after rehabilitation.[2, 8] The psychological consequences of falls may not be as apparent as the physical consequences but may result in similar adverse functional consequences, including a reduction in prosthesis use and physical activities,[14] social isolation,[16] and decreased overall QOL.[17] The psychological consequences of falling can be multidimensional,[98] and therefore, we have termed this overarching paradigm: CFF. There are five delineated subdomains of a CFF: fear of falling, falls efficacy, mobility efficacy, consequences of falls, and perception of falls. These subdomains were originally articulated from falls literature among community-dwelling older adults. The work by Moore and Ellis[98] has been modified to address the experience of falls as it relates to PLEA.[98] Importantly, each subdomain in our

paradigm is delineated from one another. Fear of falling is the emotional conditioning process of avoidance of activities that a person is physically capable of performing due to a lasting concern about falling.[149] Self-efficacy informs two subdomains – falls efficacy and mobility efficacy. Falls efficacy is the perceived confidence a person has within themselves to avoid a fall during essential, nonhazardous activities.[7, 25] Mobility efficacy is the confidence a person has in themselves to execute physical daily activities. Poor perceived mobility efficacy can have negative effects that are similar to low falls efficacy including activity avoidance, reduced confidence and safety, and social withdrawal.[13,17,136] The feared consequences of falling can negatively regulate participation in activities, similar to a fear of falling.[5] However, feared consequences of falling contextualizes the long-term anticipated and feared consequences that may be the result of a fall. The consequences of falling subdomain includes topics of physical injury, long-term functional incapacity, subjective anxiety, and social discomfort. The perceptions of falling subdomain focuses on people's agency to have the knowledge of and belief in their ability to have control over falling. Areas that can be evaluated within this domain include ability to manage falls, control over falling and falls prevention strategies. Previous research in falls literature has not effectively delineated the multiple domains of a CFF,[98] such that the terms fear of falling, activity avoidance, falls efficacy, balance confidence, and mobility confidence have been used interchangeably.[99] Additionally, each subdomain within our model includes at least one commonly used standardized scale from falls literature. The literature for PLEA has primarily focused on falls efficacy to the exclusion of evaluating the other subdomains of a CFF.[109,129,135] Many of the scales included within our CFF paradigm were originally developed for use in community-dwelling older adults. The ABC, PLUS-M, and LCI scales are the only CFF scales previously evaluated among PLEA.[101,129,142] Anecdotally, we are aware of clinician reports that the ABC scale includes questions about activities that are not physically possible for most PLEA, such as standing on their tip toes or standing on a chair. Thus, there is still much to understand about the psychological consequences of falls within each of the subdomains of a CFF in PLEA. This enhanced knowledge has the potential to improve rehabilitation through targeted interventions.

Understanding the challenges of living with limb loss is limited to exploring mobility skills and peer support from other individuals with lower limb amptuations,[56] themes of pain, planning, and organization that influence having a 'good' or 'bad' day as someone living with limb loss,[155] and finally the categorization of activities preceding a fall, landing of a fall, the result of the fall, and

how a memory of a fall persists overtime among PLEA.[156] These initial studies evaluating the lived experience of PLEA have provided researchers and clinicians a better understanding of what living with limb loss entails but does not capture the spectrum of subdomains within CFF or how these different subdomains of CFF are associated with QOL. The unique experiences can only be captured by discussing with PLEA the mobility and functional capability challenges they face. In order to effect change in rehabilitative programs to address a CFF among PLEA, a comprehensive understanding of the multiple subdomains that make up a CFF is required.

### 3.1.1 Purpose

The purpose of this study is to 1) evaluate the multiple subdomains of a CFF and their inter-relationships using nine standardized scales of measurement and open-ended questions among PLEA and 2) to evaluate the association between each of the different CFF scales on QOL in PLEA.

### 3.1.2 Hypotheses

It was hypothesized that: 1) the nine CFF scales would have moderate to strong correlations amongst other scales categorized within the respective subdomains and have moderate to strong correlations across multiple subdomains. Open-ended responses would reveal additional activities or tasks that were not currently included in standardized measurements that were developed for community-dwelling older adults and 2) each CFF scale would be independently associated to QOL among PLEA.

## 3.2 Methodology

### 3.2.1 Participants

This was a web-based, cross-sectional study. A convenience sample of PLEA were recruited from the Outpatient Amputee Clinic at Parkwood Institute in London, Canada following a regularly scheduled physician appointment. Sample size for this study was limited by the four-month allotted window available of this research project and clinical operations that were constrainted by adaptions under COVID-19 precautions. This study was approved by the Health Sciences Research Ethics Board at the University of Western Ontario and by the Clinical Research Impact Committee

of Lawson Health Research Institute (REB# 115507). Recruitment for the online survey occurred between July 2020 and March 2021, the survey was closed on March 5, 2021. Consent was implied through survey completion.

### 3.2.2 Inclusion & Exclusion Criteria

Individuals who were stable community ambulators were recruited for this study. To be considered to have stable mobility, individuals must have been using their prosthesis for at least one year. Individuals were eligible to participate if they had a unilateral or bilateral amputation at either the TF or TT level, the LEA be of any etiology, were 18 years of age or older, completed a prosthetic rehabilitation program, had functional use of the English language, and were currently using a prosthesis for ambulation. Availability of a device (e.g., smartphone, tablet, computer) with internet access and an email address was required to complete the study. Individuals were excluded if they were unable to provide informed consent.

### 3.2.3 Survey Development

The online survey used Qualtrics software, Version 4.02 (Qualtrics, Provo, UT, USE). Nine standardized CFF scales and two affect scales were included within the survey. Six open-ended questions were constructed with input from researchers and clinicians with expertise in amputee rehabilitation. There was no limit to the amount of text participants could provide in the open-ended responses. The survey was developed and conducted using the CHERRIES guidelines to ensure complete reporting of Web-based surveys.[177] The survey was first piloted for usability and functionality among three graduate students in the Faculty of Health Sciences at the University of Western Ontario from June 2020 to August 2020. Time to complete the survey was anticipated at 45 minutes. A link was emailed to each participant. Reminder emails were sent at one and two weeks after the initial link was sent.

The survey consisted of thirteen sections: 1) ABC, and an additional question asking for activities listed in the ABC Scale that the respondent was unable to perform due to current abilities; 2) Challenging activities – an open-ended question asking about challenging activities to perform since the amputation; 3) COF Scale, and two open-ended questions asking about any consequences that would negatively impact their ability to be functionally independent and damaging to identity;

4) FES-I, and an open-ended question asking for activities not listed in the FES-I that the person was concerned about performing; 5) FOF-VAS; 6) mSAFFE, and an open-ended question asking for activities not listed in mSAFFE that are avoided because of a fear of falling; 7) Aspirational activities – an open-ended question asking about activities the person wished they could perform since the amputation; 8) LCI Scale; 9) PCOF Scale; 10) PAMF Scale; 11) PLUS-M Scale; 12) Affect – included the DASS-21 and the World Health Organization Quality of Life (WHOQOL) Scale; and 13) Demographics and information about the amputation, prosthesis, and falls. (See Appendix G for the complete survey)

## 3.2.4 Outcome Measures

Demographic and clinical characteristics collected were age, gender, height (centimeters) and weight (kilograms) to calculate body mass index, years of education, comorbidities, current number of prescription medications, etiology of amputation, level of amputation, time since amputation, duration of prosthesis use, 12-month falls history, and mobility aid used. A fall was defined as "unintentionally coming to rest on the ground, floor or other lower level".[51] The DASS-21 has 21 items that assess mental health, focusing on the three traits of depression, anxiety, and stress that were experienced in the last two weeks.[178] Items are scored on a 4-point Likert scale including "does not apply to me at all" (0), "applied to me to some degree or some of the time" (1), "applied to me a considerable degree" (2), and "applies to me very much, or most of the time" (3).[178] A higher total score on the DASS-21 indicates more severe symptoms of depression, anxiety, and stress, and total scores can range from 0 to 63.[178]

### 3.2.4.1.1 Concern for Falling

#### 3.2.4.1.1.1 Fear of Falling

Fear of falling was assessed through the mSAFFE, which evaluates avoidance of activities of daily living due to a perceived fear of falling.[5] The scale contains 17 tasks. All items are scored on a 3-point Likert scale; "would never avoid" (1), "sometimes avoid" (2), and "always avoid" (3). Scores can range from 17 to 51, higher scores indicate a worse fear of falling. The mSAFFE has satisfactory test-retest reliability among community-dwelling older adults.[5,160]

Fear of falling was also measured using the FOF-VAS.[108,179] The FOF-VAS is a single-item question which asks participants to rate their level of fear of falling with anchored ends of 0 (no concern) to 10 (greatest concern). Participants were able to drag a cursor to a point on the scale which best described their fear of falling.

## 3.2.4.1.1.2 Falls Efficacy

The FES-I is a 16-item scale which measures an individual's belief in successfully completing a task (e.g., physical and social activities) without falling.[160] Items are rated on a 4-point Likert scale, with lower and upper anchors being "not at all concerned" (1) and "very concerned" (4). Total scores can range from 16 to 64. The FES-I has demonstrated excellent reliability and discriminate validity in community-dwelling older adults.[6,160] Threshold values that differentiate between low, moderate, and high concern among community-dwelling older adults are 16-19, 20-27, and 28-64, respectively.[133]

The ABC scale is a 16-item self-report measure that quantifies balance confidence in various activities of daily living.[128] Items are rated on a scale from 0 to 100, where a score of 0 indicates no confidence and a score of 100 indicates complete confidence. The final reported score is the average of all items for a possible score ranging from 0 to 100 percent. If respondents do not currently do an activity in the list, they are instructed to imagine how confident they would be if they had to do the activity. The ABC scale has good reliability and construct validity in people with LEAs.[129] ABC scores above 80 percent are indicative of high functioning and ABC scores below 50 percent are considered low level functioning among older adults.[180]

Individuals were also asked to identify any of the 16 items on the ABC scale that they were not able to perform due to their functional capacity with the prosthesis and LEA. The number of responses for each item on the ABC scale was recorded.

## 3.2.4.1.1.3 Mobility Efficacy

The PLUS-M was developed specifically for people with an LEA to evaluate the level of difficulty a participant has performing an activity while wearing a prosthesis.[100] The scale contains 12 questions that are scored on a 5-point Likert scale: "unable to do" (1) to "without any difficulty"

(5). The PLUS-M scores range from 12 to 60, higher scores indicate better mobility efficacy. Validity and normative scores have been established for the PLUS-M.[100]

The LCI is a subscale of the Prosthetic Profile of the Amputee scale and evaluates the ability to perform functional activities. The scale has 14 questions which are scored on a 5-point Likert scale: "no" (0), "yes, if someone helps me" (1), "yes, if someone is near me" (2), "yes, along, with ambulation aids" (3), "yes, alone, without ambulation aids" (4). Seven items pertain to basic activities and seven items asks the participant to consider more advanced activities. Total scores range from 0 to 56, with higher scores indicating better mobility efficacy. The LCI has demonstrated acceptable reliability and validity.[139]

## 3.2.4.1.1.4 Consequences of Falling

The COF scale measures perceived consequences that may occur after a fall.[5] The scale has 12 items which are measured on a 4-point Likert scale, ranging from "disagree strongly" (1) to "agree strongly" (4). The COF scale is divided into two subtopics: damage to identity (6-items) and functional limitations (6-items). The damage to identity items focus on statements that reflect social consequences of falling, including embarrassment and becoming a nuisance to others.[5] The functional limitations subtopic highlights the immediate and future consequences of falling with a concentration on the physical and functional consequences.[5] The total score can range between 12 to 48, and a lower score indicates a lower perceived negative impact of falls. The COF scale has excellent internal reliability and satisfactory test-retest reliability in community-dwelling older adults.[5]

## 3.2.4.1.1.5 Perceptions of Falling

The PAMF scale assesses a participant's certainty that they would be able to manage a fall and find a way to get up. The scale has 5 items measured with a 4-point Likert scale from "strongly disagree" (1) through "strongly agree" (4).[114] Scores range from 5 to 20, higher scores indicate greater perceived ability to manage falls.

The PCOF scale assesses the ability to control the environment and one's own mobility.[114] The scale has 4 items measured on a 5-point Likert scale, which range from "strongly disagree" (1)

through “strongly agree” (5). Scores range from 4 to 20, higher scores indicate greater control over falling.

#### 3.2.4.1.2 Quality of Life

The WHOQOL scale is a self-report survey assessing perceptions of life, including cultural and value systems that relate to goals, expectations, standards, and concerns.[181] Questions are referenced to the time frame of the previous 2 weeks. Items are scored on a 5-point Likert scale ranging from “not at all” (1) to “an extreme amount” (5). An overall QOL score is made up of four general health and wellbeing questions. The summation of the four general health items is reported as a proportion out of 100 to yield a summary QOL score.

### 3.2.4.2 Statistical Analysis

Demographic and clinical characteristics were summarized using means and standard deviations or frequencies and percentages, as appropriate.

To address Objective 1, the data from the CFF outcome measures (mSAFFE, FOF-VAS, FES-I, ABC, PLUS-M, LCI, COF, PAMF, and PCOF) were first evaluated for assumptions of normality. None of the measures met normality and scores were reported as medians and interquartile ranges ($25^{th}$, $75^{th}$ percentiles). The relationship among the nine CFF scales were analyzed using Spearman bivariate correlation analysis. Spearman’s rho values of greater or equal value to ±0.0 to ±0.59 are considered fair; values between ±0.60 and ±0.79 are considered moderate; values between ±0.80 and ±0.99 are considered very strong.[182] An analysis using descriptive statistics evaluated how many tasks within the ABC scale were reported as activities people did not perform.

Open-ended responses were categorized using the framework described by Graneheim and Lundman.[183] Two researchers independently coded responses from each open-ended question, sorted into categories, and then analyzed using descriptive statistics of the number of activities in each category. Operational definitions of categories were constructed based on the World Health Organization - International Classification of Functioning.[184] (Table 3.1)

To address Objective 2, the nine CFF variables (mSAFFE, FOF-VAS, FES-I, ABC, PLUS-M, LCI, COF, PAMF, and PCOF) were used to evaluate their independent association on QOL

through nine separate linear regression models (one model for each CFF variable as the main exposure of interest). The general health summary score from the WHOQOL scale was used as the dependent variable. Each of the CFF and QOL data were modelled as continuous variables. Univariate linear regression modelling was initially performed for each of the nine CFF independent variables on the one dependent outcome variable. Multivariable regression modelling was then performed with adjustment for confounding. Confounders were age (continuous), level of amputation (binary: transtibial, transfemoral), number of comorbidities (continuous), and DASS-21 score (continuous) and were selected according to clinical significance, previous research,[13,16,17] availability of variables, and an observed change of ≥10% in the unstandardized beta values of the independent variables in bivariate analysis.

All statistical analyses were performed using SPSS version 26.0 (IBM Inc., Chicago, IL, USA) with a 0.05 experiment-wise alpha.

Table 3.1: Operational definitions constructed based on response data from six open-ended questions in a sample of adults with a major lower extremity amputation. (n=48)

| **Category** | **Operational Definition** |
|---|---|
| Activities of Daily Living: | Essential or routine activities.[184] |
| Recreation and Leisure Activities: | Activities relating to personal interests and enjoyment. |
| Environmental Consequences: | Factors that include natural environment (i.e., weather); human made tools (i.e., built environment); social attitudes, customs, and institutions, and other individuals which has an impact on a person's functioning and participation of activities.[184] |
| Functional Mobility Consequences: | A health condition which negatively impacts participation of activities due to physical functioning and disability.[184] |
| Activities of Specified Environment Factors: | Activities influenced by factors of the environment, including the natural environment (i.e., weather) and human made tools (i.e., built environment).[184] |

## 3.3 Results

### 3.3.1 Demographic and Clinical Characteristics

Sixty-four individuals consented and enrolled in the study, but 16 individuals had incomplete data. Therefore, the study sample analyzed in this study consisted of 48 participants. (Table 3.2) The mean age of the sample was 61.8±11.6 years and the majority of participants were males (68.8%). Thirty-eight (79.2%) participants had a unilateral transtibial amputation and two participants had bilateral transtibial amputations. Dysvascular-related diseases was the primary cause of amputation for 23 (47.9%) participants. The average time since amputation was 140.9±173.8 months, ranging from 14 to 775 months. The median score for the DASS-21 was 23 (22, 31) and scores ranged from 21 to 60. The median value for the overall QOL domain on the WHOQOL scale was 75, with scores ranging from 18.75 to 100.

### 3.3.2 Concern for Falling Subdomains

The median score on the mSAFFE was 20 (18, 24). Distribution of item responses demonstrated that the statement, "*Going out when it is slippery",* was the most "Always avoided" item at 32.6% (n=15) of individuals. (Figure 3.1) The median score on the FOF-VAS was 21 (10, 61). Both scores indicated a low level of fear of falling. Participants reported 31 unique text responses on activities avoided since the amputation due to a fear of falling that were not listed in the mSAFFE scale. (Table 3.3) The category with the greatest number of responses for avoided activities was "*Recreation and Leisure Activities"* with 41.9% of all unique text responses.

Responses on the FES-I ranged from 16 to 59 with a median score of 24 (20, 31). The item, "*Walking on a slippery surface (i.e., wet or icy)"* had the greatest number of responses in the "Very concerned" (4) category (29.2%) and the item "*Preparing simple meals*" had the greatest number of responses in the "Not at all concerned" (1) category (83.3%). (Figure 3.2) FES-I scores indicated a moderate concern of falling. Participants had 15 unique text responses for activities not listed in the FES-I that they were concerned about performing since the amputation. (Table 3.4) The most commonly reported activities were within the category of *"Activities of Daily Living"* which included "*Climbing ladders*", "*Yard work*", and "*Standing on elevated surfaces*". In comparison, two participants provided responses categorized within *"Recreation and Leisure Activities"*,

which included *"Playing with kids"* and *"Sports (unspecified)".* The FES-I scores demonstrate a moderate level of falls efficacy and a high level of functioning among this sample.

Table 3.2: Demographic and clinical characteristics for a sample of adults with a major lower extremity amputation. (n=48)

| **Variable** | **Mean±SD Frequency (%)** |
|---|---|
| Age (years) | 61.8±11.6 |
| Gender (*n*, male %) | 33 (68.8%) |
| Body mass index (kilogram/meter$^2$) | 30.4±5.9 |
| Years of education (years) | 15.7±2.9 |
| Time since most recent amputation (months) | 140.9±173.8 |
| **Level of amputation:** | |
| Unilateral transtibial | 38 (79.2%) |
| Unilateral transfemoral | 5 (10.4%) |
| Bilateral transtibial | 2 (4.2%) |
| Other (undefined) | 3 (6.3%) |
| **Primary amputation etiology:** | |
| Dysvascular disease | 23 (47.9%) |
| Trauma | 16 (33.3%) |
| Failed operation | 1 (2.1%) |
| Cancer | 1 (2.1%) |
| Congenital defect | 2 (4.2%) |
| Other (undefined) | 5 (10.4%) |
| **Comorbidities:** | |
| Average number of comorbidities | 1.9±1.7 |
| Hypertension (*n*, yes %) | 26 (54.2%) |
| Diabetes (*n*, yes %) | 25 (52.1%) |
| Hyperlipidemia (*n*, yes %) | 11 (22.9%) |
| Stroke (*n*, yes %) | 2 (4.2%) |
| Myocardial infarction (*n*, yes %) | 5 (10.4%) |
| Arrhythmia (*n*, yes %) | 3 (6.3%) |

| | |
|---|---|
| Angioplasty (*n*, yes %) | 4 (8.3%) |
| Bypass surgery (*n*, yes %) | 4 (8.3%) |
| Osteoarthritis (*n*, yes %) | 3 (6.3%) |
| Arthroplasty (hip/knee) (*n*, yes %) | 4 (8.3%) |
| **Fall within the last 12 months:** | |
| Number of people who fell | 31 (79.2%) |
| Number of falls among fallers | 5.0±6.1 |
| Injured in the fall (*n*, yes %) | 18 (58.1%) |
| **Prosthesis use:** | |
| Hours of prosthesis wear per day (hours) | 12.8±3.8 |
| Days of prosthesis wear per week (days) | 6.4±1.3 |
| **Mobility aid use (e.g., cane, walker)** | 20 (41.7%) |

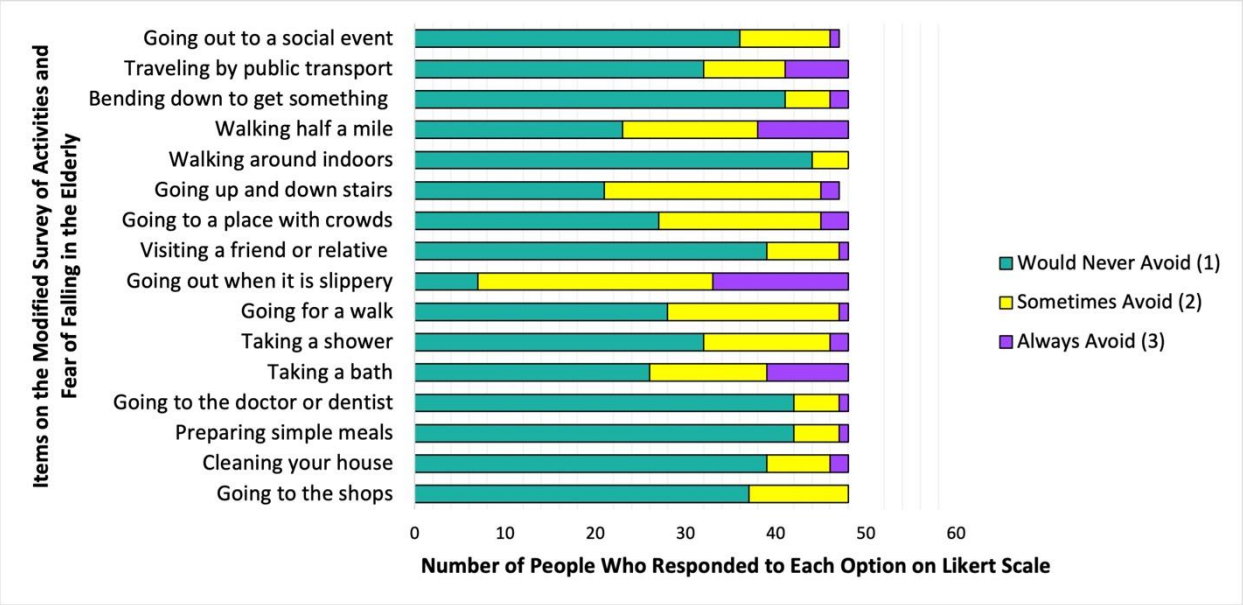



Figure 3.1: Response distribution of the Modified Survey of Activities and Fear of Falling in the Elderly for a sample of adults with a major lower extremity amputation. (n=46)

Table 3.3: Categories and codes to the open-ended question for activities not listed in the Modified Survey of Activities and Fear of Falling in the Elderly in a sample of adults with a major lower extremity amputation. (n=16)

| **Category:** | **Activities of Daily Living** | **Recreation and Leisure Activities** | **Activities of Specified Environment Factors** |
|---|---|---|---|
| **Code:** | - Yard work (unspecified)<br>- Occupation requirements (e.g., fireman)<br>- Climbing ladders<br>- Standing on step stool without railing<br>- Walking and carrying objects<br>- Sit to stand motion | - Running<br>- Bicycling<br>- Skating<br>- Skiing<br>- Baseball<br>- Golf<br>- Gardening<br>- Horseback riding<br>- Attend the beach<br>- Sports (unspecified) | - Activities performed in dim lighting<br>- Activities with noise distractions<br>- Activities on uneven ground<br>- Activities in inclement weather conditions<br>- Dog pulling during walk |
| **Total Responses:** | 10 | 13 | 8 |

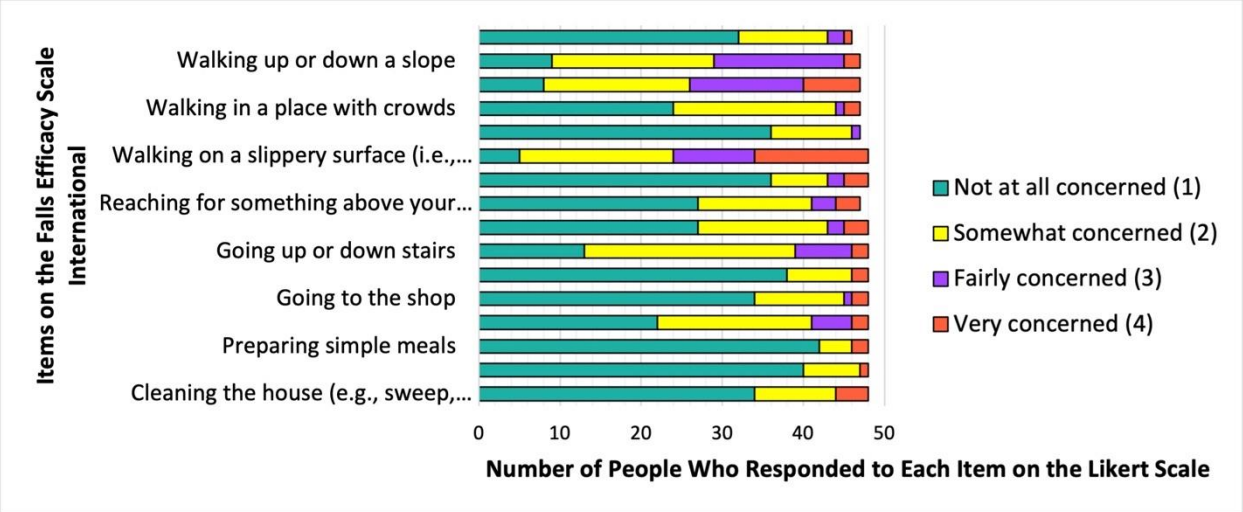



Figure 3.2: Response distribution of the Falls Efficacy Scale – International for a sample of adults with a major lower extremity amputation. (n=41)

Table 3.4: Categories and codes to the open-ended question for activities not listed in the Falls-Efficacy Scale International for a sample of adults with a major lower extremity amputation. (n=10)

| **Category:** | **Activities of Daily Living** | **Recreation and Leisure Activities** |
|---|---|---|
| **Code:** | - Climbing ladders<br>- Yard work<br>- Shovelling<br>- Walking without mobility device<br>- Jumping<br>- Standing on elevated surfaces (i.e., a ladder, step stool)<br>- Sit to stand movement in public | - Playing with kids<br>- Sports (unspecified) |
| **Total Responses:** | 13 | 2 |

The median score on the ABC scale was 85% (73%, 93%), with total scores ranging from 32% to 100%. (Figure 3.3) Forty-two percent of participants had scores below 80% (n=20). Respondents identified items on the ABC that they did not perform in their current abilities, including "*Stand on a chair and reach for something",* "*Step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing"*, "*Walk outside on icy sidewalks"*, and "*Stand on your tiptoes and reach for something above your head".* The ABC scores demonstrate a high level of balance confidence among this sample.

The PLUS-M scale median score was 51.5 (42, 54.3), which is in the 70.2% percentile of mobility efficacy. Summed individual scores ranged from 17 to 60. The lowest scored item on the PLUS-M was the item, *"Are you able to hike about 2 miles on uneven surfaces, including hills"* with the majority of participant responses (56.3%) in the categories: "Unable to do" and "With much difficulty". (Figure 3.4) Overall, the PLUS-M score indicates this sample of PLEA had high mobility efficacy.

The median score for the LCI was 53 (41.25, 56). Seven individuals (14.6%) indicated that they were not able to "*Go up a few steps (stairs) without a handrail",* and six individuals (12.5%) reported that they were not able to "*Walk outside in inclement weather (e.g., snow, rain, ice)".* (Figure 3.5) The LCI score indicates this sample of PLEA had high mobility efficacy.

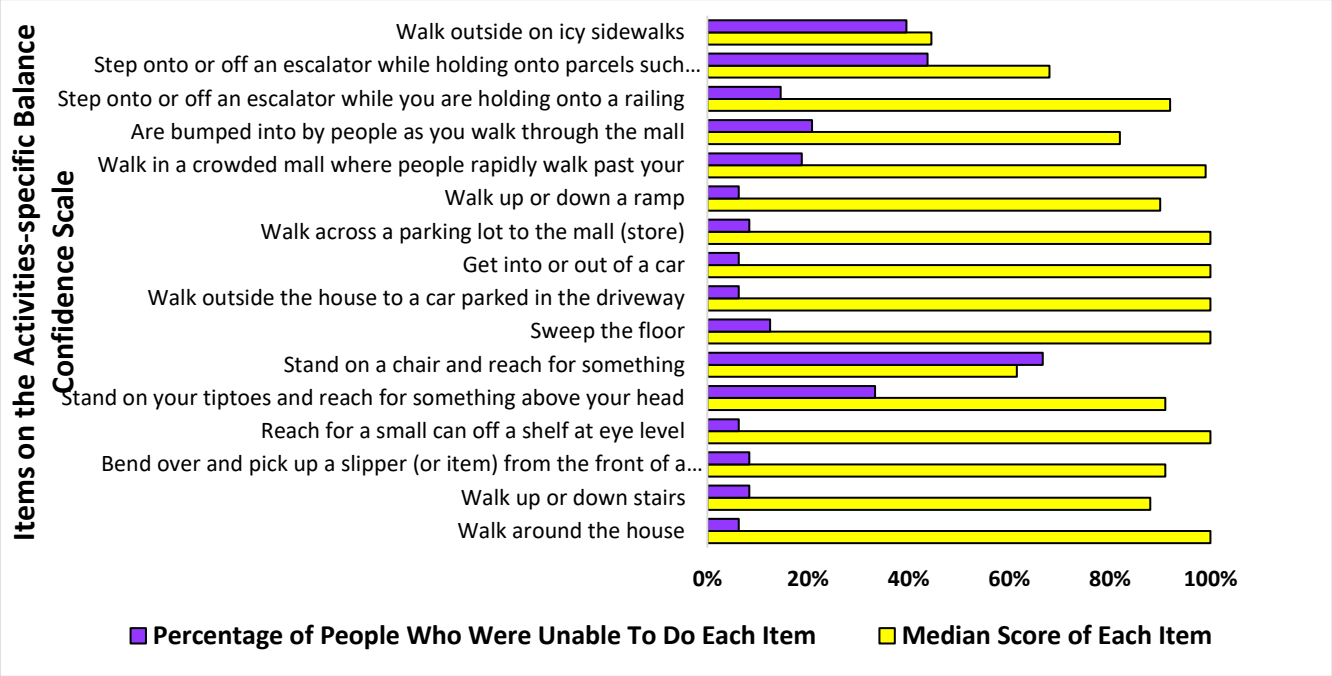



Figure 3.4: Response distribution of the Activities-specific Balance Confidence Scale for a sample of adults with a major lower extremity amputation. (n=48)


Figure 3.3: Response distribution of the Prosthetic Limb Users Survey of Mobility Scale for a sample of adults with a major lower extremity amputation. (n=48)

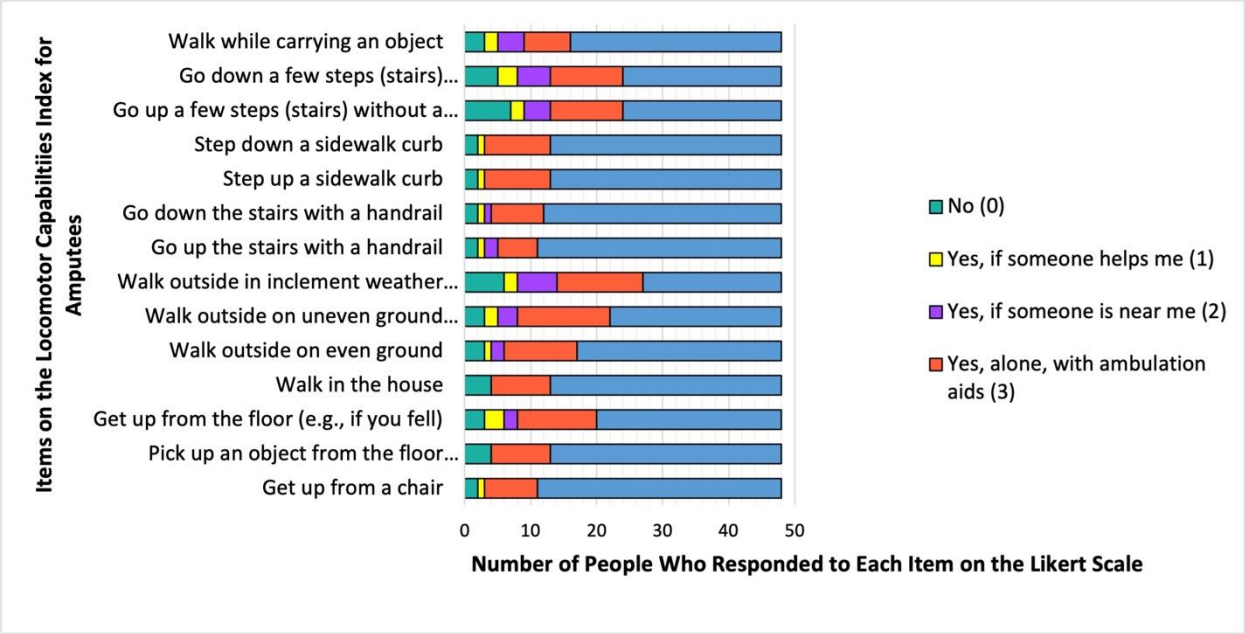



Figure 3.6: Response distribution of the Locomotor Capabilities Index for Amputees for a sample of adults with a major lower extremity amputation. (n=48)

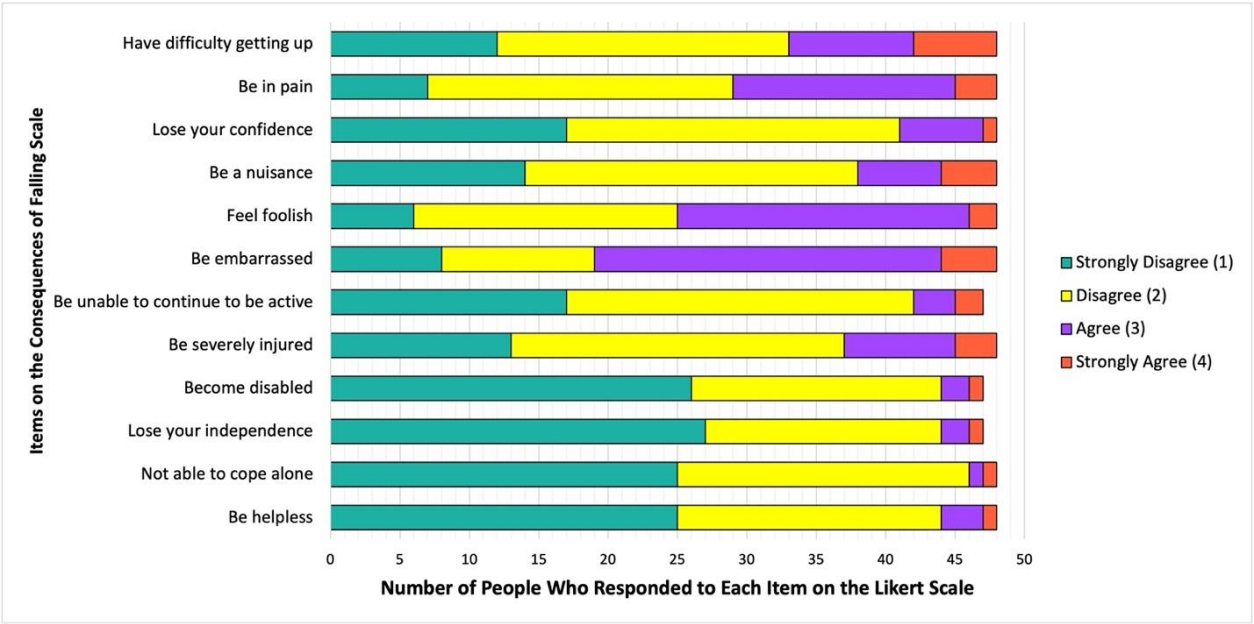



Figure 3.5: Response distribution of the Consequences of Falling Scale for a sample of adults with a major lower extremity amputation. (n=46)

Median score for the COF scale among the sample was 23 (19, 26). The majority of participants (52.1%) responded "Agree (3)" to the specific item, *"Be embarrassed"* if you fell. This was also the only item to have a median value of 3 (2 to 3) among the 12 items, meaning the responses for this item were more skewed to the upper anchor "Strongly agree (4)" than the lower "Strongly disagree (1)". (Figure 3.6)

The most frequently reported open-text response to the functional independence consequence of falling was if the prosthetic device was unavailable to use within the category *"Environmental Consequences"*. (Table 3.5) In response to the open-ended question about the subscale theme of damage to identity on the COF scale, responses were similarly split between the two categories of "*Environmental Consequences"* and "*Functional Mobility Consequences*". (Table 3.6)

The median value on the PAMF was 15 (14, 18). The majority of responses to all items on the PAMF scale were scored above 1 (Strongly disagree). (Figure 3.7) The median value on the PCOF scale was 15 (14 to 16). The greatest variation in responses was for the item, "*Do you feel falling is something you cannot control"*, with 36.3% individuals disagreeing and 31.9% individuals agreeing to the statement. (Figure 3.8) Scores on the perceptions of falling scales (i.e., PAMF, PCOF) indicate a moderate perceived ability to manage falls and moderate perceived control over falling.

Table 3.5: Categories and codes to the open-ended question for the perceived consequences to functional independence from falling that are not listed in the Consequences of Falling Scale for a sample of adults with a major lower extremity amputation. (n=12)

| **Category:** | **Environmental Consequences** | **Functional Mobility Consequences** |
|---|---|---|
| **Code:** | - Negatively perceived by others<br>- Required assisted living<br>- Breaking the prosthesis<br>- Losing friends and/or family due to inability to accommodate needs<br>- Not being able to do activities because of the weather | - Physical injury<br>- Not being able to drive<br>- Not be able to go on long walks<br>- Limiting day-to-day activities<br>- Not be able to get up from the ground<br>- Feeling 'not normal' |
| **Total Responses:** | 8 | 9 |

Table 3.6: Categories and codes to the open-ended question for the perceived consequences to identity from falling that are not listed in the Consequences of Falling Scale for a sample of adults with a major lower extremity amputation. (n=15)

| **Category:** | **Environmental Consequences** | **Functional Mobility Consequences** |
|---|---|---|
| **Code:** | - Living in a home with physical barriers<br>- Prosthesis is unavailable to use<br>- Not having available transportation | - Not doing things as fast<br>- Not doing yard work<br>- Not participating in sports<br>- Restricted movement<br>- Not participating in activities of daily living |
| **Total Responses:** | 7 | 7 |

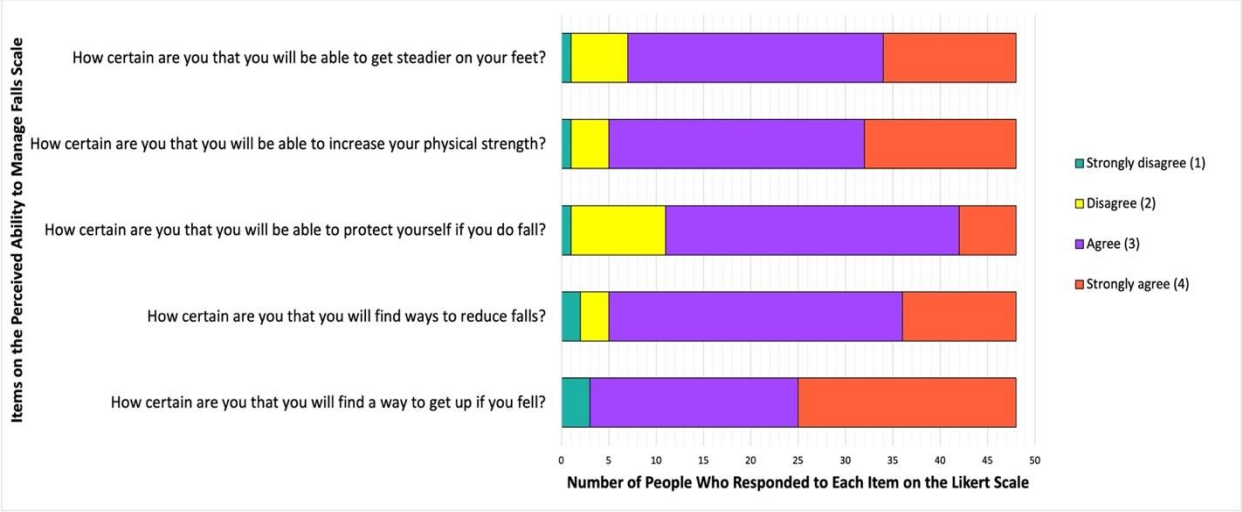



Figure 3.8: Response distributions for the Perceived Ability to Manage Falls Scale in a sample of adults with a major lower extremity amputation. (n=48)

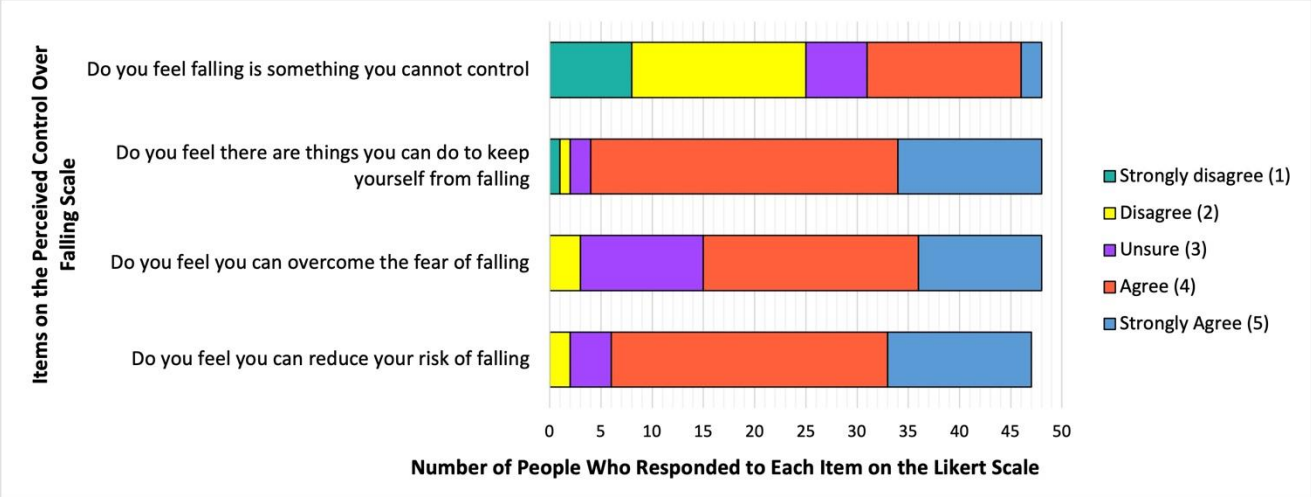



Figure 3.7: Response distribution of the Perceived Control Over Falling Scale for a sample of adults with a major lower extremity amputation. (n=47)

In response to the open-ended question for activities that are challenging to perform because of the amputation and/or prosthesis, 45 participants provided 157 text responses, which was condensed into 43 separate activities. (Table 3.7) The most frequently reported challenging activities included "*Climbing ladders*" (n=18), "*Walking on slippery surfaces*" (n=9), and "*Long periods of walking*" (n=10). Alternatively, the challenging activity most reported in the "*Recreation and Leisure*" category was "*Running*", indicated by 10 participants.

The open-ended question on activities that participants wish they could participate in since the amputation had 95 unique text responses from 35 participants, coded into 41 separate activities. (Table 3.8) The majority of activities were categorized in the "*Recreation and Leisure Activities*" category (71.6%, n=65). The most frequently reported activities in the "*Recreation and Leisure Activities*" category were "*Swimming*" (n=11) and "*Nature walks/hikes*" (n=10). In the category "*Activities of Daily Living*", the most common reported activity was "*Occupational requirements*" reporting this activity as something they wish they could participate in since the amputation.

### 3.3.3 Concern for Falling Spearman Correlation

Results of the Spearman correlation indicated that there were statistically significant associations between many of the CFF scales. (Table 3.9) The strongest statistically significant associations were found between the mSAFFE and FES-I (0.83, $p < 0.05$), and the mSAFFE and PLUS-M (-0.87, $p < 0.05$). The PAMF scale and COF scale had a moderate association (-0.61, $p < 0.05$), while the PAMF and all other CFF scales demonstrated poor correlations (-0.46 to 0.43) but were statistically significant. No associations were found between the PCOF scale and any other CFF scale.

### 3.3.4 Regression Modeling

The mSAFFE, FES-I, ABC, and PLUS-M were independently associated with QOL in the multivariable linear regression modelling. (Table 3.10) A 1-unit increase in the mSAFFE and FES-I was related to a 1.15 (-2.12, -0.18) and a 0.95 (-1.51, -0.40) reduction in QOL, respectively. A 1% increase in ABC and 1-unit increase in PLUS-M was related to a 0.34 (0.06, 0.61) and 0.54 (0.02, 1.05) increase in QOL, respectively. Overall, 42-58% of the variance in QOL was explained by the full regression models.

Table: 3.7 Categories and codes to the open-ended question for activities that are challenging to perform because of the amputation for a sample of adults with a major lower extremity amputation. (n=45)

| **Category:** | **Activities of Daily Living** | **Recreation and Leisure Activities** |
|---|---|---|
| **Code:** | - Walking<br>- Walking in unfamiliar settings<br>- Walking on a slant<br>- Walking on a hill<br>- Walking on sand<br>- Walking on slippery surfaces<br>- Walking on uneven ground<br>- Walking in deep snow<br>- Ascending and descending stairs<br>- Long periods of sitting<br>- Long periods of walking<br>- Long periods of standing<br>- Climbing ladders<br>- Putting on shoes<br>- Standing on tippy toes<br>- Standing on furniture (e.g., chairs, step stool)<br>- Rapid movements<br>- Carrying objects while walking<br>- Walking without mobility support (e.g., railing, walker, cane)<br>- Stepping in/out of the shower/tub<br>- Bending down/over<br>- Reaching for object<br>- Kneeling<br>- Showering<br>- Balancing (unspecified)<br>- Getting out of bed at night<br>- Occupation requirements (unspecified) | - Running<br>- Long bike rides<br>- Bike rides<br>- Golf<br>- Skating<br>- Horse-back riding<br>- Curling<br>- Sports (unspecified)<br>- Dancing<br>- Fishing<br>- Walking the dog<br>- Yard/housework<br>- Swimming<br>- Camping<br>- Vacuuming<br>- Jumping |
| **Total Responses:** | 96 | 52 |

Table: 3.8 Categories and codes to the open-ended question for activities that participants wished they could participate in since the amputation for a sample of adults with a major lower extremity amputation. (n=35)

| **Category:** | **Activities of Daily Living** | **Recreation and Leisure Activities** |
|---|---|---|
| **Code:** | - Occupation requirements (e.g., bedside nursing, full time work)<br>- Operate machinery<br>- Walking<br>- Long periods of walking<br>- Walking without pain<br>- Walking with balance<br>- Walking on a hill<br>- Walking the dog<br>- Lifting heavy objects<br>- Activities of daily living without restriction (unspecified)<br>- Climbing ladders<br>- Shower regularly | - Skateboard<br>- Ice skating<br>- Skiing<br>- Ice hockey<br>- Toboggan<br>- Fishing<br>- Hunting<br>- Riding a bike<br>- Riding motorcycle<br>- Flying model airplanes<br>- Jujitsu<br>- Running<br>- Swimming<br>- Stand-up paddle board<br>- Water ski<br>- Water sports (unspecified)<br>- Home renovations<br>- Baseball<br>- Skydiving<br>- Golfing<br>- Curling<br>- Gardening<br>- Sports (unspecified)<br>- Attend the beach<br>- Dancing<br>- Nature walks/hikes<br>- Traveling (i.e., different city, international)<br>- Shopping<br>- Playing with kids/grandkids |
| **Total Responses:** | 23 | 68 |

Table 3.9: Correlation matrix for bivariate analysis using Spearman correlation among nine concern for falling scales for a sample of adults with a major lower extremity amputation. (n=48)

| | **Fear of Falling** | | **Falls Efficacy** | | **Mobility Efficacy** | | **Consequences of Falling** | **Perceptions of Falling** | |
|---|---|---|---|---|---|---|---|---|---|
| **Variable** | **mSAFFE** | **FOF-VAS** | **FES-I** | **ABC** | **LCI** | **PLUS-M** | **COF** | **PCOF** | **PAMF** |
| **mSAFFE** | 1.0 | 0.67 **(<0.001)** | 0.83 **(<0.001)** | -0.75 **(<0.001)** | -0.64 **(<0.001)** | -0.87 **(<0.001)** | -0.43 **(<0.001)** | -0.02 (0.875) | -0.46 **(0.001)** |
| **FOF-VAS** | | 1.0 | 0.65 **(<0.001**) | -0.60 **(<0.001)** | -0.59 **(<0.001)** | -0.64 **(<0.001)** | 0.47 **(<0.001)** | -0.03 (0.864) | -0.41 **(0.005)** |
| **FES-I** | | | 1.0 | -0.63 **(<0.001)** | -0.60 **(<0.001)** | -0.78 **(<0.001)** | 0.69 **(<0.001)** | 0.02 (0.901) | -0.42 **(0.004)** |
| **ABC** | | | | 1.0 | 0.66 **(<0.001)** | 0.72 **(<0.001)** | -0.43 **(0.003)** | -0.02 (0.901) | 0.33 **(0.022)** |
| **LCI** | | | | | 1.0 | 0.69 **(<0.001)** | -0.32 **(0.031)** | 0.02 (0.911) | 0.28 (0.058) |
| **PLUS-M** | | | | | | 1.0 | -0.52 **(<0.001)** | 0.11 (0.480) | 0.43 **(0.003)** |
| **COF** | | | | | | | 1.0 | -0.11 (0.475) | -0.61 **(<0.001)** |
| **PCOF** | | | | | | | | 1.0 | 0.24 (0.106) |
| **PAMF** | | | | | | | | | 1.0 |

Note: mSAFFE = Modified Survey of Activities and Fear of Falling in Elderly; FOF-VAS = Fear of Falling – Visual Analogue Scale; FES-I = Falls Efficacy Scale – International; ABC = Activities-specific Balance Confidence; LCI = Locomotor Capabilities Index for Amputees; PLUS-M = Prosthetic Limb Users Survey of Mobility; COF = Consequences of Falling; PCOF = Perceived Control Over Falling; PAMF = Perceived Ability to Manage Falls. The values in parenthesis indicate p-values (bold p-values indicate significance at $p<0.05$).

Table 3.10: Multiple variable linear regression modeling for the association of nine concern for falling measures on quality of life for a sample of adults with a major lower extremity amputation. (n=48)

| Concern for Falling Measure | Unadjusted unstandardized β (95%CI) | p-value | Adjusted $R^2$ | Adjusted unstandardized β (95%CI)* | p-value | Adjusted $R^2$ |
|---|---|---|---|---|---|---|
| **mSAFFE** | -1.82 (-2.62, -1.03) | <0.001 | 0.30 | -1.15 (-2.12, -0.18) | 0.021 | 0.42 |
| **FOF-VAS** | -0.27 (-0.47, -0.07) | 0.010 | 0.12 | -0.13 (-0.31, 0.05) | 0.159 | 0.45 |
| **FES-I** | -1.54 (-2.10, -0.98) | <0.001 | 0.40 | -0.95 (-1.51, -0.40) | 0.001 | 0.58 |
| **ABC** | 0.51 (0.21, 0.80) | 0.001 | 0.19 | 0.34 (0.06, 0.61) | 0.019 | 0.50 |
| **LCI** | 0.49 (0.05, 0.92) | 0.029 | 0.08 | 0.33 (-0.12, 0.78) | 0.150 | 0.45 |
| **PLUS-M** | 0.87 (0.48, 1.26) | <0.001 | 0.29 | 0.54 (0.02, 1.05) | 0.041 | 0.48 |
| **COF** | -1.74 (-2.70, -2.70) | <0.001 | 0.21 | -0.00 (-1.21, 1.21) | 0.998 | 0.42 |
| **PCOF** | -4.81 (-8.08, -1.53) | 0.005 | 0.14 | -2.17 (-5.52, 1.19) | 0.199 | 0.47 |
| **PAMF** | 3.00 (0.60, 5.40) | 0.016 | 0.10 | -0.66 (-3.31, 2.00) | 0.621 | 0.43 |

Note: mSAFFE = Modified Survey of Activities and Fear of Falling in Elderly; FOF-VAS = Fear of Falling – Visual Analogue Scale; FES-I = Falls Efficacy Scale – International; ABC = Activities-specific Balance Confidence Scale; LCI = Locomotor Capabilities Index for Amputees; PLUS-M = Prosthetic Limb Users Survey of Mobility; COF = Consequences of Falling Scale; PCOF = Perceived Control Over Falling Scale; PAMF = Perceived Ability to Manage Falls; CI: Confidence Interval; *, regression model adjusted for age, Depression Anxiety Stress Scale score, level of amputation, and number of comorbidities. Statistical significance was set to $p<0.05$.

## 3.4 Discussion

The study demonstrated the majority of scales within the subdomains of fear of falling, falls efficacy, and mobility efficacy had moderate to strong correlations between one another. The PAMF and COF scale had fair correlations among scales within subdomains of fear of falling, falls efficacy, and mobility efficacy. This study was the first to ask PLEA to describe additional functional mobility tasks or activities not included as items on the standardized scales of a CFF. A systematic analysis of the open-ended responses indicated that there are numerous activities of daily living, recreation, and leisure that resulted in a CFF are not included within any of the standardized scales. Respondents reported numerous activities which were discontinued since their amputation, such as hockey, swimming, running, and gardening. Finally, this study found a low fear of falling, a high falls efficacy, and a high mobility efficacy were independently associated with a greater QOL.

The ABC, PLUS-M, and LCI scales have been most commonly used in PLEA literature.[100,101,129,132] Median scores on the ABC, PLUS-M, and LCI in this current study were greater compared to previous studies, particularly for the ABC.[16,100,143,185] A greater perceived falls efficacy has been previously equated with a greater perceived prosthetic capability and prosthetic performance.[13,186] Previous studies have suggested that a greater amount of time ambulating with a prosthesis can improve the psychological and physical adjustment to prosthesis use.[187] The average time since amputation in our study was greater than previous studies.[16,100,143,185] This may reflect more time mastering skills with a prosthesis at home and in the community, contributing to greater ABC, PLUS-M, and LCI scores among our group when compared to the average PLEA.[1] Numerous scales evaluated in this study (i.e., mSAFFE, FOF-VAS, FES-I, COF, PAMF, and PCOF) have not been previously quantified among PLEA. For the use of these new scales in PLEA, the scores were comparable to that of other mobility-impaired clinical populations.[175,188] This study adds to the literature by providing novel scores for CFF standardized scales among PLEA.

Previous research has demonstrated that a greater fear of falling is correlated with low falls efficacy among community-dwelling older adults.[51,98,107] As fear of falling increases, one's perceived self-efficacy to successfully complete a task without falling decreases, and vice versa.[51,98,105,107] Our

study has confirmed this relationship among PLEA. The standardized scales within the mobility efficacy subdomain were theoretically based off of a self-efficacy framework, similar to the falls efficacy subdomain, and were the only scales without our study that were developed specifically for PLEA.[100,101,142] We anticipated the two scales would demonstrate a strong correlation, yet this was not supported by the findings. The PLUS-M and LCI have many similar items, including walking or stepping up/down stairs, walking on various surfaces (i.e., gravel, inclement weather, uneven ground), and walking while carrying an object.[100,101] The scales differ based on their respective Likert scale options which may cause different interpretations of similar activities. Further exploration of how the PLUS-M and LCI scales differ is needed.

The ABC scale had pre-existing evidence to support reliability and validity among PLEA.[129] To the author's knowledge, this is the first study to ask PLEA to identify any activities on the ABC scale which they currently do not perform and therefore had to guess their level of confidence. Descriptive analysis results demonstrated that within our perceived high functioning group, one activity commonly identified was "*Stand on your tiptoes and reach for something above your head*". This functional movement was removed from PLEA focus groups in the developmental stages of the PLUS-M because participants reported that, "*Standing on tiptoes was not appropriate for persons who have typical prosthetic feet*".[142] The results of the present study further support the anecdotal concerns of clinicians and PLEA who indicate some items on the ABC do not represent the unique functional capabilities of PLEA. In the development of the PLUS-M, the option *"Not applicable"* was included to allow individuals to not have to speculate on activities that they current do not perform.[142] This may be beneficial to improve the validity of scales for CFF paradigm that were not developed among PLEA.

Previous studies have demonstrated the significant influence an LEA may have on overall QOL. Challenges reported by PLEA include social withdrawal,[186] increased anxiety and depression,[17,187,189] negative body image and identity issues,[190] and reduced independent mobility[17,136,186] as driving factors contributing to a reduced QOL. However, the present study is the first to evaluate the association of independently delineated CFF subdomains on QOL. Our findings expand upon previous work through identifying a statistically significant association of three CFF subdomains (i.e., fear of falling, falls efficacy, and mobility efficacy) with overall QOL among PLEA. These results are novel contributions, as it outlines a CFF influencing QOL, which

will provide support for further investigations to determine how these areas can be addressed in rehabilitative programs. Undergoing an LEA has the goal of improving overall QOL through improved functional mobility and a reduction of pain for an individual.[20] If a CFF drives PLEA to sacrifice meaningful activities that would otherwise improve their QOL, mobility, and community re-integration, then the ultimate goal of an LEA has yet to be achieved.

The present study was the first to ask PLEA to itemize functional movements or activities that cause a CFF on a daily basis. The study by Anderson and colleagues reported themes relating to how PLEA approach challenges, the importance of peer support, and desire to improve functional capability while attending a mobility clinic.[72] Similarly, Senra and colleagues found limited mobility due to an LEA had a negative impact to a person's professional life.[190] Our study also had individuals who wished they could continue to participate in their profession after their amputation. Interestingly, none of the CFF standardized scales had items pertaining to occupation. Occupation and professional identity are recognized factors contributing to a sense of independence and improved QOL.[181,184]

One of the major strengths of this study is the theoretical framework containing multiple subdomains comprising the CFF paradigm.[51,98,107] A clear operational definition of each subdomain in the context of previous psychological and falls prevention research addressed the gap within PLEA research of the interchangeable use of terms, including fear of falling, falls efficacy, and balance confidence.[51,98,107] Another strength within this study is the heterogeneity of the sample. There was a wide range in reported demographic and clinical characteristics among participants (i.e., age, years since amputation, and etiology of amputation) and functional capabilities, which provided this study with a breadth of varying experiences of a CFF from PLEA. There are limitations to this study that are worth noting. The original study protocol included an in-person L-test of functional mobility to further compare the CFF subdomains with a measure of physical performance. However, due to the ongoing COVID-19 pandemic and in-person limitations, this could not be included in the present study.

## 3.5 Conclusion

Individuals with an LEA have the desire and resilience to be high functioning contributing members of our society. This was clearly demonstrated through the breadth and desire that PLEA described in open-ended responses to participate in recreation and daily activities. However, even

among high functioning individuals with an LEA, a CFF was pervasive and limited specific activities that give PLEA enjoyment. A fear of falling, falls efficacy, and mobility efficacy influence QOL among PLEA. As such, these areas should be addressed in rehabilitative programs to improve community re-integration and overall QOL for PLEA.

# Chapter 4

## 4.1 General Summary

The main objective of the present thesis was to comprehensively understand a CFF among PLEA. In study 1, the mSAFFE, FES-I, COF, and PAMF scales demonstrated acceptable reliability in an online format among individuals with an LEA. Study 2 evaluated the association of each CFF subdomain on QOL. A lower fear of falling, and a greater falls efficacy and mobility efficacy demonstrated statistically significant independent associations to improved QOL. Numerous items on the ABC scale were identified by participants as activities that they are currently unable to do. Participants provided open-ended responses describing the functional movements or activities that cause a CFF. Numerous activities of daily living and activities of recreation and leisure were reported to have caused a CFF. These activities are not included in any of the CFF scales and were activities that participants wish they could return to since their amputation but avoid due to a CFF.

The findings of these studies are novel additions to LEA literature and provide evidence that a CFF can be pervasive, impacting the lives of PLEA who have successfully completed a prosthetic rehabilitation program. It is overwhelmingly clear that PLEA face unique mobility challenges compared to other clinical populations. The findings of the present thesis confirm that PLEA have a CFF long after their amputation and there are significant mobility and activity participation sacrifices made due to a CFF. This suggests the need to further evaluate a CFF among PLEA throughout an individual's life.

# Chapter 5

## 5.1 Future Directions

Evidence to support the reliable use of the mSAFFE, FES-I, COF, and PAMF scales in an online format among PLEA was demonstrated in Study 1. This allowed for the assessment of the inter-relationships among the multiple CFF subdomains that was done in Study 2. Future studies using these standardized scales among PLEA can use the values established within the present studies for comparison across study samples. Additionally, future studies can incorporate an established LEA functional outcome, such as an L test to evaluate validity of these CFF standardized scales among PLEA.

The studies within this thesis have demonstrated the substantial influence a fear of falling, falls efficacy, and mobility efficacy have on QOL among PLEA. These findings provide support for future research to use already established standardized scales among PLEA.

There are many areas that can be developed to further our understanding of CFF among PLEA. One area that can be developed from the work of this thesis to effectively address a CFF among PLEA during and after rehabilitation programs is to understand how Canadian healthcare professionals address a CFF in clinical practice. It is recommended to get a broad understanding of the current state of practice at this point and that would be best achieved through use of an online national level survey. The content of the survey would specifically address clinicians' knowledge of CFF and the types of interventions that are currently implemented to reduce a CFF among PLEA. The results of this study would outline the scope of strategies used within practice, identify barriers and facilitators to interventions, and education needs to better understand how to support PLEA through the functional mobility challenges.

This thesis demonstrated through the open-ended responses from PLEA that there are numerous activities and functional movements that are not captured within available standardized scales. To continue to comprehensively understand the lived experience of PLEA with a CFF, expanding research to include qualitative methodology can use the open-ended responses and themes that emerged from this thesis as interview prompts to discuss the mobility challenges these individuals have on a daily basis. Future research that included interviews should ensure PLEA of all levels of mobility and time since amputation are recruited to provide the broad lived experience of this group. Understanding the experiences of PLEA who use a prosthetic device in their community through the use of interviews will give us a unique and novel perspective of the challenges and facilitators to mobility. This information will inform discharge planning and practice for reintegration back into the community after discharge from prosthetic rehabilitation.

It is well known that even after the successful completion of a prosthetic rehabilitation program, a CFF is still prominent and pervasive, and dictates participation in activities of daily living.[1]This study identified the gap in the literature for PLEA on the lack of a clear definition for successful mobility with a prosthesis. Future research should aim to operationally define successful mobility for a person with an LEA who completed a prosthetic rehabilitation program. Surveying both

healthcare professionals and PLEA as to what defines successful mobility with a prosthesis looks like can allow us to incorporate the unique functional capabilities of PLEA into definitions and expectations of mobility after prosthetic rehabilitation.

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# Appendix A: Ethics Approval Notice

## LAWSON FINAL APPROVAL NOTICE

**LAWSON APPROVAL NUMBER: R-20-161**

PROJECT TITLE: Evaluating concern for falling in people with lower extremity amputations

PRINCIPAL INVESTIGATOR: Dr. Susan Hunter

LAWSON APPROVAL DATE: 20/04/2020

ReDA ID: 9542

Overall Study Status: Active

Please be advised that the above project was reviewed by Lawson Administration and the project was approved.

"COVID-19: Please note that Lawson is continuing to review and approve research studies. However, this does not mean the study can be implemented during the COVID-19 pandemic. Principal Investigators, in consultation with their program leader or Chair/Chief, should use their judgment and consult Lawson's research directive and guidelines to determine the appropriateness of starting the study. Compliance with hospital, Lawson, and government public health directives and participant and research team safety supersede Lawson Approval."

**Please provide your Lawson Approval Number (R#) to the appropriate contact(s) in supporting departments (eg. Lab Services, Diagnostic Imaging, etc.) to inform them that your study is starting. The Lawson Approval Number must be provided each time services are requested.**

**Dr. David Hill**
**V.P. Research**
**Lawson Health Research Institute**

**Date:** 20 April 2020

**To:** Dr. Susan Hunter

**Project ID:** 115507

**Study Title:** Evaluating concern for falling in people with lower extremity amputations

**Application Type:** HSREB Initial Application

**Review Type:** Delegated

**Meeting Date / Full Board Reporting Date:** 05/May/2020

**Date Approval Issued:** 20/Apr/2020

**REB Approval Expiry Date:** 20/Apr/2021

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Dear Dr. Susan Hunter

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above mentioned study as described in the WREM application form, as of the HSREB Initial Approval Date noted above. This research study is to be conducted by the investigator noted above. All other required institutional approvals must also be obtained prior to the conduct of the study.

**In the Response to REB Recommendations document, the study team had queried the scrutiny given by the Board to one of the scientific elements of your protocol (why age was treated as a continuous rather than a categorical variable). As this is a minor issue unto itself, it raises an important principle. Please permit us to reply: This comment came from a content expert who evaluated your study. It is the responsibility of every Ethics Board to ensure scientific validity is present. This is an underlying principle of ethics boards around the world. For but one example of where this principle is codified, please see https://www.nih.gov/health-information/nih-clinical-research-trials-you/guiding-principles-ethical-research where scientific validity is listed second in the concerns for Boards. TCPS-2 contains similar language in section 2.7. The Western REB will continue, as it always has, to discharge this important responsibility by scrutinizing scientific validity as part of its review process.**

**Documents Approved:**

| Document Name | Document Type | Document Date | Document Version |
|---|---|---|---|
| ABC_Scale_v3 | Paper Survey | 18/Apr/2020 | 3 |
| CoF_Scale_v3 | Paper Survey | 18/Apr/2020 | 3 |
| DASS_v3 | Paper Survey | 18/Apr/2020 | 3 |
| Data_Collection_Form_Retest_v2 | Other Data Collection Instruments | 18/Apr/2020 | 2 |
| Data_Collection_Form_v3 | Other Data Collection Instruments | 18/Apr/2020 | 3 |
| Falls_Efficacy_Scale_v3 | Paper Survey | 18/Apr/2020 | 3 |
| FOF_Scale_v2 | Paper Survey | 18/Apr/2020 | 2 |
| LCI_Scale_v3 | Paper Survey | 18/Apr/2020 | 3 |
| Letter_of_Information_Main_Study_v3 | Written Consent/Assent | 18/Apr/2020 | 3 |
| Letter_of_Information_Reliability_Study_v3 | Written Consent/Assent | 18/Apr/2020 | 3 |
| Perception_Scales_v3 | Paper Survey | 18/Apr/2020 | 3 |
| PLUS-M_Scale_v3 | Paper Survey | 18/Apr/2020 | 3 |
| Protocol | Protocol | 11/Feb/2020 | 1 |
| QOL_Scale_v2 | Paper Survey | 18/Apr/2020 | 2 |
| Sup_Scales_v3 | Paper Survey | 18/Apr/2020 | 3 |

**Date:** 29 March 2021

**To:** Dr. Susan Hunter

**Project ID:** 115507

**Study Title:** Evaluating concern for falling in people with lower extremity amputations

**Application Type:** Continuing Ethics Review (CER) Form

**Review Type:** Delegated

**REB Meeting Date:** 20/April/2021

**Date Approval Issued:** 29/Mar/2021

**REB Approval Expiry Date:** 20/Apr/2022

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Dear Dr. Susan Hunter,

The Western University Research Ethics Board has reviewed the application. This study, including all currently approved documents, has been re-approved until the expiry date noted above.

REB members involved in the research project do not participate in the review, discussion or decision.

Western University REB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The REB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Please do not hesitate to contact us if you have any questions.

Sincerely,

The Office of Human Research Ethics

***Note: This correspondence includes an electronic signature (validation and approval via an online system that is compliant with all regulations).***

# Appendix B: Letter of Information and Consent – Study 1

**School of Physical Therapy and Department of Physical Medicine & Rehabilitation**

*Letter of Information – Sub-Study*

**Evaluating concern for falling in people with lower extremity amputations**

**Principal Investigator:** Susan Hunter PT PhD, Associate Professor
Elborn College [redacted]

**Co-investigators:** Kristin Nugent MSc (Student), Ricardo Viana MD, Michael Payne MD, Eva Pila PhD

**Invitation to Participate**
You are being invited to participate in a research project because you have a lower extremity amputation(s). People with lower extremity amputations have a particularly high concern for falling compared to people without a lower extremity amputation. We will be looking at concern for falling in people with lower extremity amputations who are currently using their prosthesis for ambulation. Specifically, we will be evaluating fear of falling, mobility efficacy, falls efficacy, consequences of falling, and perception of falling.

The purpose of this letter is to provide you with the information that will help you decide whether you wish to participate in this sub-study. It is important that you know why this sub-study is being conducted and what it will involve. Please take your time to make an informed decision.

**Description of Study**
This study is a sub-study of a major study, the 'Main Study'. This sub-study will be assessing the reliability of five scales among individuals with lower extremity amputations. The five questionnaires we will be evaluating are: modified Survey of Activities and Fear of Falling in the Elderly (mSAFFE), The Falls Efficacy Scale – International (FES-I), The Consequences of Falling (CoF) Scale, The Perceived Control over Falling (PCF) tool, and The Perceived Ability to Manage Falls (PAMF). These scales were developed for community-dwelling older adults, but we will be assessing whether they are reliable scales to use for individuals with lower extremity amputations. Reliability testing is an essential aspect of research and will ensure all scales and data collected in the Main Study are valid.

Up to 20 people with lower extremity amputations will participate in this sub-study. If you agree to participate in this sub-study, information will be collected on two occasions. Both assessments will take approximately twenty minutes to complete and will be completed through an online survey. You will receive an email with a unique link to the sub-study questionnaire. You will be

answering five questionnaires relating to your concern for falling: modified Survey of Activities and Fear of Falling in the Elderly (mSAFFE), The Falls Efficacy Scale – International (FES-I), The Consequences of Falling (CoF) Scale, The Perceived Control over Falling (PCF) tool, and The Perceived Ability to Manage Falls (PAMF). The second assessment will occur within two days of the initial online questionnaire. The second assessment will ask you to answer the same five questionnaires again and will be accessed through a second unique link that will be emailed to you. After each unique questionnaire link that is sent to you, there will be two follow-up emails to encourage completion of the study components. The first will be within one week and then two weeks after the initial email.

**Participation Withdrawal**
Participation in this sub-study is voluntary. You may refuse to participate, refuse to answer any questions, or withdraw from the study at any time with no effect on your future care. If you choose to withdraw from the sub-study, any information that was provided will not be used for any sub-study purposes. No response after the second follow-up email to encourage completion of the sub-study components will indicate no longer interested in participating in the sub-study.

We are seeking volunteers who are 18 years of age and older, have a major unilateral or bilateral lower limb amputation, are currently using a prosthesis for ambulation at or after the completion of a prosthetic rehabilitation, able to provide informed consent and have a functional use of the English language. However, there are certain conditions that would exclude you from participating in the sub-study. These conditions are as follows: (1) not currently using a prosthesis(es) for ambulation and (2) not able to provide informed consent.

**Risk and Benefits**
Risks
The risks associated with taking part in this sub-study are minor, though include feeling discomfort answering questions. Some participants may feel uncomfortable sharing their personal experiences and feelings in the questionnaires. To minimize this, your responses will be anonymized.

Benefits
You many not benefit directly from your participation in this sub-study. You will have contributed information that will help to increase scientific understanding of standardized scales measuring concern for falling constructs in lower extremity amputees.

**Reimbursement for Participation in the study**
You will not be paid to participate in this research project.

**Confidentiality**

We will be collecting identifying information for the study that includes your full name, sex, age, hospital identification numbers and contact information (telephone number, email address, postal address). All records and research materials that would identify in the recruitment phases of the research project will be transferred to Western University using Parkwood Rehabilitation Institute's secure file transfer. Once this information is downloaded to Western University's file

it will be stored behind the university's firewalls. Identifiable information will be kept in an electronic copy and held confidential and, to the extent permitted by the application laws and regulations, will not be made publicly available. Participants will be assigned a unique study ID which will link responses from Qualtrics questionnaires for reliability assessment. Study IDs will be kept in a paper copy master list. The paper records will be kept separately from other research information in a locked office. Electronic data of age, sex and responses to study materials will collected through Qualtrics, which is housed through university password protected and kept behind the university's firewall. The electronic data will only be available through an encrypted OneDrive folder to members of the study team. Measures for data security will be in place, though there is a risk for breach of privacy. All information collected will be kept for a period of 15 years. After 15 years, all documents and data from the study will be destroyed during an annual shredding day. If the results of this were to be published in the medical literature, your identity will not be revealed. There are no conflicts of interests to declare related to this study. You do not waive any legal rights by signing the consent form.

Representatives of the University of Western Ontario's Health Sciences Research Ethics Board (HSREB) may contact you or require access to your study related records in order to monitor the conduct of research. For quality assurance (QA) purposes, representatives of Lawson QA Education Program may require access to study data.

**Contacts**

If you have any questions about this project, please contact the Principal Investigator: Dr. Susan Hunter at [redacted]

If you have any questions about your rights as a research participant or the conduct of this sub-[redacted]

# Appendix C: Letter of Information and Consent – Study 2

**School of Physical Therapy and Department of Physical Medicine & Rehabilitation**

*Letter of Information*

**Evaluating concern for falling in people with lower extremity amputations**

**Principal Investigator**: Susan Hunter PT PhD, Associate Professor
Elborn College, [redacted]

**Co-investigators:** Kristin Nugent MSc (Student), Ricardo Viana MD, Michael Payne MD, Eva Pila PhD

**Invitation to Participate**
You are being invited to participate in a research study because you have a lower extremity amputation(s). People with lower extremity amputations have a particularly high concern for falling compared to people without a lower extremity amputation. We will be looking at the concern for falling in people with lower extremity amputations who are currently using their prosthesis for ambulation. Specifically, we will be evaluating fear of falling, mobility efficacy, falls efficacy, consequences of falling, and perception of falling.

The purpose of this letter is to provide you with the information that will help you decide whether you wish to participate in this study. It is important that you know why this study is being conducted and what it will involve. Please take your time to make an informed decision.

**Description of Study**
This study will include up to 100 participants with lower extremity amputations. There is a sub-study of this research project, which will assess the reliability of scales that have not been used before in research among people with lower extremity amputations. A person is able participate in both The Main Study (this letter of information) and The Sub-Study if they choose to do so. You will receive an email with a unique link to the study questionnaire. After the unique questionnaire link is sent to you, there will be two follow-up emails to encourage completion of the study components. The first will be within one week and then two weeks after the initial email.

If you agree to participate in this study, information will be collected on one occasion through an online format. You will be answering nine questionnaires related to a concern for falling including the Activities-specific Balance Confidence (ABC) Scale, Consequences of Falling (CoF) Scale, Falls Efficacy Scale – International (FES-I), Fear of Falling – Visual Analogue Scale, the modified Survey of Activities and Fear of Falling in the Elderly (mSAFFE), Prosthetic Limb Users Survey of Mobility (PLUS-M), and the Locomotor Capabilities Index in Amputees (LCI), the Perceived Control over Falling (PCF), and Perceived Ability to Manage Falls

(PAMF). One questionnaire for mental health symptoms which includes the Depression, Anxiety, and Stress Scale (DASS), and a questionnaire regarding overall quality of life which is titled World Health Organization Quality of Life Scale (WHOQOL). After completing each of the concern for falling questionnaires you will be asked to list any activities you are currently participating in but are concerned about falling, as well as activities that you are physically able to do but are avoiding due to a concern for falling. These supplementary questions are provided for you to elaborate on the challenges you have in your everyday life.
The assessment will take approximately 45 minutes to complete.

**Participation Withdrawal**
Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions, or withdraw from the study at any time with no effect on your future care. If you choose to withdraw from the study, any information that was provided will not be used for any study purposes. No response after the second follow-up email to encourage completion of the study components will indicate a person is no longer interested in participating in the study.

We are seeking volunteers who are 18 years of age and older, have a major unilateral or bilateral lower limb amputation, are currently using a prosthesis for ambulation at or after completion of prosthetic rehabilitation, able to provide informed consent and have a functional use of the English language. However, there are certain conditions that would exclude you from participating in the study. These conditions are as follows: (1) not currently using a prosthesis(es) for ambulation and (2) not able to provide informed consent.

**Risk and Benefits**
Risks
The risks associated with taking part in this study are minor. Some participants may feel uncomfortable sharing their personal experiences and feelings in the questionnaires. To minimize this, your responses will be anonymized.

Benefits
You may not benefit directly from your participation in this study. You will have contributed information that will help to increase scientific understanding of standardized scales measuring concern for falling constructs in lower extremity amputees.

**Reimbursement for Participation in the study**
You will not be paid to participate in this research project.

**Confidentiality**

We will be collecting identifying information for the study that includes your full name, sex, age, hospital identification numbers and contact information (telephone number, email address, postal address). All records and research materials that would identify in the recruitment phases of the research project will be transferred to Western University using Parkwood Rehabilitation Institute's secure file transfer. Once this information is downloaded to Western University's file it will be stored behind the university's firewalls. Identifiable information will be kept in an electronic copy and held confidential and, to the extent permitted by the application laws and

regulations, will not be made publicly available. Electronic data of age, sex and responses to study materials will collected through Qualtrics, which is housed through university password protected and kept behind the university's firewall. The electronic data will only be available through an encrypted OneDrive folder to members of the study team. Measures for data security will be in place, though there is a risk for breach of privacy. All information collected will be kept for a period of 15 years. After 15 years, all documents and data from the study will be destroyed during an annual shredding day. If the results of this were to be published in the medical literature, your identity will not be revealed. There are no conflicts of interests to declare related to this study. You do not waive any legal rights by signing the consent form.

Representatives of the University of Western Ontario's Health Sciences Research Ethics Board (HSREB) may contact you or require access to your study related records in order to monitor the conduct of research. For quality assurance (QA) purposes, representatives of Lawson QA Education Program may require access to study data.

**Contacts**

If you have any questions about this project, please contact the Principal Investigator: Dr. Susan Hunter at [redacted]

If you have any questions about your rights as a research participant or the conduct of this study, [redacted]
ext01234 or by email at patientrelations@sjhc.london.on.ca

# Appendix D: Recruitment Letter

(Date)

To whom it may concern,

Enclosed please find the letter of information for a study being conducted in the Amputee Rehabilitation Program at Parkwood Institute with patients who currently use a lower extremity prosthesis for ambulation. This study is called "***Evaluating concern for falling in people with lower extremity amputations***". Our research team for this study is comprised of Principal Investigator-Dr. Susan Hunter and Co-Investigators Dr. Michael Payne, Dr. Ricardo Viana, and Dr. Eva Pila, and Master of Science student Kristin Nugent.

You are being contacted because you had an appointment at Parkwood Institute in the last 12 months, and I thought you might be interested to take part in this study. The enclosed letter of information describes the research study and your role if you decide to participate. The purpose of the study is to assess physical and psychological factors that contribute to a concern for falling, and whether those factors have an impact on quality of life. **If you are interested in participating, we ask that you contact the research team through telephone or email, listed at the top of the letter of information.** There is no obligation to reach out to the research team and all study participation is voluntary. All information used for the research study will be kept confidential and you will not be identified personally in any publications or communications resulting from this study. You **do not waive** any legal rights by agreeing to participate in this study.

Please do not hesitate to contact the research team if you have any questions or concerns. Thank you for taking the time to consider this study.

Yours truly,

Michael Payne, MD MSc FRCPC
Medical Director Regional Amputee Rehabilitation Program
St. Joseph's Health Care, London
Associate Professor, Western University

Version Date: July 23 2020
V3

# Appendix E: Telephone Call Screening Tool

**Study: Evaluating concern for falling in people with lower extremity amputations**

**Telephone Script**

Hello. My name is Kristin Nugent and I am a graduate student in the Master of Science program in the Department of Kinesiology at Western University. I am involved in a research project for my thesis working with Dr. Michael Payne and Dr. Ricardo Viana in the Amputee Rehabilitation Program at Parkwood Institute. May I please speak to Mr/Mrs _____?

| | |
|---|---|
| 1. When desired person is on the phone | Hello. My name is Kristin Nugent and I am a graduate student in the Master of Science program in the Department of Kinesiology at Western University. I am involved in a research project for my thesis working with Dr. Michael Payne and Dr. Ricardo Viana in the Amputee Rehabilitation Program at Parkwood Institute.<br><br>- I am calling you about a study we are doing with people who visited the Amputation Rehabilitation Program at Parkwood Institute in the last 12 months for an appointment in the Amputee Rehabilitation Program. This project is entitled, *"Evaluating concern for falling in people with lower extremity amputations."*<br>- At a recent appointment, you indicated to the medical team in the Amputation Rehabilitation Program that you were interested in being contacted about research studies the Amputation Rehabilitation Program in the future.<br>- Are you interested in finding out more information about the new study we are actively recruiting for now?<br><br>- *If NO – Go to step 2a*<br>- *If YES – Go to step 2b* |
| 2. a) If the desired person responded NO | - Is there a better day and time to speak with you/Mr/Mrs _____?<br>- Thank you for your assistance. I will call back then.<br>- *End call.*<br>- *Note and enter into person's contact log.* |
| - If Interrupted or strong immediate refusal | - Thank you for your time. Goodbye.<br>- *End call.*<br>- *Note and enter into person's contact log.* |

| | |
|---|---|
| b) If the desired person responded YES | - To give you a brief summary about this research project – people with lower extremity amputations have a particularly high risk for falling, even after the completion of a comprehensive rehabilitation plan. Past research has focused on the physical limitations that may contribute to a concern for falling. We want to evaluate both physical and psychological factors that may play a part in a person's concern for falling.<br>- We hope to identify the specific factors contribute to concern for falling and the affect this may have on a person's quality of life.<br>- This research project is divided into two sections. This first section is *The Sub-Study.* In this section participants will be answering five short questionnaires online on two separate occasions. This will take approximately 20 minutes each time.<br>- The other section of this project is called *The Main Study*, which participants will be answering nine questionnaires online, only once. This section will take approximately 40 minutes.<br>- Participants may participate in both of the sections or just one. |
| 3. Asking person if they have any questions | Do you have any questions for me about the study or your participation in the study?<br><br>*If NO*: Do you think you might be interested in participating?<br><br>- *If NO:* Thank you for your time and consideration in the research project. Have a good day. *End call. Note and enter into person's contact log.*<br>- *If YES* -Thank you for your interest to participation in the study. Now I want to ask you a few questions to check your eligibility for the study, is that okay with you for me to proceed?<br>- *If YES – Refer to telephone screening eligibility document and proceed below.*<br>- *If NO* – To be eligible to participate in this study, we are looking for people who meet all the eligibility criteria. To identify if you meet all the criteria, I need to ask you a few questions. If you do not want to answer these questions you |

| | |
|---|---|
| | are not eligible. Thank you again for your time and consideration to take part in the study. Goodbye.<br><br>- *End call. Note and enter into contact log.* |
| 4. Eligibility Criteria | - *Ask each question on the eligibility document and determine if the person qualifies for the study.*<br>- *If person does not meet eligibility, go to 5.*<br>- *If person does meet eligibility, go to 6.* |
| 5. If the person does not meet the eligibility criteria | - To be eligible to participate in this study, we are looking for people who meet all the eligibility criteria. You meet most of the criteria expect for a few which are important for this study and therefore you are not eligible. Thank you again for your time and consideration to take part in the study. Goodbye.<br>- *End call. Note and enter into person's contact log.* |
| 6. If the person does meet eligibility criteria | - As I explained the research project is divided into two sections which both involve the completion of online questionnaires. This smaller project is called *The Sub-Study*. In this section participants will be answering five short questionnaires online on two separate occasions. This will take approximately twenty minutes each time. The other section of this project is called *The Main Study,* which participants will be answering nine questionnaires online, only once. This section will take approximately 40 minutes.<br>- Participants may participate in both of the sections or just one. The risks associated with taking part in this study are minor. Some participants may feel uncomfortable sharing their personal experiences and feelings in the questionnaires. To minimize this, your responses will be anonymized.<br>- You will not be paid to participate in this research project.<br>- We will be collecting identifying information for the study that includes your full name, sex, age, hospital identification numbers and contact information (telephone number, email address, postal address). All records and research materials that would identify you will be through an online format and held confidential and, to the extent permitted by the applicable laws and regulations, will not be made publicly available.<br>- For further details of the study assessment, I can email you the letter of information. Alternatively, the same letter of information will be imbedded at the beginning of the online surveys for your viewing.<br>- If you have any questions about the study assessment after reading the letter of information, please do not hesitate to ask me at any point during this phone call. |

| | |
|---|---|
| | - Do you want to participate in this research project?<br><br>*IF NO/NO LONGER INTERESTED:*<br>- Thank you for your time and consideration to take part in the study. Goodbye.<br>- *End call. Note and enter into person's contact log.*<br><br>*IF YES/INTERESED:*<br>- I will take your response as verbal consent to participate in the study. Participants may participate in both of the sections or just one. Would you like the participate in *The Sub-Study, The Main Study*, or both?<br><br>*If The Sub-Study section, go to 7a.*<br>*If Main Study section, go to 7b.*<br>*If both study sections, go to 7c.* |
| 7. a) Participate in The Sub-Study section | As I mentioned all of the questionnaires will be completed virtually, there will be no in-person meeting between yourself and any of the research project team members. Information will be collected on two occasions. Both assessments will take approximately twenty minutes to complete and will be completed through an online survey. You will receive an email with a unique link to the study questionnaire. You will be answering five questionnaires relating to your concern for falling: modified Survey of Activities and Fear of Falling in the Elderly (mSAFFE), The Falls Efficacy Scale – International (FES-I), The Consequences of Falling (CoF) Scale, The Perceived Control over Falling (PCF) tool, and The Perceived Ability to Manage Falls (PAMF). The second assessment will occur within two days of the initial online questionnaire. The second assessment will ask you to answer the same five questionnaires again and will be accessed through a second unique link that will be emailed to you. After each unique questionnaire link that is sent to you, there will be two follow-up emails to encourage completion of the study components. The first will be within one week and then two weeks after the initial email.<br><br>At this time, can you provide me with an email address that I can send the research questionnaire to?<br><br>*If YES, note the email address in person's contact log and proceed to 8a.*<br><br>*If NO* – This research project is only offered through an online format. If you do not want to provide an email address to be sent the link to the study's questionnaire you are not eligible. Thank you |

| | |
|---|---|
| | again for your time and consideration to take part in the study. Goodbye.<br><br>*End call. Note in person's contact log.* |
| b) Participate in Main Study section | As I mentioned all of the questionnaires will be completed virtually, there will be no in-person meeting between yourself and any of the research project team members. Information will be collected on one occasion through an online format. You will be answering nine questionnaires related to a concern for falling including the Activities-specific Balance Confidence (ABC) Scale, Consequences of Falling (CoF) Scale, Falls Efficacy Scale – International (FES-I), Fear of Falling – Visual Analogue Scale, the modified Survey of Activities and Fear of Falling in the Elderly (mSAFFE), Prosthetic Limb Users Survey of Mobility (PLUS-M), and the Locomotor Capabilities Index in Amputees (LCI), the Perceived Control over Falling (PCF), and Perceived Ability to Manage Falls (PAMF). One questionnaire for mental health symptoms which includes the Depression, Anxiety, and Stress Scale (DASS), and a questionnaire regarding overall quality of life which is titled World Health Organization Quality of Life Scale (WHOQOL). After completing each of the concern for falling questionnaires you will be asked to list any activities you are currently participating in but are concerned about falling, as well as activities that you are physically able to do but are avoiding due to a concern for falling. These supplementary questions are provided for you to elaborate on the challenges you have in your everyday life. After the unique questionnaire link that is sent to you, there will be two follow-up emails to encourage completion of the study components. The first will be within one week and then two weeks after the initial email.<br><br>At this time, can you provide me with an email address that I can send the research questionnaire to?<br><br>*If YES, note the email address in person's contact log and proceed to 8b.*<br><br>*If NO* – This research project is only offered through an online format. If you do not want to provide an email address to be sent the link to the study's questionnaire you are not eligible. Thank you again for your time and consideration to take part in the study. Goodbye.<br><br>*End call. Not in person's contact log.* |

| | |
|---|---|
| c) Participate in both Study sections | As I mentioned all of the questionnaires will be completed virtually, there will be no in-person meeting between yourself and any of the research project team members. Information will be collected on two occasions. The first assessment will take approximately 40 minutes to complete and the second assessment will take approximately twenty minutes to complete. Information will be completed through an online survey. On the first assessment you will be answering nine questionnaires related to a concern for falling including the Activities-specific Balance Confidence (ABC) Scale, Consequences of Falling (CoF) Scale, Falls Efficacy Scale – International (FES-I), Fear of Falling – Visual Analogue Scale, the modified Survey of Activities and Fear of Falling in the Elderly (mSAFFE), Prosthetic Limb Users Survey of Mobility (PLUS-M), and the Locomotor Capabilities Index in Amputees (LCI), the Perceived Control over Falling (PCF), and Perceived Ability to Manage Falls (PAMF). One questionnaire for mental health symptoms which includes the Depression, Anxiety, and Stress Scale (DASS), and a questionnaire regarding overall quality of life which is titled World Health Organization Quality of Life Scale (WHOQOL). After completing each of the concern for falling questionnaires you will be asked to list any activities you are currently participating in but are concerned about falling, as well as activities that you are physically able to do but are avoiding due to a concern for falling. These supplementary questions are provided for you to elaborate on the challenges you have in your everyday life.<br><br>The second assessment will occur within two days of the initial online questionnaire and will ask you to answer only five of the nine questionnaires from the previous assessment. You will be answering five questionnaires relating to your concern for falling: modified Survey of Activities and Fear of Falling in the Elderly (mSAFFE), The Falls Efficacy Scale – International (FES-I), The Consequences of Falling (CoF) Scale, The Perceived Control over Falling (PCF) tool, and The Perceived Ability to Manage Falls (PAMF).<br><br>After each unique questionnaire link that is sent to you, there will be two follow-up emails to encourage completion of the study components. The first will be within one week and then two weeks after the initial email.<br><br>At this time, can you provide me with an email address that I can send the research questionnaire to? |

| | |
|---|---|
| | *If YES, note the email address in person's contact log and proceed to 8a.*<br><br>*If NO* – This research project is only offered through an online format. If you do not want to provide an email address to be sent the link to the study's questionnaire you are not eligible. Thank you again for your time and consideration to take part in the study. Goodbye.<br><br>*End call. Not in person's contact log.* |
| 8. A) Re-iterate number of emails sent to participants | Thank you for providing me with an email address to send the link to the questionnaires to. To re-iterate, you will receive six emails from the study team in total. The first email will include a unique link to the first questionnaire, there will be two follow-up emails to encourage completion of the study components. The fourth email will include a unique link to the second questionnaire, and the fifth and sixth email will be two follow-up emails to encourage completion of the study components. You will not be contacted outside of these six emails. If you do not respond to any of the questionnaire within three weeks of the initial email, it will be assumed that you are no longer interested in participating in the study. |
| B) Re-iterate emails sent to participants | Thank you for providing me with an email address to send the link to the questionnaires to. To re-iterate, you will receive three emails from the study team in total. The first email will include a unique link to the first questionnaire, there will be two follow-up emails to encourage completion of the study components. You will not be contacted outside of these three emails. If you do not respond to any of the questionnaire within three weeks of the initial email, it will be assumed that you are no longer interested in participating in the study. |
| 9. Ending the call | Thank you again for your time and interest to participate in the study. Do you have any questions?<br><br>*If NO* – Once we end this call, the study team will send you the first email with the link the questionnaire to the email you provided. Again, my name is Kristin Nugent. If you have any questions after this phone call you can contact me at 519-661-2111 ext88845. Thank you for your time today. Goodbye. *End call.* |

# Appendix F: Qualtrics Survey – Study 1

**Concern for Falling – Reliability Study on Qualtrics**
Letter of Information
SKIP LOGIC – If person indicates 'No, do not consent' the survey will end.

**Section 1: Conseqeunces of Falling Scale**

This section asks you to identify whether you believe each of the following statements would apply to you if you fell. **A fall** will be defined as: *Unintentionally coming to rest on the ground, floor, or other lower level.*
Please indicate on the scale from 'Strongly Disagree' to 'Strongly Agree' which applies the most to you.

**Loss of Functional Independence**
1=Strongly Disagree 2=Disagree 3=Agree 4=Strongly Agree

"If you fell, would you …."

| | | | | |
|---|---|---|---|---|
| 1. Be helpless? | 1 | 2 | 3 | 4 |
| 2. Not able to cope alone? | 1 | 2 | 3 | 4 |
| 3. Lose your independence? | 1 | 2 | 3 | 4 |
| 4. Become disabled? | 1 | 2 | 3 | 4 |
| 5. Be severely injured? | 1 | 2 | 3 | 4 |
| 6. Be unable to continue to be active? | 1 | 2 | 3 | 4 |

**Damage to Identity**
1=Strongly Disagree 2=Disagree 3=Agree 4=Strongly Agree

"If you fell, would you …"

| | | | | |
|---|---|---|---|---|
| 7. Be embarrassed? | 1 | 2 | 3 | 4 |
| 8. Feel foolish? | 1 | 2 | 3 | 4 |
| 9. Be a nuisance? (a person, thing, or circumstance causing inconvenience or annoyance) | 1 | 2 | 3 | 4 |
| 10. Lose your confidence? | 1 | 2 | 3 | 4 |
| 11. Be in pain? | 1 | 2 | 3 | 4 |
| 12. Have difficulty getting up? | 1 | 2 | 3 | 4 |

**Section 2: Falls Efficacy Scale-International**

The following section asks details about **falls efficacy.** Falls efficacy is defined as:
The level of concern of falling that you have when performing physical and social activities.

Please indicate on a scale of 'Not at all concerned' to 'Very concerned' whether you are concerned that you may fall if you did the following activities. If you currently do not do the activity, please answer to show whether you think you would be concerned if you did it.

| **"Are you concerned you may fall when …..?"** | **Not at all concerned** | **Somewhat concerned** | **Fairly concerned** | **Very concerned** |
|---|---|---|---|---|
| 13. Cleaning the house (e.g. sweep, vacuum, dust) | 1 | 2 | 3 | 4 |
| 14. Getting dressed or undressed | 1 | 2 | 3 | 4 |
| 15. Preparing simple meals | 1 | 2 | 3 | 4 |
| 16. Taking bath or shower | 1 | 2 | 3 | 4 |
| 17. Going to the shop | 1 | 2 | 3 | 4 |
| 18. Getting in or out of a chair | 1 | 2 | 3 | 4 |
| 19. Going up or down stairs | 1 | 2 | 3 | 4 |
| 20. Walking around in the neighborhood | 1 | 2 | 3 | 4 |
| 21. Reaching for something above your head or on the ground | 1 | 2 | 3 | 4 |
| 22. Going to answer the telephone before it stops ringing | 1 | 2 | 3 | 4 |
| 23. Walking on a slippery surface (i.e. wet or icy) | 1 | 2 | 3 | 4 |
| 24. Visiting a friend or relative | 1 | 2 | 3 | 4 |
| 25. Walking in a place with crowds | 1 | 2 | 3 | 4 |
| 26. Walking on an uneven surface (i.e. rocky ground, poorly maintained pavement) | 1 | 2 | 3 | 4 |
| 27. Walking up or down a slope | 1 | 2 | 3 | 4 |
| 28. Going out to a social event (i.e. religious service, family gathering, or club meeting) | 1 | 2 | 3 | 4 |

**Section 3: Modified-Survey of Activities and Fear of Falling in the Elderly**
The following section asks about whether you **avoid doing any activities** in case you will fall over. Please indicate your level of avoidance, if any, on the scale of 'Would never avoid' to 'Always avoid'. If you do not currently do a listed activity for reasons other than fear of falling, answer how you would feel if you did the activity.

| **"Please rate your level of avoidance for doing the following activities?"** | **Would Never Avoid (1)** | **Sometimes Avoid (2)** | **Always Avoid (3)** |
|---|---|---|---|
| 29. Going to the shops. | 1 | 2 | 3 |
| 30. Cleaning your house. | 1 | 2 | 3 |
| 31. Preparing simple meals. | 1 | 2 | 3 |
| 32. Going to the doctor or dentist. | 1 | 2 | 3 |
| 33. Taking a bath. | 1 | 2 | 3 |
| 34. Taking a shower. | 1 | 2 | 3 |
| 35. Going for a walk. | 1 | 2 | 3 |

| | | | |
|---|---|---|---|
| 36. Going out when it is slippery. | 1 | 2 | 3 |
| 37. Visiting a friend or relative. | 1 | 2 | 3 |
| 38. Going to a place with crowds. | 1 | 2 | 3 |
| 39. Going up and down stairs. | 1 | 2 | 3 |
| 40. Walking around indoors. | 1 | 2 | 3 |
| 41. Walking half a mile. | 1 | 2 | 3 |
| 42. Bending down to get something. | 1 | 2 | 3 |
| 43. Travelling by public transport. | 1 | 2 | 3 |
| 44. Going out to a social event. | 1 | 2 | 3 |
| 45. Reaching for something above your head. | 1 | 2 | 3 |

**Section 4: Perceived Control Over Falling**

The following statement explore views regarding perceived ability to control falls. Please select the response which most accurately applies to your views on a scale of 'Strongly Disagree' to 'Strongly Agree'.

46. Do you feel you can reduce your risk of falling? 1 2 3 4 5
47. Do you feel you can overcome the fear of falling? 1 2 3 4 5
48. Do you feel there are things you can do to keep yourself from falling?
1 2 3 4 5
49. Do you feel falling is something you cannot control? 1 2 3 4 5

**Section 5: Perceived Ability to Manage Falls**

The following statements explore views regarding perceived ability to manage falls. Please select the response which most accurately applies to your views on a scale of 'Strongly Disagree' to 'Strongly Agree'.

50. How certain are you that you will find a way to get up if you fell?
1 2 3 4
51. How certain are you that you will find ways to reduce falls? 1 2 3 4
52. How certain are you that you will be able to protect yourself if you do fall?
1 2 3 4
53. How certain are you that you will be able to increase your physical strength?
1 2 3 4
54. How certain are you that you will be able to get steadier on your feet?
1 2 3 4

**Section 6: Demographic and Clinical Characteristics**

55. What is your age:_____
56. What is your gender: Male Female Other
57. What is your height (cm)?_____

58. What is your weight (kg)?_____
59. Starting from Grade 1, how many years of education do you have?____
60. Please indicate from the following list any current or ongoing health conditions that a physician has diagnosed you having (Check all that apply):

High Blood Pressure
Lung Disease
Congestive Heart Failure
Osteoarthritis
Diabetes
Cancer
Parkinson's Disease
Hearing Problems
Anemia
Arthroplasty (hip/knee)
Osteoporosis
High Cholesterol
Stroke
T.I.A

61. Do you smoke? Yes No
62. Do you have a history of cerebral vascular disease? Yes No
63. Do you have vision problems?

| | | | | | |
|---|---|---|---|---|---|
| Glasses: | Yes | No | Cataracts: | Yes | No |
| Cataract surgery: | Yes | No | Glaucoma: | Yes | No |
| Macular degeneration: | Yes | No | Legally blind: | Yes | No |

64. Do you have cardiac problems?

| | | | | | |
|---|---|---|---|---|---|
| Heart attack: | Yes | No | Pacemaker: | Yes | No |
| Arrhythmia: | Yes | No | Bypass: | Yes | No |
| Angioplasty: | Yes | No | Atrial fibrillation: | Yes | No |
| Angina | Yes | No | | | |

65. Rating of current overall quality of health.

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| (Poor) | (Fair) | (Good) | (Very Good) | (Excellent) |

66. Number of prescription medications currently taking? _____
67. Current employment status:

Employed
Unemployed
Student
Retired
Other (Describe):
_____

68. Type of current residence:

2-storey house
Bungalow
Condominium
Apartment
Assisted living facility
Retirement residence
Nursing home
Other (describe):
_____

69. What is the level of the amputation?

One-side below the knee
One-side below the ankle
One-side above the knee
Both sides below the knee
Both sides above the knee
Both sides below the ankle
Other _____

70. Prior to the amputation, what leg was the dominant leg (i.e., foot kick a ball with)?

Right Left

71. What was the cause of the amputation?

| | |
|---|---|
| Peripheral vascular disease | Cancer |
| Diabetes | Congenital defect |
| Traumatic Accident | Other (describe) |
| Failed operation | _____ |

72. What month and year did you receive the most recent amputation? _____

73. Do you have any problems with the stump? Please select all that apply.

Pain
Phantom pain
Open wounds
Ulcers
Swelling
Hypersensitivity
Loss of sensation
Contracture
Other (describe)

74. Do you have any problems with the <u>non-amputated leg or foot</u>?

Pain
Open wounds
Swelling
Hypersensitivity
Loss of sensation
Other (describe) _____
Not applicable – received bilateral amputation

75. How long have you been using a prosthesis? Please indicate in number of months (e.g. 2 months, 1.5 months)? _____months

76. How many hours and days is the prosthesis worn?

_____ hours per day
_____ days per week

77. On a scale from 0 – 10, how comfortable is the socket at the moment?

Most **uncomfortable** Most comfortable

0 1 2 3 4 5 6 7 8 9 10

78. What best describes the use of your prosthesis? (heck one)
    Don't wear it
    Only for appearance
    Only for transfers
    Walking
79. Do you currently use any walking aids? (i.e. crutches, cane, walker)
    Yes (please specify) _____ No
SKIP LOGIC: If 'No', skip to question 81.

80. Do you use the walking aid all the time? Yes No
81. Have you fallen in the previous 12 months? Yes No
SKIP LOGIC: If 'No', skip to end of survey.

82. How many times have you fallen in the past 12 months? _____
83. Did you hurt yourself in the fall or on any of the falls?
    Yes (please specify) _____ No
84. Did the fall involve a hospital visit? Yes No
85. Were you wearing the prosthesis when you fell? Yes No
86. What activity were you doing when you fell? Please describe.
    _____
87. Did the fall involve a wheelchair? Yes No

# Appendix G: Qualtrics Survey – Study 2

**Concern for Falling – Main Study on Qualtrics**
Letter of Information
SKIP LOGIC – If person indicates 'No, do not consent' the survey will end.

**Section 1: Activities-specific Balance Confidence Scale**

For each of the following activities, please indicate **your level of confidence** in doing the activity without losing your balance or becoming unsteady. Please choose one of the percentage points on the scale from 0% (No Confidence) to 100% (Completely Confident). If you **do not currently** do the activity in the question, try and imagine how confident you would be if you had to do the activity. If you normally use a walking aid to do the activity or hold onto someone, rate your confidence as if you were using these supports.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
No confidence ---------- Completely confident

**How confident are you that you will not lose balance or become unsteady when you...**

1. Walk around the house? _____%
2. Walk up or down stairs? _____%
3. Bend over and pick up a slipper (or item) from the front of a closet floor _____%
4. Reach for a small can off a shelf at eye level? _____%
5. Stand on your tiptoes and reach for something above your head? _____%
6. Stand on a chair and reach for something? _____%
7. Sweep the floor? _____%
8. Walk outside the house to a car parked in the driveway? _____%
9. Get into or out of a car? _____%
10. Walk across a parking lot to the mall (store)? _____%
11. Walk up or down a ramp? _____%
12. Walk in a crowded mall where people rapidly walk past you? _____%
13. Are bumped into by people as you walk through the mall? _____%
14. Step onto or off an escalator while you are holding onto a railing? _____%
15. Step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? _____%
16. Walk outside on icy sidewalks? _____%

17. Please indicate if you do not perform any of the above activities due to limitations you expereince from the amputation and/or prosthesis? (please check all that apply)
    - Walk around the house
    - Walk up or down stairs
    - Bend over and pick up a slipper (or item) from the front of a closet floor
    - Reach for a small can off a shelf at eye level
    - Stand on your tiptoes and reach for something above your head
    - Stand on a chair and reach for something

Sweep the floor
Walk outside the house to a car parked in the driveway
Get into or out of a car
Walk across a parking lot to the mall (store)
Walk up or down a ramp
Walk in a crowded mall where people rapidly walk past you
Are bumped into by people as you walk through the mall
Step onto or off an escalator while you are holding onto a railing
Step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing
Walk outside on icy sidewalks

**Section 2: Challenging Activities Open-ended Question**

18. Please specify up to 5 activities that are challenging to perform because of the amputation and/or prosthesis:

_____

_____

19. Has your confidence to complete an activity due to the amputation negatively impacted your overall quality of life?

Yes No

**Section 3: Conseqeunces of Falling Scale**

This section asks you to identify whether you believe each of the following statements would apply to you if you fell. **A fall** will be defined as: *Unintentionally coming to rest on the ground, floor, or other lower level.*
Please indicate on the scale from 'Strongly Disagree' to 'Strongly Agree' which applies the most to you.

**Loss of Functional Independence**

1=Strongly Disagree 2=Disagree 3=Agree 4=Strongly Agree

"If you fell, would you …."

| | | | | |
|---|---|---|---|---|
| 20. Be helpless? | 1 | 2 | 3 | 4 |
| 21. Not able to cope alone? | 1 | 2 | 3 | 4 |
| 22. Lose your independence? | 1 | 2 | 3 | 4 |
| 23. Become disabled? | 1 | 2 | 3 | 4 |
| 24. Be severely injured? | 1 | 2 | 3 | 4 |
| 25. Be unable to continue to be active? | 1 | 2 | 3 | 4 |

**Damage to Identity**

1=Strongly Disagree 2=Disagree 3=Agree 4=Strongly Agree

"If you fell, would you …"

26. Be embarrassed? 1 2 3 4
27. Feel foolish? 1 2 3 4
28. Be a nuisance? (a person, thing, or circumstance causing inconvenience or annoyance)
1 2 3 4
29. Lose your confidence? 1 2 3 4
30. Be in pain? 1 2 3 4
31. Have difficulty getting up? 1 2 3 4

32. Are there any other consequences not listed above that would negatively impact your ability to be **functionally independent (not relying on others for the completion of activities of daily living)?** These can be any you have personally experienced or imagine would affect you. Please list up to 5 examples.
_____

33. Are there any consequences not listed above that would negatively impact **your identity?** These can be any you have personally experienced or imagine would affect you. Please list up to 5 examples.
_____

34. Has dealing with a loss of functional independence after the amputation negatively impacted your overall quality of life?
Yes No

35. Has dealing with a damage to your identity after the amputation negatively impacted your overall quality of life?
Yes No

**Section 4: Falls Efficacy Scale-International**

The following section asks details about **falls efficacy.** Falls efficacy is defined as:
The level of concern of falling that you have when performing physical and social activities.

Please indicate on a scale of 'Not at all concerned' to 'Very concerned' whether you are concerned that you may fall if you did the following activities. If you currently do not do the activity, please answer to show whether you think you would be concerned if you did it.

| **"Are you concerned you may fall when …..?"** | **Not at all concerned** | **Somewhat concerned** | **Fairly concerned** | **Very concerned** |
|---|---|---|---|---|
| 36. Cleaning the house (e.g. sweep, vacuum, dust) | 1 | 2 | 3 | 4 |
| 37. Getting dressed or undressed | 1 | 2 | 3 | 4 |
| 38. Preparing simple meals | 1 | 2 | 3 | 4 |

| | | | | |
|---|---|---|---|---|
| 39. Taking bath or shower | 1 | 2 | 3 | 4 |
| 40. Going to the shop | 1 | 2 | 3 | 4 |
| 41. Getting in or out of a chair | 1 | 2 | 3 | 4 |
| 42. Going up or down stairs | 1 | 2 | 3 | 4 |
| 43. Walking around in the neighborhood | 1 | 2 | 3 | 4 |
| 44. Reaching for something above your head or on the ground | 1 | 2 | 3 | 4 |
| 45. Going to answer the telephone before it stops ringing | 1 | 2 | 3 | 4 |
| 46. Walking on a slippery surface (i.e. wet or icy) | 1 | 2 | 3 | 4 |
| 47. Visiting a friend or relative | 1 | 2 | 3 | 4 |
| 48. Walking in a place with crowds | 1 | 2 | 3 | 4 |
| 49. Walking on an uneven surface (i.e. rocky ground, poorly maintained pavement) | 1 | 2 | 3 | 4 |
| 50. Walking up or down a slope | 1 | 2 | 3 | 4 |
| 51. Going out to a social event (i.e. religious service, family gathering, or club meeting) | 1 | 2 | 3 | 4 |

52. Are there any activities NOT listed in questions above that you are concerned about performing during your daily activities since the amputation?

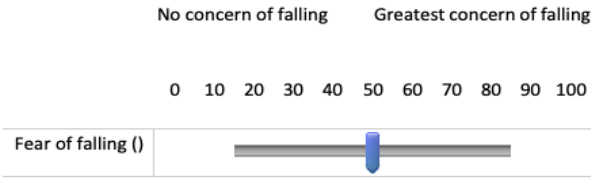
_____

53. Has your concern about performing your daily activities impacted your overall quality of life?

Yes No

**Section 5: Fear of Falling – Visual Analogue Scale**

54. Please rate your **level of fear of falling** on this sliding scale from 'No concern of falling' to 'Greatest concern of falling':




**Section 6: Modified-Survey of Activities and Fear of Falling in the Elderly**

The following section asks about whether you **avoid doing any activities** in case you will fall over. Please indicate your level of avoidance, if any, on the scale of 'Would never avoid' to 'Always avoid'. If you do not currently do a listed activity for reasons other than fear of falling, answer how you would feel if you did the activity.

| **"Please rate your level of avoidance for doing the following activities?"** | **Would Never Avoid (1)** | **Sometimes Avoid (2)** | **Always Avoid (3)** |
|---|---|---|---|
| 55. Going to the shops. | 1 | 2 | 3 |
| 56. Cleaning your house. | 1 | 2 | 3 |
| 57. Preparing simple meals. | 1 | 2 | 3 |
| 58. Going to the doctor or dentist. | 1 | 2 | 3 |
| 59. Taking a bath. | 1 | 2 | 3 |
| 60. Taking a shower. | 1 | 2 | 3 |
| 61. Going for a walk. | 1 | 2 | 3 |
| 62. Going out when it is slippery. | 1 | 2 | 3 |
| 63. Visiting a friend or relative. | 1 | 2 | 3 |
| 64. Going to a place with crowds. | 1 | 2 | 3 |
| 65. Going up and down stairs. | 1 | 2 | 3 |
| 66. Walking around indoors. | 1 | 2 | 3 |
| 67. Walking half a mile. | 1 | 2 | 3 |
| 68. Bending down to get something. | 1 | 2 | 3 |
| 69. Travelling by public transport. | 1 | 2 | 3 |
| 70. Going out to a social event. | 1 | 2 | 3 |
| 71. Reaching for something above your head. | 1 | 2 | 3 |

72. Are there any activities which are not listed in the activities above that you avoid doing since the amputation because of a fear of falling? **Please list up to 5 examples.**

_____

**Section 7: Aspiring Activities Open-ended Question**

73. Please state any of the activities that you **wish you could participate** in since you have the amputation. Please list up to 5 examples.

_____

**Section 8: Locomotor Capabilities Index**

The following questions ask you about your **physical function abilities** on a scale ranging from 'No' to 'Yes, alone, without ambulation aids'. Whether or not you wear your prosthesis at the present time, would you say that you are able to do the following activities with your **prosthesis on?**

| | No (0) | Yes, if someone helps me (1) | Yes, if someone is near me (2) | Yes, alone, with ambulation aids (3) | Yes, alone, without ambulation aids (4) |
|---|---|---|---|---|---|
| 74. Get up from a chair | 0 | 1 | 2 | 3 | 4 |
| 75. Pick up an object from the floor when you are standing up with your prosthesis | 0 | 1 | 2 | 3 | 4 |
| 76. Get up from the floor (e.g., if you fell) | 0 | 1 | 2 | 3 | 4 |
| 77. Walk in the house | 0 | 1 | 2 | 3 | 4 |
| 78. Walk outside on even ground | 0 | 1 | 2 | 3 | 4 |
| 79. Walk outside on uneven ground (e.g., grass, gravel, slope) | 0 | 1 | 2 | 3 | 4 |
| 80. Walk outside in inclement weather (e.g., snow rain, ice) | 0 | 1 | 2 | 3 | 4 |
| 81. Go up the stairs with a handrail | 0 | 1 | 2 | 3 | 4 |
| 82. Go down the stairs with a handrail | 0 | 1 | 2 | 3 | 4 |
| 83. Step up a sidewalk curb | 0 | 1 | 2 | 3 | 4 |
| 84. Step down a sidewalk curb | 0 | 1 | 2 | 3 | 4 |
| 85. Go up a few steps (stairs) without a handrail | 0 | 1 | 2 | 3 | 4 |
| 86. Go down a few steps (stairs) without a handrail | 0 | 1 | 2 | 3 | 4 |
| 87. Walk while carrying an object | 0 | 1 | 2 | 3 | 4 |

**Section 9: Perceived Control Over Falling**

The following statement explore views regarding perceived ability to control falls. Please select the response which most accurately applies to your views on a scale of ‘Strongly Disagree’ to ‘Strongly Agree’.

88. Do you feel you can reduce your risk of falling? 1 2 3 4 5
89. Do you feel you can overcome the fear of falling? 1 2 3 4 5
90. Do you feel there are things you can do to keep yourself from falling?
1 2 3 4 5
91. Do you feel falling is something you cannot control? 1 2 3 4 5

**Section 10: Perceived Ability to Manage Falls**

The following statements explore views regarding perceived ability to manage falls. Please select the response which most accurately applies to your views on a scale of 'Strongly Disagree' to 'Strongly Agree'.

92. How certain are you that you will find a way to get up if you fell?
1 2 3 4
93. How certain are you that you will find ways to reduce falls? 1 2 3 4
94. How certain are you that you will be able to protect yourself if you do fall?
1 2 3 4
95. How certain are you that you will be able to increase your physical strength?
1 2 3 4
96. How certain are you that you will be able to get steadier on your feet?
1 2 3 4

**Section 11: Prosthetic Limb Users Survey – Mobility**

The following questions evaluate the **level of difficulty** one has performing an activity **while wearing a prosthesis.** On a scale from 'Unable to do' to 'Without any difficulty', please select the response that best describes your abilities.

| | **Unable to do (1)** | **With much difficulty (2)** | **With some difficulty (3)** | **With a little difficulty (4)** | **Without any difficulty (5)** |
|---|---|---|---|---|---|
| 97. Are you able to walk a short distance in your home? | 1 | 2 | 3 | 4 | 5 |
| 98. Are you able to step up and down curbs? | 1 | 2 | 3 | 4 | 5 |
| 99. Are you able to walk across a parking lot? | 1 | 2 | 3 | 4 | 5 |
| 100. Are you able to walk over gravel surfaces? | 1 | 2 | 3 | 4 | 5 |
| 101. Are you able to move a chair from one room to another? | 1 | 2 | 3 | 4 | 5 |
| 102. Are you able to walk while carrying a shopping basket in one hand? | 1 | 2 | 3 | 4 | 5 |

| | | | | | |
|---|---|---|---|---|---|
| 103. Are you able to keep walking when people bump into you? | 1 | 2 | 3 | 4 | 5 |
| 104. Are you able to walk on an unlit street or sidewalk? | 1 | 2 | 3 | 4 | 5 |
| 105. Are you able to keep up with others when walking? | 1 | 2 | 3 | 4 | 5 |
| 106. Are you able to walk across a slippery floor? | 1 | 2 | 3 | 4 | 5 |
| 107. Are you able to walk down a steep gravel driveway? | 1 | 2 | 3 | 4 | 5 |
| 108. Are you able to hike about 2 miles on uneven surfaces, including hills? | 1 | 2 | 3 | 4 | 5 |

**Section 12: Affect**

**Depression, Anxiety, Stress Scale**

An amputation can affect one's physical ability to participate in daily living activities and it can also impact one's mental wellbeing. These physical changes can impact the way one views themselves and can impact on their participation in their life activities. People often feel stressed, anxious, and even depressed after major medical procedures such as an amputation. This following section asks you to indicate if you have **felt any of the following mental health symptoms** over the past **two weeks.**

**0= Did not apply at all**
**1= Applied to some degree, or a good part of time**
**2= Applied a considerable degree, or a good part of time**
**3= Applied very much, or most of the time**

| | | | | |
|---|---|---|---|---|
| 109. I found myself getting upset by quite trivial things | 0 | 1 | 2 | 3 |
| 110. I was aware of dryness of my mouth | 0 | 1 | 2 | 3 |
| 111. I couldn't seem to experience any positive feeling at all | 0 | 1 | 2 | 3 |
| 112. I experienced breathing difficulty (i.e. excessively rapid breathing, breathlessness in the absence of physical exertion) | 0 | 1 | 2 | 3 |
| 113. I just couldn't seem to get going | 0 | 1 | 2 | 3 |
| 114. I tended to over-react to situations | 0 | 1 | 2 | 3 |
| 115. I had a feeling of shakiness (i.e. legs going to give way) | 0 | 1 | 2 | 3 |
| 116. I found it difficult to relax | 0 | 1 | 2 | 3 |
| 117. I found myself in situation that made me so anxious I was most relieved when they ended | 0 | 1 | 2 | 3 |
| 118. I felt that I had nothing to look forward to | 0 | 1 | 2 | 3 |
| 119. I found myself getting upset rather easily | 0 | 1 | 2 | 3 |
| 120. I felt that I was using a lot of nervous energy | 0 | 1 | 2 | 3 |
| 121. I felt sad and depressed | 0 | 1 | 2 | 3 |

| | | | | | |
|---|---|---|---|---|---|
| 122. | I found myself getting impatient when I was delayed in any way (i.e. lifts, traffic lights, being kept waiting) | 0 | 1 | 2 | 3 |
| 123. | I had a feeling of faintness | 0 | 1 | 2 | 3 |
| 124. | I felt that I had lost interest in just about everything | 0 | 1 | 2 | 3 |
| 125. | I felt that I wasn't worth much as a person | 0 | 1 | 2 | 3 |
| 126. | I felt that I was rather touchy | 0 | 1 | 2 | 3 |
| 127. | I perspired noticeably (i.e. hands sweaty) in the absence of high temperature or physical exertion | 0 | 1 | 2 | 3 |
| 128. | I felt scared without any good reason | 0 | 1 | 2 | 3 |
| 129. | I felt that my life wasn't worthwhile | 0 | 1 | 2 | 3 |

**Quality of Life Scale – Overall Domain**

The complete online World Health Organization – Quality of Life 100 Questionnaire can be found at: https://www.who.int/publications/i/item/WHO-HIS-HSI-Rev.2012.03 or access the PDF version: https://www.who.int/mental_health/who_qol_field_trial_1995.pdf

**Note: The following four questions were used to calculate the overall quality of life for participants.**

The following questions ask how you feel about your **quality of life, health, and other areas of your life**. Please answer all the questions. If you are unsure about which response to give to a question, please choose the one that appears most appropriate. This can often be your first response. Please keep in mind your standards, hopes, pleasures and concerns. Please consider each statement in regards to the **past two weeks.**

**1 = Very dissatisfied**
**2 = Dissatisfied**
**3 = Neither satisfied nor dissatisfied**
**4 = Satisfied**
**5 = Very satisfied**

| | | | | | | |
|---|---|---|---|---|---|---|
| 130. | How would you rate your quality of life? | 1 | 2 | 3 | 4 | 5 |
| 131. | How satisfied are you with the quality of your life? | 1 | 2 | 3 | 4 | 5 |
| 132. | In general, how satisfied are you with your life? | 1 | 2 | 3 | 4 | 5 |
| 133. | How satisfied are you with your health? | 1 | 2 | 3 | 4 | 5 |

**Section 13: Demographic and Clinical Characteristics**

134. What is your age:____
135. What is your gender: Male Female Other
136. What is your height (cm)?___
137. What is your weight (kg)?___
138. Starting from Grade 1, how many years of education do you have?____

139. Please indicate from the following list any current or ongoing health conditions that a physician has diagnosed you having (Check all that apply):

High Blood Pressure
Lung Disease
Congestive Heart Failure
Osteoarthritis
Diabetes
Cancer
Parkinson's Disease
Hearing Problems
Anemia
Arthroplasty (hip/knee)
Osteoporosis
High Cholesterol
Stroke
T.I.A

140. Do you smoke? Yes No

141. Do you have a history of cerebral vascular disease? Yes No

142. Do you have vision problems?

| | | | | | |
|---|---|---|---|---|---|
| Glasses: | Yes | No | Cataracts: | Yes | No |
| Cataract surgery: | Yes | No | Glaucoma: | Yes | No |
| Macular degeneration: | Yes | No | Legally blind: | Yes | No |

143. Do you have cardiac problems?

| | | | | | |
|---|---|---|---|---|---|
| Heart attack: | Yes | No | Pacemaker: | Yes | No |
| Arrhythmia: | Yes | No | Bypass: | Yes | No |
| Angioplasty: | Yes | No | Atrial fibrillation: | Yes | No |
| Angina | Yes | No | | | |

144. Rating of current overall quality of health.

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| (Poor) | (Fair) | (Good) | (Very Good) | (Excellent) |

145. Number of prescription medications currently taking? _____

146. Current employment status:

Employed
Unemployed
Student
Retired
Other (Describe): _____

147. Type of current residence:

2-storey house
Bungalow
Condominium
Apartment
Assisted living facility
Retirement residence
Nursing home
Other (describe): _____

148. What is the level of the amputation?

One-side below the knee
One-side below the ankle
One-side above the knee
Both sides below the knee
Both sides above the knee
Both sides below the ankle
Other _____

149. Prior to the amputation, what leg was the dominant leg (i.e., foot kick a ball with)?
Right Left

150. What was the cause of the amputation?

| | |
|---|---|
| Peripheral vascular disease | Cancer |
| Diabetes | Congenital defect |
| Traumatic Accident | Other (describe) |
| Failed operation | _____ |

151. What month and year did you receive the most recent amputation? _____
152. Do you have any problems with the stump? Please select all that apply.
Pain
Phantom pain
Open wounds
Ulcers
Swelling
Hypersensitivity
Loss of sensation
Contracture
Other (describe)
153. Do you have any problems with the <u>non-amputated leg or foot</u>?
Pain
Open wounds
Swelling
Hypersensitivity
Loss of sensation
Other (describe) _____
Not applicable – received bilateral amputation
154. How long have you been using a prosthesis? Please indicate in number of months (e.g. 2 months, 1.5 months)? _____months
155. How many hours and days is the prosthesis worn?
_____ hours per day
_____ days per week
156. On a scale from 0 – 10, how comfortable is the socket at the moment?
Most **uncomfortable** Most comfortable
0 1 2 3 4 5 6 7 8 9 10

157. What best describes the use of your prosthesis? (heck one)
Don't wear it
Only for appearance
Only for transfers
Walking

158. Do you currently use any walking aids? (i.e. crutches, cane, walker)
Yes (please specify) _____ No

SKIP LOGIC: If 'No', skip to question 160.

159. Do you use the walking aid all the time? Yes No

160. Have you fallen in the previous 12 months? Yes No

SKIP LOGIC: If 'No', skip to end of survey.

161. How many times have you fallen in the past 12 months? _____

162. Did you hurt yourself in the fall or on any of the falls?
Yes (please specify) _____ No

163. Did the fall involve a hospital visit? Yes No

164. Were you wearing the prosthesis when you fell? Yes No

165. What activity were you doing when you fell? Please describe.

_____

166. Did the fall involve a wheelchair? Yes No

**END OF SURVEY**

# Appendix H: Curriculum Vitae

**KRISTIN NUGENT**

## EDUCATION

**Master of Science in Integrative Bioscience, Kinesiology (MSc)** September 2019 – Present
*University of Western Ontario, London, ON*

- Research in the field of mobility and rehabilitation outcomes in adults with lower extremity amputations. Supervisor: Dr. Susan Hunter

**Honours Specialization in Kinesiology (BA)** September 2015 – June 2019
*University of Western Ontario, London, ON*

- Dean's Honour List, 2017, 2018, 2019
- Western Scholarship of Excellence, 2015

## RESEARCH & CAREER RELATED TRAINING

- COVID-19 Rapid Antigen Testing Certification (March 2021)
- Crisis Prevention Intervention Certification (January 2020)
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (September 2019)
- First Aid and CPR/AED – First Responder Level (August 2018)
- Schwinn Cycle Instructor Certification (April 2016)

## ACADEMIC PRESENTATIONS & PUBLICATIONS

- **Nugent K**, Pila E, Payne M, Viana R, Hunter SW. (2021) "*Evaluation of five measures of concern for falling in people with lower extremity amputations".* Canadian Association of Physical Medicine & Rehabilitation, Virtual Conference [Poster Presentation]
- **Nugent K**, Pila E, Payne M, Viana R, Hunter SW. (2021) "*Evaluation of five measures of concern for falling in people with lower extremity amputations".* Ontario Association for Amputee Care, Virtual Conference [Poster Presentation]
- **Nugent K**, Pila E, Payne M, Viana R, Hunter SW. (2021) "*Evaluation of five measures of concern for falling in people with lower extremity amputations".* Parkwood Institute Research Day, London, Canada [Poster Presentation]
- **Nugent K**, Pila E, Payne M, Viana R, Hunter SW. (2021) "*Evaluation of five measures of concern for falling in people with lower extremity amputations".* London Health Research Day, London, Canada [Poster Presentation]
- **Nugent K**, Pila E, Payne M, Viana R, Hunter SW. (2021) *"Evaluating the concern for falling model in people with lower extremity amputations"*. Western Research Forum, London, Canada [Abstract Publication]
- **Nugent K**, Pila E, Payne M, Viana R, Hunter SW. (2021) *"Evaluating the concern for falling model in people with lower extremity amputations"*. Western Research Forum, London, Canada [Oral Presentation]
- **Nugent K**, Pila E, Payne M, Viana R, Hunter SW. (2021) *"Evaluating reliability of scales relating to concern for falling among people with lower extremity amputations".* Kinesiology Graduate Student Research Conference, London, Canada [Poster Presentation]

- **Nugent K**, Pila E, Payne M, Viana R, Hunter SW. (2021) *"Evaluating reliability of scales relating to concern for falling among people with lower extremity amputations".* Health and Rehabilitation Sciences Conference for Graduate Students, London, Canada [Poster Presentation]
- **Nugent K.** (2020) "*Jack of all trades, master of none*". 3-Minute Thesis Competition: Health Sciences Faculty, University of Western Ontario, Canada [Oral Presentation]
- **Nugent K**, Pila E, Payne M, Viana R, Hunter SW. (2020) "*Evaluating concern for falling in people with lower extremity amputations*". Health and Rehabilitation Sciences Conference for Graduate Students, University of Western, Ontario, Canada [Poster Presentation]
- **Nugent K**, Pila E, Payne M, Viana R, Hunter SW. (2020) "*Concern for falling assessment in lower extremity amputation: Jack of all trades, master of none*". Kinesiology Graduate Student Association Conference, University of Western, Ontario, Canada ** *Accepted, but cancelled due to COVID-19.*
- **Nugent K**, Pila E, Payne M, Viana R, Hunter SW. (2020) "*Concern for falling assessment in lower extremity amputation: Jack of all trades, master of none*". Parkwood Institute Research Day, London, Canada ** *Accepted, but cancelled due to COVID-19.*

## DISTINCTIONS & AWARDS

- Parkwood Institute Research Day 2021 – Best Mobility and Aging Poster Presentation - $100 (April 2021)
- Health and Rehabilitation Sciences Conference – Best Poster Presentation in Masters Review Category - $100 (February 2021)
- Canadian Institute Health Research, Graduate Scholarship – Waitlisted (September 2020)
- Ontario Graduate Scholarship, Western University – Waitlisted (September 2020)
- Health and Rehabilitation Sciences Conference - Best Poster Presentation in Master's In-Progress Category - $100 (February 2020)