Perceived risk of falling: The relationship to balance and falls

Perceived risk of falling: The relationship to balance and falls in community-dwelling older adults with type 2 diabetes mellitus

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CONTRIBUTIONS

This thesis is comprised of three studies linked by an introduction and a discussion. The co-author of these studies had the following roles: second reader for the systematic review, assisted with study design and execution as well as manuscript revision. Janelle Gravesande was responsible for all elements of these studies including: study design, data collection, analysis and writing.

ABSTRACT

The purpose of this thesis was to determine the perceived risk of falling and its relationship to balance and falls in older community-dwelling adults with type 2 diabetes mellitus (DM2). Study One was a systematic review of published literature on risk factors for falling in older adults with DM2. Study Two was a prospective cohort study for parameter estimation, the goal was to determine the test-retest reliability, internal consistency, construct validity and factor structure of a falls Risk Perception Questionnaire in older community-dwelling adults with DM2. Study Three was also a prospective cohort study; the goals of this study were to determine the association between perceived of falling and balance in older adults with DM2 and to determine whether older adults alter their perceived risk of falling after receiving feedback about their balance. The information gained from these studies will be used to guide subsequent research as well as falls risk assessment and prevention in older adults with DM2.

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Outline of thesis

The main objectives of this thesis were to determine the perceived risk of falling and balance of community-dwelling older adults with Type 2 Diabetes Mellitus (DM2) as well as to determine whether feedback about one's balance has any impact on his/ her perceived risk of falling. This thesis is composed of three related studies. Study One was a systematic review (Chapter 2), Study Two was a measurement study (Chapter 3) and Study Three was a prospective longitudinal study (Chapter 4). The objective of Study One was to identify the non-pharmacological risk factors for falling in older community-dwelling adults with DM2. The objective of Study Two was to determine the test-retest reliability, internal consistency and construct validity of a falls Risk Perception Questionnaire (RPQ). The objective of Study Three was to determine the association between perceived risk of falling as measured by a Risk Perception Questionnaire (from Study Two) and balance as measured by the Berg Balance Scale of community-dwelling older adults with DM2 and to determine whether individuals alter their perceived risk of falling when given feedback about their balance. This introduction also includes a literature review discussing: DM2, falls in older adults, falls in older adults with DM2, balance in older adults and perceived risk of falling, the relationship between perceived risk and health behaviour change and finally, the theoretical framework used to guide Study Three. A discussion of the findings of this thesis and the implications for future research is also included (Chapter 5).

Literature Review

Type 2 Diabetes Mellitus

Prevalence and burden

Type 2 diabetes mellitus (DM2) is a chronic metabolic disorder characterized by hyperglycaemia due to insulin resistance and a relative deficiency of insulin secretion (50). Older adults have the highest risk of developing Type 2 Diabetes Mellitus (DM2) because the body's ability to produce and use insulin deteriorates with age (1). In 2008, approximately 2.4 million (6.8 %) Canadians had diabetes mellitus (DM) (1), 90% of these cases were Type 2 Diabetes Mellitus (DM2) (2). The highest rates of DM have been reported in Newfoundland and Labrador, Nova Scotia and Ontario (1). In Canada, the prevalence of DM is higher among males (7.2 %) compared to females (6.4 %) (1). Analysis of blood samples, obtained from the 2007 – 2009 Canadian Health Measures Survey, revealed that 20% of DM cases were undiagnosed (1). It is projected that by 2018 the number of Canadians living with DM will increase to 3.7 million (1). Risk factors for diabetes include: advancing age, ethnicity (e.g. South Asian and African), physical inactivity, obesity and a family history of diabetes (1). Persons with DM are more likely to be hospitalized due to cardiovascular disease, end stage renal disease and non-traumatic lower limb amputations compared to persons without DM (age-adjusted) (1). In 2009/10, approximately 40% of Canadian adults living with DM rated their overall health as fair or poor compared to only 10% of Canadian adults without DM (1). In addition, 25% of individuals with DM suffer from depression as determined by physician diagnosis and self-report (7). The link between DM and depression is not fully understood however, it has been suggested that the stress of dealing with a DM diagnosis can negatively impact individuals' mental health thus predisposing them to depression (1). Additionally, complications associated with DM such as vision loss decrease one's quality of life which may also explain the link with depression (1). Both DM and Depression are conditions which are associated with similar neuroendocrine abnormalities which may also explain the relationship between DM and depression (49). For example, a review by Champaneri et al. (2010) outlined three neuroendocrine abnormalities implicated in both DM and depression: 1) dysregulation and over activation of the Hypothalamic-Pituitary-Adrenal (HPA) axis which reduces the body's ability to appropriately terminate its stress response, 2) increased activity of the Sympathetic Nervous System (SNS) demonstrated by an elevated resting heart rate and a reduced heart rate variability and 3) a proinflammatory state: visceral fat due to the overproduction of cytokines may result in insulin resistance (49). Mortality rates among individuals with DM are at least two times higher than individuals without DM (1). Between 2008 and 2009, at least one in ten deaths among Canadian adults was attributed to DM (1). Medical expenses are as much as three times higher for Canadians with DM than those without (7). In 2008/09, Canadian adults (aged 20 to 49 years) with DM visited a family physician twice as often as those without DM, they also visited specialists two to three times more often than persons without DM (1). In 2008, persons with DM were three times more likely to be hospitalized at least once and had longer hospital stays than persons without DM (1). In 2010, health care expenditure due to DM in Canada was estimated at $12.2 billion, by 2020 this figure is projected to increase by $4.7 billion (7). Individuals with DM2 are also at increased risk for falling due to diabetes-related complications such as diabetic peripheral neuropathy, diabetic retinopathy, autonomic neuropathy and diabetic foot ulcers (3). The following sections will address falls in older adults and falls in older adults with DM2.

Falls in older adults

According to the Public Health Agency of Canada, a fall is defined as "a sudden and unintentional change in position resulting in an individual landing at a lower level such as an object, the floor or the ground, with or without injury (10, p.3)." Falls are the leading cause of injury-related hospitalizations among older adults (20); approximately 30% of community-dwelling adults ≥ 65years, and 50% ≥ 85 years fall each year (21). Evidence shows that older women are more likely to fall than older men, a prospective cohort study of 761 individuals, ≥70 years, who were followed for one year showed that women were at least 1.5 times more likely to fall than men (21). Tchalla et al. (2014) followed 765 community-dwelling older adults, ≥70 years, prospectively for 5 years and identified four distinct trajectories with respect to falls: no falls, cluster falls, increasing falls and chronic recurring falls (42). The incidence of injurious falls based on fall trajectories were: 172 per 1000 person-years, 126 per 1000 person-years and 112 per 1000 person-years for chronic recurring falls, cluster falls and increasing falls respectively. This study showed that each trajectory could be predicted by the presence of specific factors (42). Cluster falls were predicted by faster gait speeds and falls during the past year, increasing falls were predicted by diabetes mellitus and cognitive impairment and chronic recurring falls were predicted by multimorbidity and falls in the past year (42). Symptoms of depression were associated with all 3 fall trajectories (42). Individuals who were classified as having chronic recurring falls had the highest rate of injurious falls and fractures (42). Approximately 50% of falls in older adults occur at home; bathrooms and stairs have been identified as the most hazardous areas (10). Falls may result in various consequences such as bruises, abrasions, lacerations and strains as well as hip and wrist fractures (21). In severe cases, falls may even result in death (23). Additionally, falls are often associated with reduced quality of life, dependence in activities of daily living, confusion, depression (23) and fear of falling (24). Research shows that the consequences of falls vary by gender. A retrospective cohort study of 204 persons, ≥ 65 years, who reported at least one fall in the previous year were asked about the consequences of their most recent fall (40). This study found that older women reported physical injury after a fall significantly more than older men; older women were also more likely than older men to experience functional decline and reduced physical activity levels after a fall (40). Gender differences also exist with respect to the way older adults respond to falls (44). A retrospective study of 12,052 community-dwelling older adults, ≥ 65 years, obtained from the 2005 Medicare Current Beneficiary Survey (MCBS) found that older women who fell were significantly more likely to report the fall to a health care provider and discuss fall prevention strategies compared to older men who fell (44).

Risk factors for falling

Risk factors for falling are divided into two categories: intrinsic and extrinsic risk factors (21). Intrinsic risk factors are influenced by an individual's characteristics such as their physical, demographic and health-related characteristics (21). Extrinsic risk factors are influenced by the physical and socio-economic characteristics of an individual's environment (21). Intrinsic factors can be further divided into several types namely: demographic risks, medical risks, risks related to activity level and dependence as well as medication risks (21). Demographic risk factors include: advancing age, being female, history of falling and fear of falling (21). Medical risk factors include: chronic conditions such as a history of stroke, cognitive impairment, arthritis as well as impaired balance and gait (21). A secondary analysis of community-dwelling older adults, ≥65 years, who were at risk for falling showed that older adults with mild cognitive impairment engaged in more risky mobility activities, in part due to poor judgment, which increased their risk for falling (41). The more chronic conditions an individual has the higher their risk for falling (21). Advancing age, in association with an individual's decreasing activity levels due to deteriorating health, often leads to reduced muscle strength and balance which increases the individual's risk for falling (21). Taking multiple medications has also been linked to increased risk for falling this is because medications may cause dizziness as well as impaired coordination and balance (21). Extrinsic risk factors for falling are categorized as: tripping hazards, balance and slipping hazards and vision hazards (21). Tripping hazards include: loose rugs and uneven ground; balance and slipping hazards include: the absence of handrails as well as ice and snow while vision hazards include: cataracts and poor lighting (21). Research suggests that some risk factors for falling differ in importance based on gender. A retrospective study of 4,426 individuals, ≥65years, obtained from two national health surveys in Amsterdam revealed that limitations in activities of daily living and fear of falling were more significant risk factors in older men than older women whereas excessive alcohol consumption and lower education level were more significant risk factors among older women than older men (39).

Fall prevention

There are effective strategies that reduce risk for falling and consequences of falling. Single and multifactorial interventions are effective in preventing falls in older adults. Both individualized home-based exercise and group exercise programs are effective in reducing risk for falling and fall-related fractures (25). Exercise programs that combine various types of exercises such as balance retraining and muscle strengthening are effective. However, a randomized controlled trial of 90 individuals, 65 – 79 years, who were randomized to a walking group or a balance group and participated in a 3-month supervised fall prevention program followed by a 13-month unsupervised fall prevention program found that walking was more effective at reducing fall risk than balance training (38). However, walking as a fall risk reduction strategy, is not recommended for frail individuals due to the increased likelihood of tripping (38). Group-based exercise programs such as Tai Chi are also effective in reducing risk for falling (25). Mechanisms through which Tai Chi reduces risk for falling include improving balance and coordination as well as improving cognition, promoting calmness and increasing individuals' confidence in their ability to prevent themselves from falling (25). A retrospective study of 506 community-dwelling older adults, ≥ 50 years, showed that increased physical activity reduced the likelihood of falls and fall-related injuries (43). In particular, > 1125 metabolic expenditure (MET-min/week) of physical activity was associated with reduced likelihood of falling (43). This study also showed that likelihood of falling was reduced by 2% per 100 MET-min/week of physical activity (43). Compared to low physical activity levels, moderate and high physical activity levels reduced the likelihood of severe fall-related injuries by 76% and 58% respectively; this is because physical activity improves balance which reduces the likelihood of falling as well as improves an individual's resistance to the impact of falls (43). Home safety assessment and modification interventions conducted by occupational therapists also reduce risk for falling (25). There is also some evidence that suggests that gradual withdrawal of psychotropic medication may reduce risk for falling however, more studies need to be conducted before a consensus about the efficacy of this method can be reached (26). Effective multifactorial interventions usually include two or more of the following components: exercise including strength, balance and gait training, advice regarding the appropriate use of assistive devices, review and modification of medications, footwear modification as well as removal or modification of environmental hazards (27).

Falls in older adults with Type 2 diabetes mellitus

Older adults with DM2 are at higher risk for falling than older adults without DM2 due to additional diabetes-related risk factors. A prospective cohort study of 1,145 community-dwelling older adults (85 with DM2), ≥ 65 years, who were followed every 3 months for 3 years, found that older adults with DM2 had a 67% increased risk of recurrent falls compared to older adults without DM2 (45). A population-based study (n= 77) of individuals with DM2, ≥65 years found that poor diabetic control (HbA1C >7) was associated with increased risk for falling, RR= 7.83 (46). Type 2 diabetes mellitus (DM2) is associated with numerous complications such as diabetic peripheral neuropathy, diabetic retinopathy, autonomic neuropathy and diabetic foot ulcers which have all been linked to increased risk for falling (3). Diabetic peripheral neuropathy (DPN) causes reduced sensation in the lower extremities which results in impaired balance and increased risk for falling (4). More than 50 % of persons with diabetes ≥60 years have DPN, together with an associated fall risk, that is a leading cause of mortality in this group ≥65years (5). Diabetic retinopathy occurs when hyperglycaemia causes damage to small blood vessels in the retina of the eye which often results in visual impairment and in severe cases blindness which predispose individuals to falling (8). Autonomic neuropathy is characterized by damaged nerves in the autonomic nervous system, one consequence of this damage is orthostatic hypotension (9). Orthostatic hypotension is characterized by a drop in blood pressure (>20 mmHg for systolic & >10 mmHg for diastolic) due to postural change from supine to standing (9). Symptoms of orthostatic hypotension include: light-headedness, dizziness, weakness and blurred vision which predispose individuals to falling (9). Due to neuropathy, persons with DM2 often have reduced sensation in their feet which hinders their ability to feel when they get injured (1). Reduced sensation coupled with reduced blood flow, which may prevent wound healing, provide a suitable environment for the formation of foot ulcers (1). Persons with DM account for 80% of all non-traumatic lower extremity amputations of which 85% are preceded by a foot ulcer (11).

Women with DM are 1.6 times more likely to have experienced a fall in the past year and are twice as likely to be injured when they fall compared to women without DM (6). A population-based study of 77 individuals with DM2, ≥ 65 years, found that older women with DM2 are at higher risk for falling than older men with DM2, RR= 2.336 (46). A prospective cohort study of 3,075 community-dwelling older adults, 70 – 79 years, found that older adults with DM2 are at higher risk (RR=1.64) for fractures (22). Further a review about the link between diabetes, falls and fractures found that older adults with DM2 are 2.8 times more likely to experience hip fractures when they fall compared to older adults without DM2 (47). Finally, a prospective cohort study of community-dwelling older adults (n=1,840), 70 – 79 years, with a 3-year follow up found that older adults with DM2 experienced more rapid loss of knee extensor strength, leg lean mass and muscle quality compared to older adults without DM2 (48). DM2 is often studied because of its adverse effects on the body's cardiovascular system however, taken together, these studies highlight the fact that the effects of DM2 extend far beyond cardiovascular health to aspects of the body such as muscle strength and bone health. Therefore, fall risk assessment is an important part of the management of individuals with DM2. The following section addresses methods by which risk for falling is assessed with specific emphasis on perceived risk for falling which is less frequently assessed.

Balance in older adults

An individual's risk for falling is often assessed objectively using measures such as the Berg Balance Scale. The Berg Balance Scale (BBS) is a 14-item scale that quantitatively measures both static and dynamic balance as well as risk for falling in older community-dwelling adults (12). Administration of the BBS takes approximately 10 – 20 minutes, each item is scored from 0 – 4 with a score of 0 indicating inability to perform the task and a score of 4 indicating ability to perform the task independently (12). The maximum score that can be achieved on the BBS is 56 points (12). Individuals who score between 0 – 20 points have impaired balance and are considered to be at high risk for falling, individuals who score between 21 – 40 points have acceptable balance and are considered to be at medium risk for falling and individuals who score between 41 – 56 points have good balance and are considered to be at low risk for falling (12). However, further testing of the BBS suggested that 45 points should be used as the cut-off score to differentiate individuals who are at risk for falls from individuals who are not (13). Individuals who score < 45 points are considered at risk for falling while individuals who score ≥ 45 points are not considered at risk for falling (13). With this cut-off score, the sensitivity is reported to be 64% and the specificity is 90%, when history of falling during the past six months was used as the gold standard (13). In older community-dwelling adults, the BBS has demonstrated high inter-rater reliability, ICC = 0.88 – 0.98, high intra-rater reliability, ICC = 0.68 - 0.99 (37), moderate construct validity, r = -0.47 to -0.69, with the Timed up and Go Test (TUG) (37) and good internal consistency, Cronbach's $\alpha = 0.77$ (36).

Perceived risk of falling

Another important aspect of fall risk that is less frequently assessed is a person's own perceived risk of falling. Perceived risk has been defined in various ways, a common theme among the definitions is the idea that perceived risk is a multidimensional concept. One definition of perceived risk put forward by Satterfield et al. (2000) is a multidimensional concept that considers thoughts about the probability of disease and its potential consequences as well as judgments about the importance of the risk to the individual (14). Perceived risk has been conceptualized as consisting of several types of interacting factors which contribute to an individual's overall risk perception. These factors include: external factors, individual factors, self- efficacy in activities of daily living (ADLs) and instrumental activities of daily living (IADLs) as well as individual perceptions (15). External factors include health care practitioners, friends/family, media sources and level of education; individual factors include knowledge, age, gender and a history of falling (15). Finally, individual perceptions include perceived severity and perceived control which is further divided into perceived susceptibility and exposure to risk (15). This conceptual model has its roots in the health belief model (HBM) which was originally developed by a group of social psychologists in an attempt to understand why most people failed to participate in preventive measures such as screening for asymptomatic diseases (16). Perceived risk in this model can be equated to perceived susceptibility in the HBM (HBM will be discussed in detail later in this chapter) (15). It is important to examine perceived risk of falling in addition to balance because they are often incongruent. One widely observed phenomenon is *risk denial*, also known as unrealistic optimism or optimistic bias, which refers to the fact that individuals often perceive their own risk (personal risk) as smaller than the risk of other people (general risk) (17). Sjoberg (2003) asked a random sample of Swedish residents to rate both personal and general risk of 34 hazards including: floods, lighting, air pollution, traffic accidents and terrorist attacks and found that mean general risk was significantly higher than mean personal risk for 28 of the 34 hazards (17).

A 20-item Risk Perception Questionnaire (RPQ) was developed to assess older adults' perceived risk of falling. The items on the RPQ were formulated using the factor model of risk perception previously described as a conceptual framework (15). The questionnaire is composed of 5 sub-scales which address a different component of the model: risk-perception, risk factors, internal/external factors, individual perceptions and self-efficacy (15). Each item is rated on a 7-point Likert scale from strongly disagree to strongly agree (15). A detailed description of the development of this questionnaire is included in Study Two (Chapter 3) as well as the psychometric evaluation of the questionnaire including test-retest reliability and internal consistency. In Study Three (Chapter 4), this RPQ was used to measure the perceived risk of falling of older community-dwelling adults with DM2.

Relationship between perceived risk and health behaviour change

It is purported that risk perception itself is insufficient to lead to behaviour change however, it begins the contemplation process and elaboration about the consequences of the disease/ health condition and thoughts about the individual's competence to engage in behaviour change (18). Additionally, it has been shown that perceived risk and self-efficacy work in concert to yield behaviour change. Rimal (2001) used data from the Standard Five-City Project (FCP), a public health campaign focused on reducing morbidity and mortality in two California communities, to determine whether perceived risk and self-efficacy can be used to predict behaviour change (19). In the Five-City Project, perceived risk of Cardiovascular Diseases (CVDs) was measured by asking participants to rate on a scale from 1 to 7 their likelihood of acquiring CVDs (19). CVD-related self-efficacy was measured by asking participants to rate, on a 9 point scale, their confidence in their ability to engage in CVD-prevention behaviours such as exercising regularly and consuming a healthy diet (19). Using the perceived risk and self-efficacy data, Rimal (2001) identified four distinct groups of individuals: responsive, proactive, avoidant and indifferent (19). Responsive individuals had high perceived risk and high self-efficacy, proactive individuals had low perceived risk and high self-efficacy, avoidant individuals had high perceived risk and low self-efficacy and indifferent individuals had low perceived risk and low self-efficacy (19). Rimal (2001) found that individuals classified as responsive or proactive were significantly more likely to think about and use cardiovascular disease related information than individuals classified as avoidant or indifferent (19).

Theoretical framework

Health Belief model

The Health Belief Model (HBM) was selected as the theoretical framework for this thesis because it was also used as the theoretical framework for the Risk Perception Questionnaire (RPQ) which was the primary outcome measure for this thesis. The HBM was originally formulated in the 1950s by a group of Social Psychologists who were perplexed by the fact that the majority of people simply failed to participate in programs to detect and prevent disease (28). Subsequently, the model was extended to examine individuals' reactions to symptoms and their behaviour after receiving a diagnosis, specifically adherence to medical regimens (28). The HBM consists of various concepts which are used to predict whether people will engage in efforts to prevent, screen for or control illnesses (28). The HBM concepts are susceptibility, seriousness, benefits and barriers to a behaviour, cues to action and self-efficacy (28). *Perceived susceptibility* is defined as an individual's beliefs about the likelihood of getting a disease or condition (28). *Perceived severity* refers to an individual's feelings about the seriousness of getting a disease or leaving it untreated, these feelings are based on evaluations of both medical and clinical consequences as well as social consequences of getting a disease (28). When combined, *perceived susceptibility* and *perceived severity* produce a concept called *perceived threat* (28). *Perceived threat* is not enough to predict whether or not an individual will engage in a positive health behaviour. The model states that an individual will only consider engaging in behaviours to prevent or control an illness if they perceive the prescribed behaviours as potentially beneficial in reducing the threat of the illness, *perceived benefits* (28). *Perceived barriers* are any potentially negative aspects of a particular health behaviour, these barriers may hinder performance of a recommended health behaviour (28). Subconsciously, individuals perform a cost-benefit analysis by weighing the anticipated benefits of a behaviour against the perceived barriers (28). Altogether, "combined levels of susceptibility and severity provide the energy or force to act and the perception of benefits (minus barriers) provide a preferred path of action (28, p.49)." *Cues to action* are defined as strategies used to activate readiness to engage in a particular health behaviour (28). *Self-efficacy* refers to confidence in one's ability to perform a task or behaviour (28). In addition to the concepts described above, various demographic, sociopsychological and structural variables may influence perceptions which in turn influence whether or not individuals engage in health behaviour change (28). Examples of these variables include: age, gender, ethnicity, personality, socioeconomics and knowledge (28).

The Health Belief Model has been used to study health behaviour in various contexts including: breast and cervical cancer screening (29), weight management (30), condom use (31), seat belt use (32) and diabetes (33). A meta-analysis of the effectiveness of HBM variables in predicting the adoption of positive health behaviour found that perceived benefits and perceived barriers were the strongest predictors of positive health behaviour adoption, while perceived severity was a weak predictor and perceived susceptibility did not predict positive health behaviour adoption (34). This meta-analysis also found that perceived benefits and perceived barriers were stronger predictors of health behaviour when the goal of the behaviour was to prevent a negative health outcome rather than to treat an existing negative health outcome (34). Additionally, it was found that perceived severity and perceived benefits were better at predicting health behaviour when the time between measurement of the HBM variable and measurement of the predicted health behaviour was shorter (34). However, time had no effect on the ability of perceived barriers to predict health behaviour (34). One suggested limitation of the HBM is that it treats individuals as asocial beings whose behaviour is only influenced by internal factors when in fact they are social beings whose behaviour is often influenced by external factors such as the presence of other people (35). Another limitation of the HBM is the fact that it does not consider the role of intention formation for which there is evidence that it is an important component of the behaviour adoption process (35).

Falls are a major public health concern which will only continue to grow in significance particularly in countries like Canada which have an aging population. The link between falls and chronic conditions such as diabetes mellitus is highly complex as evidenced by the aforementioned review and further research is required in order to generate appropriate, tailored strategies to reduce falls in older adults with DM2.

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Chapter 2: Systematic Review

Title: Identifying non-pharmacological risk factors for falling in older adults with type 2 diabetes mellitus: A systematic review.

***This study has been published in Disability and Rehabilitation.**

Abstract

Purpose: To identify the non-pharmacological risk factors for falling in older adults with type 2 diabetes mellitus.

Methods: A systematic review of randomized controlled trials, prospective cohort studies, cross-sectional studies and before/ after studies was conducted. Eligible studies identified non-pharmacological risk factors for falling in older adults with type 2 diabetes mellitus (DM2). Medline, Embase, Pubmed and CINAHL were searched for relevant studies published through December 2015. Reference lists were also searched for relevant studies. Search terms were type 2 diabetes mellitus, risk factors, falls and falling, older adults, aging, non-insulin dependent diabetes mellitus, accidental falls and trip. Publication language was restricted to English.

Results: 13 studies met the inclusion criteria: 4 cross-sectional, 6 prospective cohorts, 2 randomized controlled trials and 1 before/ after study. These studies included a total of 13, 104 participants, ≥50 years. The most common risk factors for falling were impaired balance, reduced walking velocity, peripheral neuropathy and comorbid conditions. However, lower extremity pain, being overweight and comorbid conditions had the greatest impact on fall risk.

Conclusion: Interventions to reduce falling in older adults with type 2 diabetes should focus on reducing lower extremity pain, reducing body weight and managing comorbid conditions.

Introduction

In Canada, approximately 2.4 million (6.8%) people are living with diabetes mellitus (DM) [1], 90% of these cases are type 2 diabetes (DM2) [8]. However, the prevalence of DM increases exponentially with age. For instance, fewer than 1 in 200 people between the ages of 12 and 24 have been diagnosed with DM whereas 1 in 6 older men and 1 in 7 older women have been diagnosed with DM [24]. Individuals with this disease often develop complications such as diabetic peripheral neuropathy (DPN), diabetic retinopathy, autonomic neuropathy and diabetic foot ulcers which have all been linked to increased risk for falling [2]. Furthermore, more than 50 % of persons with DM1 and DM2 ≥60 years have DPN, and fall risk due to DPN is a leading cause of mortality in this group ≥65years [3]. Diabetic peripheral neuropathy is defined as having signs and/ or symptoms of peripheral nerve dysfunction in persons with diabetes mellitus after other causes have been ruled out [5]. DPN is associated with loss of sensation which often results in impaired balance and altered gait patterns which ultimately predisposes the individual to an increased risk for falling [6]. Altered gait patterns associated with DPN include reduced walking velocity, shorter stride length, reduced ankle motion and reduced peak ankle power [7].

Women with DM (type 1 & 2) reported more falls than women without diabetes during the 2 year follow up; women with diabetes reported an average of 3.1 falls compared to women without diabetes who reported an average of 2.4 falls ($p < 0.01$) [18]. Persons with diabetes are also more likely to suffer serious injuries when they fall (RR= 1.59, 1.07- 2.35) [9]. Additionally, a systematic review reported that persons with diabetes have abnormal gait characteristics such as slower walking speed, increased variability of step length and/ or step time and greater plantar pressure which increase their risk for falling [4]. However, no study has systematically reviewed the literature on risk factors for falling in older adults with DM2.

We conducted a systematic review of cross-sectional studies, prospective cohort studies, randomized controlled trials and before/after studies in order to identify the non-pharmacological risk factors for falling in older adults with type 2 diabetes mellitus.

Methods

Search strategy

We searched Medline from 1946 to December 2015 using the search terms “diabetes mellitus, type 2,” “accidental falls,” “trip” and “risk factors” with the guidance of a research librarian. We also searched Embase from 1974 to December 2015 using the search terms “non insulin dependent diabetes mellitus,” “falling,” “risk factor” and “aging.” Pubmed was searched from 1997 to December 2015 using the search terms “type 2 diabetes,” “falls,” “risk factors” and “older adults.” CINAHL was also searched from 1960 to December 2015 using the search terms “diabetes mellitus, type 2,” “accidental falls” and “risk factors.” For all databases, publication language was restricted to English. In addition, reference lists were scanned to identify additional pertinent articles.

Eligibility criteria

One hundred and seventy two potentially relevant studies were found. After title and abstract review 153 studies were excluded, reasons for exclusion were: duplicates of papers, study design, sample did not include DM2 or older adults, did not assess falls. A total of nineteen studies were included based on their abstracts only. Of these studies, six were cross-sectional studies, ten were prospective cohort studies, two were randomized controlled trials and one was a before/ after study. Studies included in this systematic review identified non pharmacological risk factors for falling in older adults with DM2. Studies that only identified pharmacological risk factors for falling such as medication use were excluded from this systematic review. Of the nineteen studies reviewed, thirteen studies were included in the final review. Six studies were excluded from the final systematic review at the full text review stage for the following reasons: assessed hypoglycemic events but not falls (*n*=2), assessed fear of falling but not falls (*n*=1), assessed fractures but not falls (*n*=1), falls was not the dependent variable (*n*=1) and medication use (*n*=1). Therefore, thirteen studies were included in the final systematic review (figure 1).

Settings and participants

This systematic review comprised of a total of 13, 104 older men and women, ≥50 years from seven countries. Eight studies only recruited participants with DM2 [10] [11] [13] [14] [18] [19] [20] [22] whereas five studies recruited participants with and without DM2 [12] [15] [16] [17] [21]. Participants were recruited from a variety of settings including: Universities [19], population-based listings [18], health databases [10] [13], outpatient clinics [12] [17], hospitals [13] [20], community settings [11] [14] [15] [17] and residential aged care institutions [16] [17]. All participants were ambulatory.

Outcome measures

Type 2 diabetes diagnosis was determined by self-report [11] [12] [14] [15] [16] [17] [18] [19], nurse's examination [15], by reviewing the participant's medication list [15], medical records [13] [15] [16] [17] [19] [21] [22] nonfasting blood glucose test results [15], fasting blood glucose results [12] [19] [20] and a national health database [10]. This systematic review included various outcomes. The main outcome was the occurrence of a fall which was measured using self-report questionnaires [10] [11] [12] [14] [15], interviews [15], fall calendars [16] [17] and post cards [18]. Balance was measured using a force plate [17], tandem stand (static balance)

[18], tandem walk (dynamic balance) [18], Tinetti Balance and Gait tool [11], a balance plate [21] [22] and dynamic balance test using a 5 meter beam [20]. Components of gait such as gait velocity, stride length and stride length variability were measured using the GAITRite walkway system [17] [21] , walking speed was measured using a 6 meter walk [18] [19], habitual walking speed was measured using gyroscopes [20] and relaxed gait velocity was measured using the timed functional walk test performed over a 6-foot path [11]. The presence of peripheral neuropathy was also assessed by measuring vibration perception using neurothesiometry [13], the Vibratron II [18] and a Bio-Thesiometer [17]. Other measures of peripheral neuropathy included Semmes-Weinstein monofilament testing [11] [14] and peroneal nerve response amplitude [19]. Multimorbidity (≥ 2 medical diagnoses) was determined by self-report [11]. Other conditions such as arthritis and stroke were also determined by self-report [18]. Functional status and mobility were also determined by self-report [15], usual walking speed over 4 meters [15], five chair stands test [15] and the Timed up and Go Test (TUG) [12]. Grip strength was measured using a dynamometer [16] [17] [18] [19]. Musculoskeletal pain and lower extremity pain were measured by self-report using a 10-point numeric rating scale [15]. Cognitive status was evaluated using the Mini-Mental State Examination (MMSE) [15] [16] [17] [19] and executive functioning was measured using the Clock Drawing Test (CDT) [17]. Renal function was assessed using cystatin C levels [19]. Physical activity and self-perceived health were determined by self-report [16]. Visual impairment was measured using the Snellen Chart [13] and Letter Charts of Bailey and Lovie [18]. Finally, diabetic retinopathy was determined using a diabetes database [13].

Data extraction

The data extraction forms were created and tested by two reviewers (JG and JR), the two reviewers tested the extraction forms by jointly extracting the data from one of the included studies. For each study included in this systematic review, the following data was extracted: first author's last name, publication year and country, source of funding and study design. Other data extracted included the research question/ purpose, the characteristics of the study population such as mean age, gender and time since type 2 diabetes diagnosis as well as risk factors for falling along with their risk estimates and corresponding 95% confidence intervals. Data was extracted independently by two reviewers and any discrepancies were resolved through discussion.

Methodological quality/ Risk of bias assessment

Risk of bias of randomized controlled trials was assessed using the GRADE tool. The criteria used to determine risk of bias were: random sequence generation, allocation concealment, adequate blinding of participants, healthcare providers and assessors, incomplete outcome data, selective outcome reporting and other sources of bias. Each study was assigned one of the following ratings for each criterion: low risk, high risk or unclear. Risk of bias of observational studies was assessed using a modified version of the GRADE tool. This modified version was developed using criteria from the GRADE website [27]. These criteria were identified as the key criteria for assessing the quality of observational studies through systematic reviews of various tools used to assess the quality of evidence of observational studies [27]. The criteria used to determine risk of bias were: allocation concealment, adequate blinding of assessors, incomplete outcome data, selective outcome reporting and other sources of bias [27]. Similarly, each study was assigned one of the following ratings for each criterion: low risk, high risk or unclear.

Results

Study characteristics

A total of thirteen studies met all of the inclusion criteria; four were cross-sectional studies (table 1), six were prospective cohort studies (table 2), two were randomized controlled trials (table 3) and one was a before/ after study (table 4). Studies were conducted in the United States (*n*=7), Switzerland (*n*=1), Belgium (*n*=1), The Netherlands (*n*=1), the United Kingdom (*n*=1), Brazil (*n*=1) and Korea (*n*=1). Of the studies included, ten studied both men and women while three studied women only. The thirteen studies included a total of 13, 104 participants.

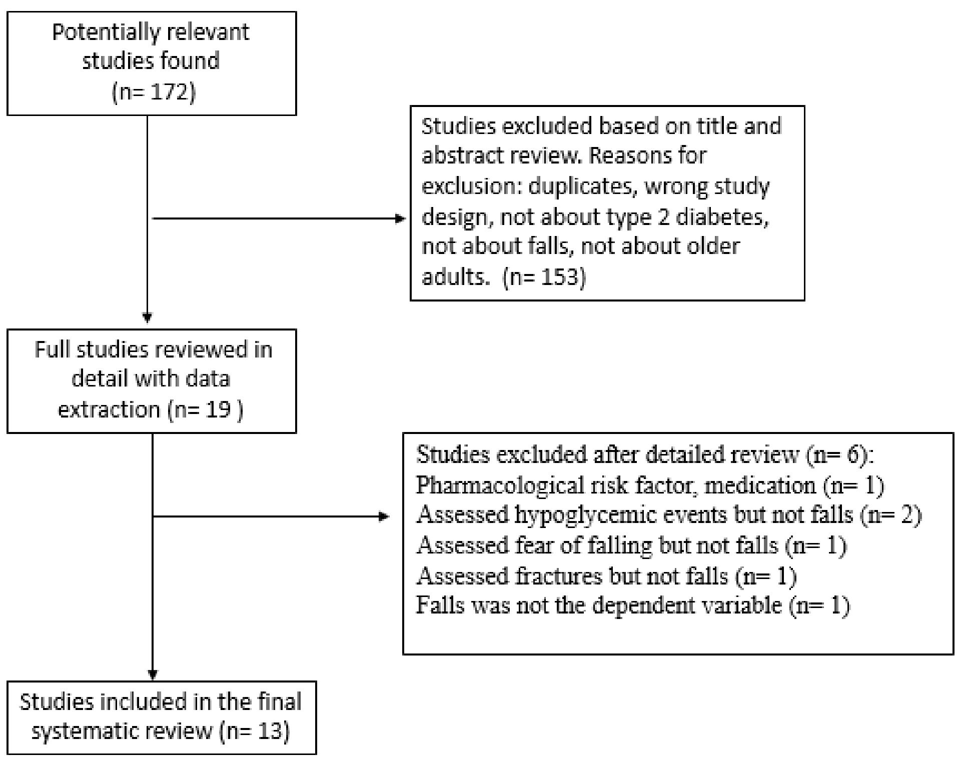

Figure 1. Flow chart of study selection based on predefined inclusion criteria.

Methodological quality/ Risk of bias assessment

Overall, methodological quality of the included studies was fair to good. This systematic review included two randomized controlled trials. With respect to random sequence generation, studies were rated as low risk of bias (*n*=1) and high risk of bias (*n*=1). With respect to allocation concealment, both studies received a rating of unclear (*n*=2). For adequate blinding of participants, healthcare providers and assessors, studies were rated as high risk of bias (*n*=1) and unclear (*n*=1). For incomplete outcome reporting, studies were rated as low risk of bias (*n*=1) and high risk of bias (*n*=1). Both studies were rated as low risk of bias with respect to selective outcome reporting (*n*=2). No other sources of bias were found. This systematic review also included eleven observational studies. With respect to allocation concealment, all eleven studies received the rating of low risk of bias (*n*=11). With respect to blinding of assessors, studies were rated as low risk of bias (*n*=8), high risk of bias (*n*=1) and unclear (*n*=2). For incomplete outcome reporting, studies were rated as low risk of bias (*n*=5) and unclear (*n*=6). All eleven studies were rated as low risk of bias for selective outcome reporting (*n*=11). No other sources of bias were found.

Non-pharmacological risk factors for falling

The most common risk factor identified was impaired balance which was identified by six studies [11] [17] [18] [20] [21] [22]. One study identified impairments in both dynamic balance and static balance as independent risk factors for falling [18]. This study used the tandem walk as a measure of dynamic balance and the tandem stand as a measure of static balance [18]. Reduced walking velocity was also a common risk factor identified by four studies [11] [17] [20] [21]. Comorbid conditions were also identified as risk factors by four studies [10] [11] [14] [18]. Among the comorbid conditions identified were hypertension [11], stroke [11], osteoarthritis

[10], arthritis [11] [18] and heart disease [18]. Peripheral neuropathy was identified as a risk factor for falling by four studies [13] [17] [18] [19]. Reduced grip strength was identified as a risk factor by two studies [16] [17] as well as impaired cognitive function [16] [17]. Impaired vision such as reduced visual acuity [12] and poorer contrast sensitivity [19] were also identified as risk factors for falling. Stride length [17] [21] and stride length variability [17] [21] were also identified as risk factors for falling by two studies. Other risk factors identified include a history of falling [11], reduced functional mobility [12], BMI ≥ 25 Kg/m^2 [14] [15], body pain especially in the lower extremities [15] [16], poor self-perceived health [16], low physical activity levels [16], age [17], poor postural coordination [21], poor executive functioning [17], loss of protective sensation in the lower extremities [11] including insensate feet [14], slower hand and foot reaction times [21] as well as more limitations in activities of daily living [16].

One study made the distinction between risk factors for a single fall compared to risk factors for multiple falls [14]. This study found that one or more comorbid conditions was a risk factor for a single fall while insensate feet, BMI ≥ 30 Kg/m^2 and one or more comorbid conditions were risk factors for multiple falls [14]. Another study recruited participants from a rural area and an urban area to determine whether location had an effect on risk factors for falling [11]. This study found that there was no statistically significant difference between urban residents and rural residents with respect to a history of falling and number of comorbid conditions [11]. However, more urban residents (100%) had loss of lower extremity protective sensation compared with rural residents (67%) [11]. Additionally, more urban residents (40%) displayed impaired balance and gait compared with rural residents (29%) [11].

Table 1: Non-pharmacological risk factors for falling, risk estimates and 95% confidence intervals from cross-sectional studies.

Articles	Risk Factors	Risk Estimates OR, HR, p-value	Settings and participants
Min Lee et al. (2014)	Osteoarthritis	OR = 2.13 (1.11- 4.10), *p* = 0.024	362 older adults with T2DM, ≥ 50 years were Recruited from a national health database in Korea
	Total body muscle mass	OR= 1.00004 (1.000001, 1.000008), *p*= 0.028	
Connor-Kerr et al. (2002)	Prior history of falling	60% of participants from the Urban Day Care Center (UDCC) and 57% of participants from the Rural Community Center (RCC) had a prior history of falling.	12 older adults, ≥ 57 years with T2DM were recruited from an urban and rural community setting in the USA
	Dysfunctional balance and gait (score ≤ 19/28)	40% of participants from the UDCC and 29% of participants from the RCC had dysfunctional gait and balance.	
	Loss of lower extremity protective sensation (loss in ≥ 1 site)	100% of participants from the UDCC and 67% of participants from the RCC had loss of lower extremity protective sensation.	
	Multimorbidity (≥ 2 medical diagnoses)	100% of participants from the UDCC and RCC had multimorbidity.	
	Relaxed gait velocity (< 45-53 cm/sec)	80% of participants from the UDCC and 67% from the RCC had reduced relaxed gait velocity.	
Pereira de Oliveira et al. (2012)	Reduced visual acuity	42.0% (T2DM) versus 61.8% (No T2DM), *p*= 0.03	50 older adults with T2DM and 68 older adults without T2DM, ≥ 50 years
	Difficulty getting up from a	22.0% (T2DM) versus	

	chair with no support	4.4% (No T2DM), *p*= 0.004	were recruited from a public healthcare facility in Brazil
	Functional mobility: assessed by the TUG test	Low risk: T2DM: 30.0 (15) No T2DM: 52.9 (36) *p*= 0.013	
Patel et al. (2008)	Reduced vibration perception (a measure of peripheral neuropathy)	Mean vibration threshold fallers: 21.0 volts Mean vibration threshold non fallers: 17.9 volts p = 0.05	150 older women with T2DM, ≥ 65 years were recruited from hospitals and a diabetes database in the United Kingdom

Note: OR stands for odds ratio, HR stands for hazard ratio and T2DM stands for type 2 diabetes mellitus.

Table 2: Non-pharmacological risk factors for falling, risk estimates and 95% confidence intervals from prospective cohort studies.

Articles	Risk Factors	Risk Estimates (OR, HR, *p*-value)	Settings and participants
Wallace et al. (2002)	Risk factor for one fall: ≥ 1 comorbid condition	OR = 2.10 (1.28 - 3.44), *p*< 0.05	400 older adults with T2DM, ≥ 45 years were recruited from a community setting in the USA
	Risk factors for multiple falls: ≥ 1 comorbid condition, insensate feet, BMI ≥ 30 Kg/m^2	- ≥ 1 comorbid condition: OR = 2.29 (1.29 – 4.08), *p*< 0.05 - Insensate feet: OR= 1.87 (1.1 - 3.2), *p*< 0.01 - BMI ≥ 30 Kg/m^2: no OR reported.	

Volpato et al. (2005)	Risk factors for recurrent falls: - Overweight (BMI 25-30) - Lower-extremity pain (1-2 sites) - Lower-extremity pain (3-4 sites) - Poor lower-extremity summary performance score (< 9 points)	- Overweight (BMI 25 - 30): OR= 3.50 (1.21-10.1), *p*=0.02 - Lower-extremity pain (1-2 sites): OR= 3.61 (1.26-10.4), *p*=0.017 - Lower-extremity pain (3-4 sites): OR=5.58 (1.89-16.5), *p*=0.002 - Poor lower-extremity summary performance score (< 9 points): OR= 7.76 (1.03- 58.8), *p*=0.047	742 older women without DM and 136 older women with DM, ≥ 65 years were recruited from a community setting in the USA
Pijpers et al. (2012)	- Higher levels of pain - Poorer self-perceived health - Lower physical activity - Lower grip strength - More limitations in activities of daily living - Cognitive impairment (MMSE score ≤ 23)	- HR = 1.54 (1.01, 2.34), *p*= 0.044 - HR = 1.55 (1.05, 2.31), *p*= 0.039 - HR = 1.59 (1.05, 2.41), *p*= 0.030 - HR = 1.58 (1.05, 2.40), *p*= 0.031 - HR = 1.51 (0.99, 2.30), *p*= 0.054 - HR = 1.59 (1.05, 2.42), *p*= 0.029	85 older adults with DM and 1060 older adults without DM, ≥ 65 years were recruited from a community setting in The Netherlands
Roman de Mettelinge et al. (2013)	- Poorer executive functioning (Clock Drawing Test) - Age - MMSE - Vibration perception	- OR = 2.13 (1.13, 4.00) - OR = 2.08 (1.11, 3.90) - OR = 2.08 (1.09, 3.95) - OR = 2.04 (1.04, 3.97)	104 older adults with T2DM and 95 older adults without T2DM, ≥ 60 years were recruited from an outpatient clinic, a community setting and a residential aged care setting in Belgium

	threshold - Medio-lateral limits of stability (LOS): balance - MMSE-CDT - Stride length - Gait velocity - MMSE-CDT categorization - Grip strength - Stride length variability	- OR = 2.03 (1.06, 3.88) - OR = 2.02 (1.06, 3.85) - OR = 1.92 (0.99, 3.72) - OR = 1.92 (0.99, 3.72) - OR = 1.94 (1.00, 3.78) - OR = 2.01 (1.06,3.79) - OR = 2.01 (1.05, 3.85)	
Schwartz et al. (2002)	- Tandem walk (a measure of dynamic balance) + Tandem stand (a measure of static balance) - History of heart disease - History of arthritis - Peripheral neuropathy	- OR = 1.34 (1.00-1.81) - OR = 1.43 (1.06-1.92) - OR = 1.45 (1.08-1.95) - OR = 1.49 (1.11-1.99)	8620 older women without DM, 530 older women with T2DM and 99 older women with T1DM, ≥ 67 years were recruited from population- based listings in the USA
Schwartz et al. (2008)	- Reduced peroneal nerve response amplitude (≤ 1.5mV) - Poorer contrast sensitivity (≤ 1.4)	- OR = 1.50 (1.07- 2.12) - OR = 1.41 (0.97- 2.04)	446 Older adults with T2DM, ≥ 70 years were recruited from universities in the USA

	- Higher cystatin-C (a measure of reduced renal function)	- OR = 1.38 (1.11- 1.71)	

Note: OR stands for odds ratio, HR stands for hazard ratio, T2DM stands for type 2 diabetes mellitus, T1DM stands for type 1 diabetes mellitus and DM stands for diabetes mellitus and was used for studies that included older adults with type 1 and type 2 diabetes but did not specify the number of persons with each type.

Table 3: Non-pharmacological risk factors for falling, risk estimates and 95% confidence intervals from randomized controlled trials.

Articles	Risk Factors	Risk estimates (OR, HR, p-value)	Settings and participants
Allet et al. (2010)	Habitual walking speed	+ 0.149 m/s compared with control group, $p < 0.001$	71 older adults with T2DM, mean age 63 years (intervention group) and 64 years (control group) were recruited from a university hospital in Switzerland
	Dynamic balance	-3.39 s compared with control group, $p < 0.0026$	
Morrison et al. (2014)	Hand reaction time	$F_{1,35}$= 12.13, $p < 0.01$	21 older adults with T2DM and 16 older adults with T2DM and peripheral neuropathy, ≥ 42 years were recruited from an unclear setting in the USA
	Foot reaction time	$F_{1,35}$= 43.11, $p < 0.001$	
	Walking velocity	$F_{1,35}$= 5.24, $p = 0.0311$	
	Step length	$F_{1,35}$= 8.86, $p = 0.02$	
	Percentage of time spent in stance	$F_{1,35}$= 6.10, $p < 0.05$	
	Stride length	$F_{1,35}$= 11.03, $p = 0.01$	
	Stride length variability	$F_{1,35}$= 7.22, $p < 0.05$	
	Balance	Eyes open/foam surface condition: - Mean velocity of sway: $F_{1,35}$= 4.67,	

		$p<0.05$. - Path length: $F_{1,35}$= 6.12, $p<0.01$. - SD COP motion in the ML direction: $F_{1,35}$= 8.02, $p<0.01$. - Range COP in the ML direction: $F_{1,35}$= 6.75, $p<0.01$. Eyes closed/foam surface condition: - Mean COP velocity: $F_{1,35}$= 5.02, $p<0.05$ - Path length: $F_{1,35}$= 5.32, $p< 0.05$. - SD of COP motion in the ML direction: $F_{1,35}$= 10.89, $p<0.01$. - Range of COP motion in the ML direction: $F_{1,35}$= 8.511, $p<0.01$	
	postural co-ordination	Postural co-ordination task: $F_{1,35}$= 7.33, $p<0.01$.	

Note: OR stands for odds ratio, HR stands for hazard ratio, T2DM stands for type 2 diabetes mellitus, m/s stands for meters per second, s stands for seconds, COP stands for center of pressure, ML stands for medio-lateral, SD stands for standard deviation and F stands for F statistic.

Table 4: Non-pharmacological risk factors for falling, risk estimates and 95% confidence intervals from before/ after study.

Study	Risk Factors	Risk Estimates (OR, HR, p-value)	Setting and participants
Morrison et al. (2012)	Balance	- COP variability AP: $F_{3,33}$= 5.98, p< 0.05 - COP variability ML: $F_{3,33}$= 2.51, p<0.05 - COP range: $F_{3,33}$= 23.06, p<0.05 - COP velocity: $F_{3,33}$= 5.06, p<0.05	21 older adults without T2DM and 16 older adults with T2DM, mean age 63.5 years were recruited from an unclear setting in the USA

Note: OR stands for odds ratio, HR stands for hazard ratio, T2DM stands for type 2 diabetes mellitus, COP stands for center of pressure, ML stands for medio-lateral, AP stands for anterior-posterior and F stands for F statistic.

Overall, lower extremity pain, being overweight and having one or more comorbid conditions had the greatest impact on risk for falling in persons with type 2 diabetes. Conducting a systematic review on risk factors for falling in older adults with type 2 diabetes was challenging since there is a dearth of related literature. There is more extensive research on risk factors for falling in older adults in general. More methodologically rigorous research, such as randomized controlled trials, on risk factors for falling specifically among older adults with DM2 is needed.

Discussion

The aim of this systematic review was to identify the non-pharmacological risk factors for falling in older adults with DM2. The most common risk factors were impaired balance, reduced walking velocity, peripheral neuropathy and comorbid conditions such as osteoarthritis,

arthritis and heart disease. Other risk factors identified include: reduced grip strength, impaired cognitive function, impaired vision, reduced physical activity and lower extremity pain. Our results are consistent with a systematic review by Allet et al. (2008) which looked at gait characteristics of persons with diabetes, which also reported that persons with diabetes had reduced walking velocity, slower reactions times and peripheral neuropathy which all increased their risk for falling [4]. Allet's review focused primarily on gait abnormalities that contribute to the increased risk for falling among persons with diabetes. In addition to gait abnormalities, our review showed that factors not specifically related to gait have also been linked to the increased risk for falling among persons with diabetes. These factors include vision impairments such as reduced visual acuity [12] and poorer contrast sensitivity [19] as well as comorbid conditions such as osteoarthritis [10], arthritis [18], heart disease [18] and reduced renal function [19].

Falling among older adults is a major public health concern. In Canada, 20 – 30% of older adults fall each year [23]. Moreover, falling is the leading cause of injury-related hospitalization among older adults [23]. Falling not only negatively impacts the physical health of older adults but also their mental health [23]. Negative mental health consequences of falling include fear of falling, confusion and depression [23]. Additionally, falling among older adults accounts for approximately two billion dollars of health care expenditure in Canada each year [23]. Older adults with diabetes mellitus have a greater risk for falling than older adults without diabetes due to diabetes-related complications such as impaired balance and peripheral neuropathy. Older adults with diabetes not only have an increased risk for falling but are also more likely to get injured if they fall [9].

One prominent risk factor for falling in persons with DM2 is peripheral neuropathy; more than 50% of persons with diabetes ≥60 years develop peripheral neuropathy [3]. Factors associated with the development of peripheral neuropathy include: deteriorating glucose tolerance, longer diabetes duration, older age, alcohol consumption and smoking [25]. The nerve damage associated with peripheral neuropathy results in reduced proprioception and sensory input to the extremities which impairs balance and gait [21]. Individuals with peripheral neuropathy also exhibit slower walking speeds, shorter stride lengths, reduced postural motion and coordination as well as slower hand and foot reaction times which have all been linked to increased risk for falling [21]. Individuals often use their hands and feet to prevent themselves from falling therefore, slower reaction times predispose individuals to falling [21]. Additionally, research has also shown that peripheral neuropathy reduces ankle strength, walking stability and balance recovery which all contribute to the increased risk for falling in older adults with diabetes [13]. Some older adults with diabetes also exhibit cognitive impairment. Gait requires cognitive processing, executive functioning as well as attention, therefore, cognitive impairment often results in altered gait and increased risk for falling [17].

Older adults with DM2 often have one or more comorbid conditions. One study included in this systematic review found that all participants had two or more comorbid conditions [11]. In this study, participants from the urban setting had 3-9 comorbid conditions per individual whereas participants from the rural setting had 2-5 comorbid conditions per individual [11]. The studies included in this systematic review reported numerous comorbid conditions; of these, osteoarthritis had the largest impact on fall risk, OR = 2.13 [10], followed by history of arthritis, OR= 1.45 [18] and history of coronary heart disease, OR= 1.43 [18].

Currently, there is a vast amount of literature on interventions to reduce risk for falling in older adults in general. However, there have only been a few interventions aimed at reducing risk for falling in older adults with DM2. Risk factors such as age, history of falling, arthritis, heart disease, hypertension, osteoarthritis and stroke are all non-modifiable. However, risk factors such as impaired balance, walking speed, postural coordination, stride length and stride length variability are modifiable and therefore have been the target of most fall prevention interventions for persons with DM2. In addition to targeting specific risk factors, interventions should also be more tailored to specific categories of persons with DM2. For instance, interventions designed to reduce falls and fall-related risk factors in persons with DM2 and diabetic peripheral neuropathy (DPN) or persons with DM2 and arthritis. One study showed that in persons with DM2 and DPN, 10 weeks of supervised exercise resulted in significant reductions in pain which is a demonstrated a risk factor for falling [26]. One limitation of this study was the absence of a control group and therefore it is unclear whether the results may have been influenced by the Hawthorne effect [26]. Another study involving participants with DPN showed that an 8 week balance exercise program in addition to a diabetes education class resulted in significant improvements in static balance assessed by reduced postural sway and increased one-leg stance test as well as significant improvements in dynamic balance assessed by the Berg Balance Scale, Functional Reach Test, Timed Up and Go test and 10-m walking time and improved trunk proprioception measured by decreased trunk repositioning errors [28]. One limitation of this study which may impact the generalizability of the results is the small sample size (n=38) with nineteen participants assigned to the intervention group [28].

Limitations

The results of our systematic review must be considered within the context of the limitations of the included studies. For instance, it is unclear whether our results can be generalized to all older adults with type 2 diabetes because many of the included studies did not provide demographic information such as race and socioeconomic status. Our results may also be more applicable to women than men; three studies included women only [13] [15] [18] whereas studies that included both men and women often had a significantly higher ratio of women to men. For instance, one study had only 1 male participant [11]. Another limitation is the fact that many of the included studies recorded covariates such as age, time since diabetes diagnosis and diabetes severity (HbA1c) but did not stratify risk factors according to these covariates. Stratifying by these covariates may be useful because different risk factors may be more applicable at different ages, times since diagnosis and diabetes severity. Another potential benefit of knowing which risk factors are more applicable to different demographic groups of persons with diabetes may result in improved tailoring of interventions.

Since aging populations are a global phenomenon, and that the increased prevalence of diabetes with age and that older adults with diabetes are more likely to fall than those without due to more risk factors; future research should seek to develop tailored interventions to reduce risk for falling in this population. In particular, interventions should focus on reducing lower extremity pain, reducing body weight in persons who are overweight and managing comorbid conditions since these risk factors have the greatest impact on risk for falling.

Declaration of interest: The authors report no declarations of interest.

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Chapter 3: Test-retest reliability, internal consistency and construct validity of a falls-related Risk Perception Questionnaire.

Abstract

Purpose: To determine the test-retest reliability, internal consistency and construct validity of a falls Risk Perception Questionnaire in older community-dwelling adults with type 2 diabetes mellitus.

Methods: A prospective cohort of 30 community-dwelling older adults, ≥ 55 years, with type 2 diabetes mellitus (determined by self-report) was assembled and data was collected on duration of diabetes, diabetes-related complications and falls in the past year as well as perceived risk of falling, physical activity levels and fear of falling. At time 1 (T1: baseline) the following were obtained: informed consent, demographic data: age, gender, duration of diabetes and presence of comorbid conditions. At T1, the following assessments were used: perceived risk of falling using a Risk Perception Questionnaire (RPQ), fear of falling using the Falls Efficacy Scale – International (FES-I) and physical activity using the Rapid Assessment of Physical Activity (RAPA). At time 2 (T2), approximately 2 days later, perceived risk of falling was assessed again to determine the test-retest reliability of the RPQ. At time 3 (T3), approximately six weeks later, and time 4 (T4), approximately 2 days after T3, perceived risk of falling was assessed by phone to determine the test-retest reliability of the RPQ when administered by phone. Test-retest reliability of the Risk Perception Questionnaire was assessed using an intraclass correlation coefficient (ICC), internal consistency of the RPQ was assessed by Cronbach's alpha and construct validity was assessed by Pearson's correlation coefficient.

Results: The Risk Perception Questionnaire demonstrated substantial test-retest reliability (26) when delivered in person (ICC = 0.78 (0.58 – 0.89)) and by phone (ICC = 0.82 (0.62 – 0.92)), good internal consistency (alpha = 0.78) and good construct validity (r = 0.52 (0.20 – 0.74), p = 0.003) in older adults with type 2 diabetes mellitus. Exploratory factor analysis revealed a five factor structure which I termed: self-efficacy, effect of information/education on risk of falling, attitudes and beliefs about falling in relation to aging, risk factors and importance of fall prevention.

Conclusion: A balance assessment, as well as an estimate of a patient's perceived risk of falling using the Risk Perception Questionnaire may help clinicians determine whether or not the patient will be motivated to engage in fall prevention behaviours and whether they will modify their behaviour or surroundings to address the risk.

Introduction

Risk perception has been defined in various ways, one definition by Satterfield et al. (2001) states that risk perception is a multi-dimensional concept that considers thoughts about the probability of disease and its potential consequences as well as judgments about the importance of the risk to the individual (1). In order to measure perceived risk of falling in older community-dwelling adults, Galessiere et al. (n.d.) developed a Risk Perception Questionnaire (RPQ, Appendix B) using a conceptual model of risk perception based on the Health Belief Model and the risk perception literature (described below) (2). According to this conceptual model, risk perception (perceived risk) consists of several types of interacting factors including: external factors, individual factors, self- efficacy in activities of daily living (ADLs) and instrumental activities of daily living (IADLs) as well as individual perceptions (2).

External factors include: health care practitioners, family/friends, media, social and physical environment, level of education as well as culture and beliefs (2). Perceived risk of a health outcome has been explored in other patient populations. For example perceived risk of cardiovascular disease (CVD) and the role that these perceptions play in motivating individuals to adopt positive lifestyle changes was evaluated. The link between perceived risk of CVD and positive lifestyle changes was examined through semi-structured interviews. Twenty individuals with type 2 diabetes (n=10 with cardiovascular disease and n= 10 without cardiovascular disease), 52 – 77 years, were interviewed (22). Seventy percent of individuals with CVD and thirty percent of individuals without CVD rated their risk of CVD as moderate to high (22). Family support and physicians' advice were sources of motivation for positive lifestyle changes (22). The physical environment also influences perceived risk for falling. In a survey of older adults n=120, sidewalk conditions and handrails were considered most likely to cause falls (23). There is also literature that suggests that the media influences individuals' risk perception, however, the extent to which media influences risk perception is still unclear (30). One factor that determines whether or not media influences risk perception is the way in which information is presented in the media (30). Information that is presented in a manner that is easy for the public to understand is more likely to influence risk perception (30). Another factor that determines the impact of the media on risk perception is the amount of coverage a topic receives, in fact the amount of coverage influences risk perception more than the actual content of the message (30). Finally, the relationship between the media and risk perception is quite complex and still poorly understood, one factor that contributes to this complexity is the fact that people do not always use information from the media when forming their opinions and perceptions (30).

Individual factors also influence an individual's perceived risk of falling, these include: knowledge, age, history of falling, self-rated health and gender (2). It has been hypothesized that individuals' knowledge about a hazard influences their risk perception. Sjöberg et al (1991) interviewed 236 power plant employees and found that employees with more knowledge about radiation perceived their jobs as less risky (6). A history of falling has also been linked to perceived risk of falling. For example, a survey of older adults (n = 3202), ≥ 60 years, found that individuals who had not fallen in the last 12 months were more likely to have low perceived risk of falling than individuals who had fallen in the last 12 months, OR = 2.41 (1.80 – 3.22), $p < 0.001$ (56). A prospective cohort study of older adults, n=199 recruited from both inpatient and outpatient settings, reported increasing age as another risk factor for falling: OR= 2.08 (95% CI =1.11, 3.90) (8). However, the relationship between age and risk perception of falling is still poorly understood. Previous research has shown that older adults who view adverse health outcomes such as falling as inevitable consequences of aging are less likely to engage in preventive behaviour (9). Moreover, a prospective cohort study of older adults, n=241, 50 – 80 years, demonstrated that older adults with more positive self-perceptions of aging were significantly more likely to practice preventive health behaviours than older adults with negative self-perceptions of aging, mean health behaviour score = 35.56 ± 0.33 and 34.54 ± 0.33, $p < 0.027$ respectively (10). It is also hypothesized that there is a relationship between self-rated health and risk perception, though the literature is very limited. A prospective cohort study of community-dwelling older adults, n=890, identified poorer self-rated health as an independent risk factor for the development of fear of falling (16). One might reason that individuals with a fear of falling would perceive themselves to be at a higher risk for falling than persons without a fear of falling. Therefore, it is reasonable to hypothesize a negative relationship between self-rated health and perceived risk of falling. Lastly, gender also has an impact on risk perception. A survey of older adults, n=146, showed that women were significantly more likely to report increased fear of falling compared to men (P = 0.007) (17). Additionally, in depth interviews of older adults, n=103, found that women (74%) were significantly more likely than men (26%) to report that they were "not confident at all" about their ability to continue living independently in their own homes for the next 20 years, χ^2 (3, n=103) = 8.79, p < 0.03) (18).

Another factor that influences individuals' perceived risk of falling is self-efficacy in activities of daily living (ADLs) and instrumental activities of daily living (IADLs). Self-efficacy refers to one's beliefs about their ability to determine their own behaviour and the events that shape their lives (19). Activities of daily living are common everyday activities needed for self-care and independent living these include: bathing, dressing and eating (20). On the other hand instrumental activities of daily living refer to more challenging, complex activities such as managing personal finances, preparing meals and shopping (20). A prospective cohort study of older adults, n=528, with one year follow up found that individuals with poorer fall-related self-efficacy (Tinetti's Falls Efficacy Scale score ≤ 75) were more likely to experience declines in their ability to perform ADLs (change in ADL score = -0.829, p< 0.001) ; these individuals were also at increased risk for subsequent falls (HR = 2.09 (1.31 – 3.33)) and increased risk for admission to an aged care facility, HR = 1.27 (0.42 – 3.83) (21). Tinetti's Falls Efficacy Scale assesses fear of falling in older adults which is conceptually similar to perceived risk of falling (11).

Lastly, perceived risk of falling is influenced by individual perceptions, these include: *perceived severity* which refers to an individual's feelings about the seriousness of getting a disease or leaving it untreated (3); *perceived control* which refers to an individual's belief in his/her ability to determine his/her own internal states and behaviour, influence his/her environment and/or achieve desired outcomes (4). Perceived control is influenced by *perceived susceptibility* which refers to a person's beliefs concerning the likelihood of getting a disease or condition (3) and *exposure to risk* (2). Individual perceptions also include: *attitudes*, *risk sensitivity*, *specific fear* and *risk denial* (optimistic bias) (2). *Attitudes* are evaluative judgments that integrate and summarize cognitive and affective responses that are related to an object (28). *Risk sensitivity* refers to the way in which individuals respond to a given hazard; some individuals may be very worried about a hazard while others may only worry a little or not at all (29). *Specific fear* refers to fear-arousing thoughts that are unique to a given hazard; for example, nuclear fear is a specific fear of radiation (29). *Risk denial* (optimistic bias) refers to the fact that individuals often perceive their own risk (personal risk) as smaller than the risk of other people (general risk) (5).

The health belief model (HBM) was used as the theoretical framework for the development of this Risk Perception Questionnaire (RPQ). The HBM was chosen as the basis for this RPQ because one of its main goals is to change one's perceptions and behaviours in order to prevent adverse health outcomes, in this case preventing a fall (2). The HBM was developed in an attempt to understand why the vast majority of people failed to participate in programs designed to detect and prevent disease (34). The HBM consists of various concepts which were designed to predict whether people will engage in behaviours to prevent, screen for or control diseases (34). These concepts include: susceptibility, seriousness, benefits and barriers to a given behaviour, cues to action and self-efficacy (34). *Perceived susceptibility* is defined as an individual's beliefs about the likelihood of acquiring a disease (34). *Perceived severity* refers to an individual's feelings about the seriousness of acquiring a disease or leaving it untreated (34).

When combined, *perceived susceptibility* and *perceived severity* result in a concept called *perceived threat* (34). The HBM states that an individual will only consider practicing behaviours designed to prevent or control illness if they perceived the behaviours as potentially beneficial in reducing the threat of the illness, *perceived benefits* (34). *Perceived barriers* are any potentially negative aspects of a particular health behaviour which may hinder performance of that behaviour (34). *Cues to action* refer to strategies used to ignite readiness to engage in a positive health behaviour (34). Lastly, *self-efficacy* refers to confidence in one's ability to perform a task or behaviour (34). Additionally, demographic, socio-psychological and structural variables often influence perceptions which in turn influence whether or not individuals will engage in health behaviour change (34). These variables include: age, gender, ethnicity, personality, socioeconomics and knowledge (34). The HBM was also chosen because of its past success in predicting health behaviour (40). A meta-analysis which examined the effectiveness of HBM variables in predicting positive health behaviour such as smoking cessation, dental care, breast cancer screening, cervical cancer screening, exercise and influenza vaccination found that perceived benefits and perceived barriers were the strongest predictors of positive health behaviour whereas perceived severity was only a weak predictor and perceived susceptibility had no predictive power at all (40). This meta-analysis also found that perceived benefits and perceived barriers were stronger predictors when the goal of the behaviour was to prevent a disease rather than to treat an existing disease (40). One critique of the HBM is that it treats individuals as asocial beings whose behaviour is only influenced by internal factors when in fact they are social beings whose behaviour is influenced by both internal and external factors (41).

The RPQ was developed based on the risk perception literature described above. During the development phase, the RPQ was presented to a group of rehabilitation professionals with expertise in aging and mobility research to gain feedback about the content of the items; it was also presented to 2 older adults to gain feedback about the comprehension and wording of the items (2). The RPQ was previously tested using a cross-sectional design (2). A convenience sample of ten community-dwelling older adults, ≥ 65 years, were recruited from an ongoing study where persons were assessed annually for risk of functional decline (2). Three participants showed that their balance was highly impaired and had a score of ≤ 2 points on the lower extremity performance test (LEPT), 5 participants had moderate balance impairment as measured by a score of 3 points on the LEPT and 2 participants had low balance impairment as measured by a score of 4 points on the LEPT (2). In this study, 60% of the participants had fallen in the past year, however, only 40% perceived themselves at risk for falling (2). This questionnaire looks promising as a risk perception measure for falls; however, its reliability and validity have not been determined.

Research questions

1) Is the test-retest reliability of the Risk Perception Questionnaire high ($ICC_{2,1} \geq 0.80$) in community-dwelling older adults with type 2 diabetes mellitus when administered in person with a two day interval between tests?
2) Is the test-retest reliability of the Risk Perception Questionnaire high (ICC ≥ 0.80) for community-dwelling older adults with type 2 diabetes mellitus when administered by phone with a two day interval between tests?
3) What is the absolute reliability of the Risk Perception Questionnaire as measured by the standard error of measurement (SEM)?

4) Is the internal consistency of the Risk Perception Questionnaire high (Cronbach's alpha ≥ 0.80) for older community-dwelling adults with type 2 diabetes mellitus.

5) What is the correlation between scores on the Risk Perception Questionnaire (RPQ) and the Falls Efficacy Scale – International (FES-I) (construct validity)? We hypothesize that individuals who score high on the RPQ will also score high on the FES-I, $r \geq 0.50$.

Methods

Design

This is a prospective cohort study

Eligibility criteria

The eligibility criteria for this study were as follows:

1) For this study we included people ≥55 years because persons with diabetes are at increased risk for falling and therefore would benefit from interventions aimed at prevention

2) A self-reported diagnosis of type 2 diabetes mellitus.

3) Persons were living independently in the community.

4) Persons were able to follow verbal instructions in English

5) Persons were able to provide written informed consent.

Participants

Convenience sampling was used to recruit participants. Using the hypothesized test-retest reliability: ICC ≥ 0.80, type I error = 0.05 and type II error = 0.20 the minimum sample size was determined to be 30 participants (see sample size calculation, appendix A). Participants were recruited from various exercise programs located at hospitals across Hamilton, Ontario (n= 14). In addition, participants were recruited through an advertisement in a local newspaper (n= 16).

Settings

Assessments were conducted at McMaster University and various outpatient settings across Hamilton Ontario. Please refer to the procedures section for more information regarding: how, when and in what order assessments were administered.

Ethics

Ethical approval for this study was granted by the Hamilton Integrated Research Ethics Board (HIREB), REB number: 15-346-S.

Outcomes

Test-retest reliability

This study assessed test-retest reliability of the RPQ using two types of administration in person and by phone. For this study, a two day test-retest interval between tests was chosen because participants were considered to be stable with respect to fall risk perception. Test-retest reliability was assessed by calculating the intraclass correlation coefficient (ICC). The ICC is defined as follows: between subjects variability ÷ (between subjects variability + error); as the error term decreases the ICC moves closer to 1 indicating excellent reliability (14). On the other hand, as the error term increases the ICC moves closer to 0 indicating poor reliability (14). The ICC measures relative reliability; that is the extent to which individuals maintain their position within the sample population over repeated measurements (24). There is no universal consensus for how the magnitude of the ICC should be interpreted. One commonly used classification for the strength of test-retest reliability of measures based on the ICC is as follows: 0.00 – 0.20 slight, 0.21 - 0.40 fair, 0.41 – 0.60 moderate, 0.61 – 0.80 substantial and 0.81 – 1.00 almost perfect (26). Another suggestion for interpretation of the ICC includes: < 0.40 poor, 0.40 – 0.75

fair to good and > 0.75 excellent (62). On the other hand, absolute reliability refers to the degree to which repeated measurements of the same instrument on the same individual vary around the true score, the smaller the variation in repeated measurements the higher the absolute reliability (24). Absolute reliability was measured by the standard error of measurement (SEM). Unfortunately, we could not find any guidelines for interpreting the size of the SEM.

Bland-Altman method

We used the Bland-Altman method to determine the agreement between RPQ scores at time 1 and time 2 (in person administration) as well as time 3 and time 4 (phone administration). The Bland-Altman method uses a plot to describe the agreement between two quantitative measurements and quantifies this agreement by constructing limits of agreement (61). The limits of agreement are calculated using the mean and the standard deviation of the differences between the two measurements; the upper limit of agreement = mean difference + (standard deviation of the difference x 1.96), the lower limit of agreement = mean difference - (standard deviation of the difference x 1.96) (61). The Y axis of the Bland-Altman plot represents the difference between paired measurements while the X axis represents the mean of the paired measurements (61). According to this method, all data points should lie within $\pm$ 2 standard deviations of the mean difference (61).

Internal consistency

Currently, there is no data on the internal consistency of the Risk Perception Questionnaire therefore, this was assessed. Internal consistency assesses the degree to which items on a test, in this case a questionnaire, are interrelated (15). Interrelatedness among items indicates that all items are measuring the same underlying concept or construct that they were intended to measure (15). Internal consistency was measured using Cronbach's alpha. Alpha varies from 0 – 1, high alpha values indicate a high degree of interrelatedness among items on a test (15). It is important to note that alpha is influenced by the number of items on a test, the more items on a test the higher alpha will be (15). Therefore, caution should be taken when interpreting alpha values since a long test may have a higher alpha value than a short test simply because of its length and not because it has higher internal consistency (15). Alpha values between 0.70 – 0.95 are considered good; however, caution should be taken when interpreting alpha values > 0.90 because this may indicate the presence of redundant items (15).

Construct validity

The construct validity of the Risk Perception Questionnaire with the Falls Efficacy Scale-International was also assessed. The falls efficacy scale- international (FES-I) was also administered at baseline. The FES-I is a 16 item tool used to assess fear of falling in older adults while performing physical and social activities (12) (Appendix B). Fear of falling is assessed on a 4 point scale with 1 indicating not at all concerned about falling to 4 indicating very concerned about falling (12). Total scores range from 16 to 64, a cut point of 23 points has been used to differentiate between individuals with low and high concern about falling, individuals who score 16 – 22 points are considered to have a low concern about falling whereas individuals who score 23 – 64 are considered to have a high concern about falling (13). With the suggested cut point, the sensitivity and specificity of the FES-I are 90.9% and 47.2% respectively (13). The FES-I has demonstrated high test-retest reliability, ICC = 0.96, as well as high internal consistency, Cronbach's alpha = 0.96 (12). Construct validity of the Risk Perception Questionnaire was assessed by determining its correlation with the Falls Efficacy Scale International using Pearson's correlation coefficient. Persons who score high on the FES-I should also score high on the RPQ. Recommendations for interpreting the strength of a correlation between two constructs suggest the following: r = 0 – 0.19 a very weak correlation, r = 0.20 – 0.39 weak correlation, r = 0.40 – 0.59 moderate correlation, r = 0.60 – 0.79 strong correlation and r = 0.80 – 1 very strong correlation (27).

Physical activity: Rapid Assessment of Physical Activity (RAPA)

The Rapid Assessment of Physical Activity (RAPA) was administered at baseline to assess participants' physical activity levels. The RAPA is a questionnaire comprising nine items which asks persons to answer yes or no to questions about their performance of varying degrees of physical activity such as light, moderate or vigorous activity (59) (Appendix B). The RAPA provides both written and pictorial examples of what constitutes light, moderate and vigorous activity (59). This questionnaire also assesses strength training and flexibility (59). During administration of the RAPA, individuals are read 7 statements in ascending order of amount and intensity of physical activity; individuals then respond yes or no to each statement depending on whether the statement accurately describes them or not (59). The RAPA is scored by choosing the highest statement (out of 7) with a 'yes' response; individuals receive one of seven possible scores: 1 = sedentary, 2 = underactive, 3 = underactive regular (light activities), 4 = underactive regular (moderate activities), 5 = underactive regular (vigorous activities), 6 = active (moderate activities) and 7 = active (vigorous activities) (59). The last two items on the RAPA assess strength and flexibility and are scored separately: 1 = strength training, 2 = flexibility training and 3 = both strength and flexibility training (59). The sensitivity and specificity of the RAPA are 81% and 69% respectively (7).

Procedures: Timeline of assessments

Participants were tested at four time points. At time 1 (T1) (baseline) the Risk Perception Questionnaire (RPQ) was administered to all participants to determine their baseline perceived risk of falling. The Rapid Assessment of Physical Activity (RAPA) and the Falls Efficacy Scale-International (FES-I) were also administered at T1 to assess participants' baseline physical activity levels and fear of falling respectively. At time 2 (T2), approximately two days later, the RPQ was administered again to assess its test-retest reliability. The RPQ was also administered at time 3 (approximately 6 weeks later) and time 4 (approximately 2 days after T3) to determine its test-retest reliability when administered by phone (Figure 1).

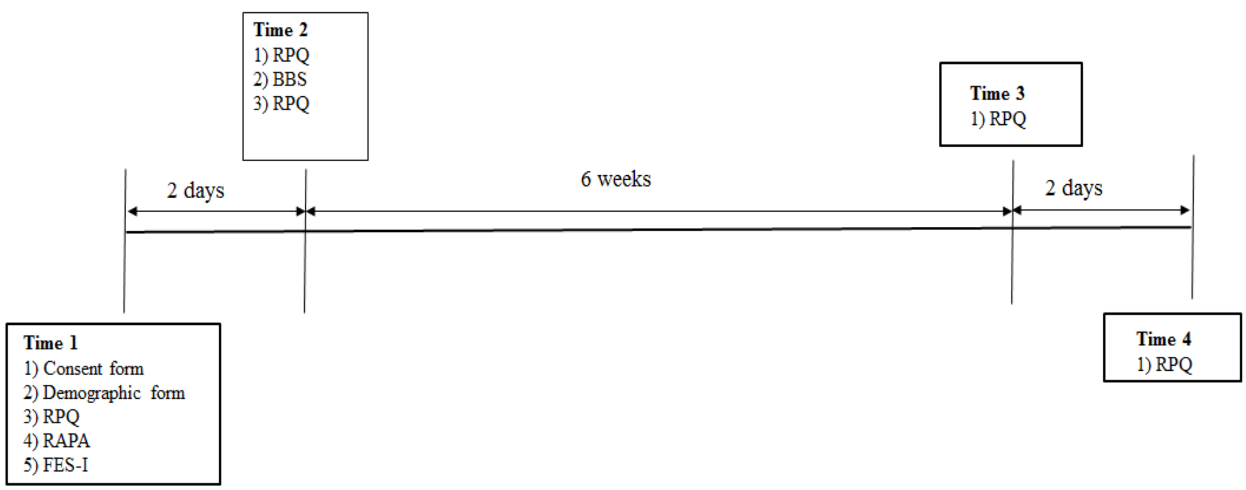

Figure 1: Timeline of assessments

Statistical Analyses

All statistical analyses were performed in STATA version 13 for Windows (52). Descriptive statistics were performed for demographic variables. Means and standard deviations were calculated for normally distributed data while medians and interquartile ranges (IQR) were calculated for data that were not normally distributed. Minimum and maximum values as well as frequencies were also calculated for the appropriate demographic variables. Test-retest reliability of the Risk Perception Questionnaire (RPQ) was determined by the intraclass correlation coefficient (ICC). Absolute reliability of the RPQ was measured by the standard error of measurement (SEM). The ICC and SEM were based on RPQ scores at Time 1 and Time 2. Inter-relatedness of items (internal consistency) on the RPQ was assessed by Cronbach's alpha. This analysis was also based on RPQ scores at Time 1 and Time 2. Baseline (Time 1) RPQ scores were used to perform an exploratory factor analysis to determine how well each of the items on the RPQ fit the predefined subscales. Finally, convergent construct validity between the RPQ and the Falls Efficacy Scale International (FES-I) was determined by Pearson's Correlation Coefficient using baseline RPQ and FES-I scores. The level of significance for all statistical tests was set at $P < 0.05$.

Results

The COSMIN reporting guidelines were used for this study (48).

Participant characteristics

A total of 30 community dwelling older adults with type 2 diabetes mellitus (DM2) were included in this study, 12 participants were male (40%) while 18 participants (60%) were female (Table 1). The mean age was 68.62 (6.90) years, mean duration of type 2 diabetes mellitus was

13.16 (8.15) years and the median number of falls in the last 12 months was 1 (Table 1). On average, participants reported a high fear of falling, median FES-I score 25 (Table 1). Twenty participants (66.67%) reported sensory changes which manifested as nerve pain in their fingers and toes (Table 1). Six participants (20%) reported having diabetic peripheral neuropathy, 1 participant (3.33%) reported having diabetic retinopathy, 2 participants (6.67%) reported diabetic foot ulcers and no participants reported autonomic neuropathy (Table 1).

Table 1: Demographic characteristics of participants

Variable	**All participants (N = 30)**
Age, Mean (SD)	68.6 (6.9)
Gender, n (%)	
Female	18 (60.0%)
Duration of diabetes in years, Mean (SD)	13.2 (8.2)
Falls Efficacy Scale – International score (median), IQR	25 (22 - 37)
Falls in the past year n, (%)	
0	14 (46.7%)
1	5 (16.7%)
2	7 (23.3%)
3 or more	4 (13.3%)
Nerve pain in the extremities, n (%)	20 (66.7%)
Diabetes related complications n (%)	
Diabetic peripheral neuropathy	6 (20.0%)
Diabetic retinopathy	1 (3.3%)
Autonomic neuropathy	0 (0.0%)
Diabetic foot ulcers, n (%)	2 (6.7%)

*IQR stands for interquartile range

The most commonly reported comorbid conditions were hypertension (70%), arthritis (43.33%) and high cholesterol (33.33%) (Table 2). Other less common comorbid conditions reported were: stroke, cardiac bypass, asthma, glaucoma and depression (Table 2). On average, participants had 2.27 comorbid conditions.

Table 2: Comorbid conditions

Comorbid condition	**Frequency (%)**
Hypertension	21 (70.0%)
Arthritis	13 (43.3%)
High Cholesterol	10 (33.3%)
Plantar Fasciitis	1 (3.3%)
Blood disorder	1 (3.3%)
Vascular disease	1 (3.3%)
Asthma	2 (6.7%)
Anaemia	1 (3.3%)
Stroke	1 (3.3%)
Glaucoma	1 (3.3%)
Cardiac bypass	3 (10.0%)
Heart attack	1 (3.3%)
Aneurysm	1 (3.3%)
Heart disease	1 (3.3%)
Osteoporosis	1 (3.3%)
Damaged spine	1 (3.3%)
Detached ribs	1 (3.3%)
Skull fracture	1 (3.3%)

Concussion	1 (3.3%)
Vertigo	1 (3.3%)
COPD	1 (3.3%)
Sleep apnea	1 (3.3%)
Depression	1 (3.3%)
Hypothyroidism	1 (3.3%)

Scores from the Rapid Assessment of Physical Activity (RAPA) indicated that the majority of participants were under active (60%) while 40% of participants were active (Table 3A). It is possible that the individuals who were underactive were restricting their activity due to fear of falling. However, in our sample the correlation between fear of falling and physical activity was not significant possibly due to our small sample size ($r = -0.28$, $p = 0.14$).

Table 3A: Physical activity levels based on the scores from the Rapid Assessment of Physical Activity (RAPA)

Physical activity level	**Frequency (%)**
Sedentary	0 (0.0%)
Under-active	2 (6.7%)
Under-active regular (light activities)	5 (16.7%)
Under-active regular (moderate activities)	10 (33.3%)
Under-active regular (vigorous activities)	1 (3.3%)
Active (moderate activities)	10 (33.3%)
Active (vigorous activities)	2 (6.7%)

Table 3B: Strength and flexibility obtained from the Rapid Assessment of Physical Activity (RAPA).

Rapa score	Strength/flexibility training	Frequency (%)
0	No strength/flexibility training	5 (16.7%)
1	Strength training only	7 (23.3%)
2	Flexibility training only	7(23.3%)
3	Strength and flexibility training	11 (36.7%)

Missing data

There are several types of missing data, namely: missing completely at random (MCAR), missing at random (MAR) and non-ignorable responses (49). MCAR refers to missing data that does not depend on the dependent variable, the covariates or the study design (49). MAR is also known as ignorable non-response occurs when the probability of the missing response depends only on the independent variables and not on the dependent variables (49). Lastly, non-ignorable response occurs when the probability of the missing response depends on the value of the response (the dependent variable) (49). Little's MCAR test showed that our data were missing completely at random (χ^2= 0.00, DF= 140, p= 1.00). The amount of missing data differed at each time point. At time 1 and time 2 there was no missing data (Table 4). At time 3 there was 10% missing data and at time 4 there was 23.33% missing data (Table 4). Overall, across all time points, there was 8.33% missing data. For time points with missing data, only participants with complete data were included in the analyses. One negative consequence of missing data is that it reduces statistical power (60).

Table 4: Number of participants with missing data at each time point

Time 1	**Time 2**	**Time 3**	**Time 4**
0 (0.0%)	0 (0.0%)	3 (10.0%)	7 (23.3%)

Table 5: Risk Perception Questionnaire scores

	Time 1 (n= 30)	**Time 2** (n= 30)	**Time 3** (n= 27)	**Time 4** (n=23)
RPQ scores, mean (SD)	78.9 (15.2)	78.7 (14.7)	79.8 (14.8)	82.0 (16.9)

Test-retest reliability

For test-retest reliability of the RPQ, a two way random effects model was used to calculate the intraclass correlation coefficient (ICC 2, 1) (45). We chose a two way random effects model because it assumes that random error comes from both the raters and the participants (45). Test-retest reliability of the RPQ was determined for two methods of administration: in person and by phone.

In person administration

The ICC (95% CI) for the RPQ was ICC= 0.78 (0.59 – 0.89), $p < 0.0001$ for older community-dwelling adults with type 2 diabetes mellitus (DM2). The standard error of measurement (SEM) of the RPQ was 7.06. The distribution of difference scores between test and retest were consistent with a normal distribution (Table 6).

Phone administration

The intraclass correlation coefficient (95% CI) of the RPQ was ICC = 0.82 (0.62 – 0.92), p< 0.0001 for community-dwelling older adults with DM2. The standard error of measurement (SEM) of the RPQ was 6.46. The distribution of difference scores between test and retest were consistent with a normal distribution. There was 23.33% missing data in this analysis, cases (participants) with missing data were excluded. Seven participants were excluded from this analysis due to missing data, therefore, 23 participants were used to calculate the ICC and SEM (Table 6).

Table 6: Test-retest reliability of the Risk Perception Questionnaire (RPQ)

Outcome measure	**In person administration** (n= 30)		**Phone adminstration** (n= 23)	
	ICC (95% CI)	**SEM**	**ICC (95% CI)**	**SEM**
RPQ	0.78 (0.59 – 0.89)	7.06	0.82 (0.62 -0.92)	6.46

*ICC stands for intraclass correlation coefficient, SEM stands for standard error of measurement, CI stands for confidence interval.

Bland-Altman results

In person administration

The mean difference in RPQ scores between time 1 and time 2 was 0.27 (-3.46, 4.0) which was not significantly different from zero (t = 0.15, p = 0.88). This indicates that on average, the RPQ produced the same scores at time 1 and time 2, thus indicating good agreement between RPQ scores at time 1 and time 2. The standard deviation of the difference was 9.9. The 95% limits of agreement were -19.31 to 19.85 (Figure 2).

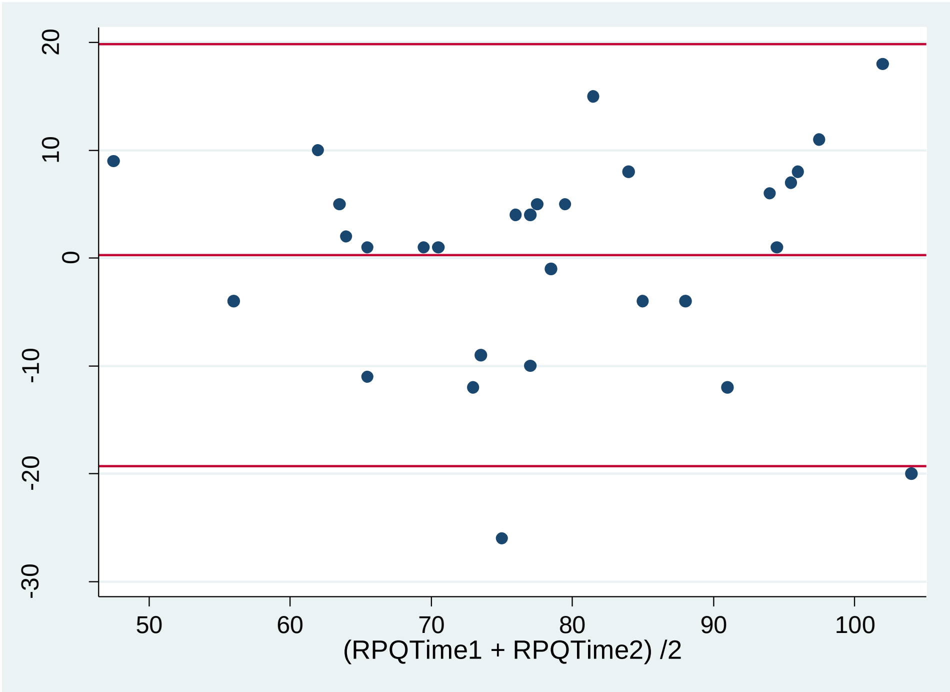

Figure 2. Bland-Altman plots for Risk Perception Questionnaire scores at time 1 and time 2. The middle line represents the mean difference between RPQ scores at time 1 and time 2. The lower and upper lines represent the upper and lower 95% confidence limits respectively.

Phone administration

The mean difference in RPQ scores between time 3 and time 4 was -3.65 (-7.60, 0.30); this mean difference was not significantly different from zero, $t = -1.92$, $p = 0.07$. This indicates that on average, the RPQ produced the same scores at time 3 and time 4, thus indicating good agreement between RPQ scores at time 3 and time 4. The standard deviation of the difference was 9.13. The 95% limits of agreement were -21.54 to 14.24 (Figure 3).

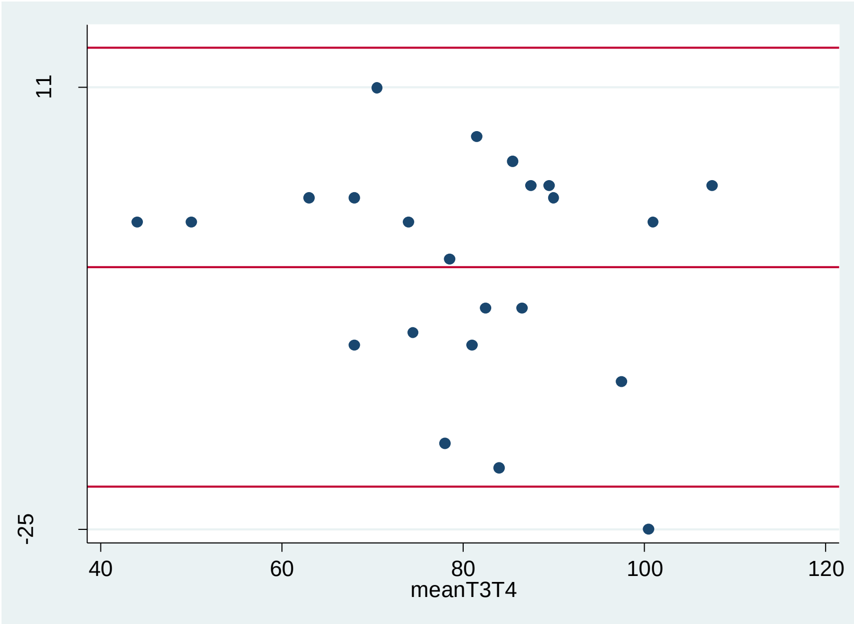

Figure 3. Bland-Altman plots for Risk Perception Questionnaire scores at time 3 and time 4. The middle line represents the mean difference between RPQ scores at time 3 and time 4. The lower and upper lines represent the upper and lower 95% confidence limits respectively.

It is possible that the mode of administration of the RPQ (in person vs. by phone) played a role in the differences in agreement observed. For example, when the RPQ was administered in person (time 1 and time 2), participants could see the RPQ items as well as the Likert scale while the assessor read the items aloud. The ability to both see and hear the items and Likert scale may have reduced the variability in RPQ scores resulting in good agreement between time 1 and time 2. On the other hand, when the RPQ was administered by phone (time 3 and time 4), participants could only hear but not see the RPQ items and Likert scale while the assessor read aloud. This may have produced greater variability in RPQ scores (compared with in person administration) which may have resulted in the lower agreement observed at time 3 and time 4.

Internal consistency

Internal consistency of the Risk Perception Questionnaire, assessed by Cronbach's alpha. We assessed the internal consistency of the questionnaire as a whole as well as the internal consistency of each subscale. The internal consistency of the entire questionnaire was good (15), alpha= 0.78 (Table 7). The self-efficacy subscale had the highest internal consistency, alpha= 0.79 followed by the internal/external factors subscale, alpha= 0.64 (Table 7). The individual perceptions subscale and the risk factors subscale had the lowest internal consistencies, alpha= 0.60 and alpha= 0.63 respectively (Table 7).

Table 7: Internal consistency of the Risk Perception Questionnaire

	Entire questionnaire	**Risk factors subscale**	**Internal/external subscale**	**Individual perceptions subscale**	**Self-efficacy subscale**
Cronbach's alpha	0.78	0.63	0.64	0.60	0.79

Construct validity

Construct validity of the Risk Perception Questionnaire (RPQ) was assessed by determining its correlation with the Falls Efficacy Scale International (FES-I) using Pearson's correlation coefficient. RPQ total scores were normally distributed while FES-I total scores were positively skewed. Therefore, we performed a logarithmic transformation to the FES-I scores before Pearson's correlation coefficient was calculated. There was a moderate correlation between the RPQ and the FES-I, $r = 0.52$ (0.20 – 0.74), $p = 0.003$. We therefore conclude that the RPQ has good construct validity.

Exploratory factor analysis

Data obtained from the Risk Perception Questionnaire (RPQ) was subjected to exploratory factor analysis (EFA) using the principal factors method and oblique Promax rotation. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was 0.35. Datasets with KMO > 0.50 are considered acceptable for EFA (58). Although our KMO < 0.50 we conducted the EFA as a pilot. Further EFA should be done with a larger sample size to confirm the factor structure of the RPQ. Bartlett's test of sphericity showed that there were patterened relationships between items on the RPQ that can be explored using EFA, χ^2 (190) = 290.11, p< 0.001. Using the recommended eigenvalue cut-off of 1.0 (58), 5 factors were retained. Together, these 5 factors explained 77.55% of the variance in the data. A scree plot of the eigenvalues confirmed the 5 factor structure (Figure 4). Figure 5 shows the factor loadings after rotation, factor loadings > 0.30 were considered significant. The 5 factors were named as follows: 1) self-efficacy, 2) effect of information/ education on risk for falling, 3) attitudes and beliefs about falling in relation to aging, 4) risk factors and 5) importance of fall prevention. These 5 factors were similar to the 5 subscales of the RPQ; namely: risk perception of falling, risk factors, internal/ external factors, individual perceptions and self-efficacy.

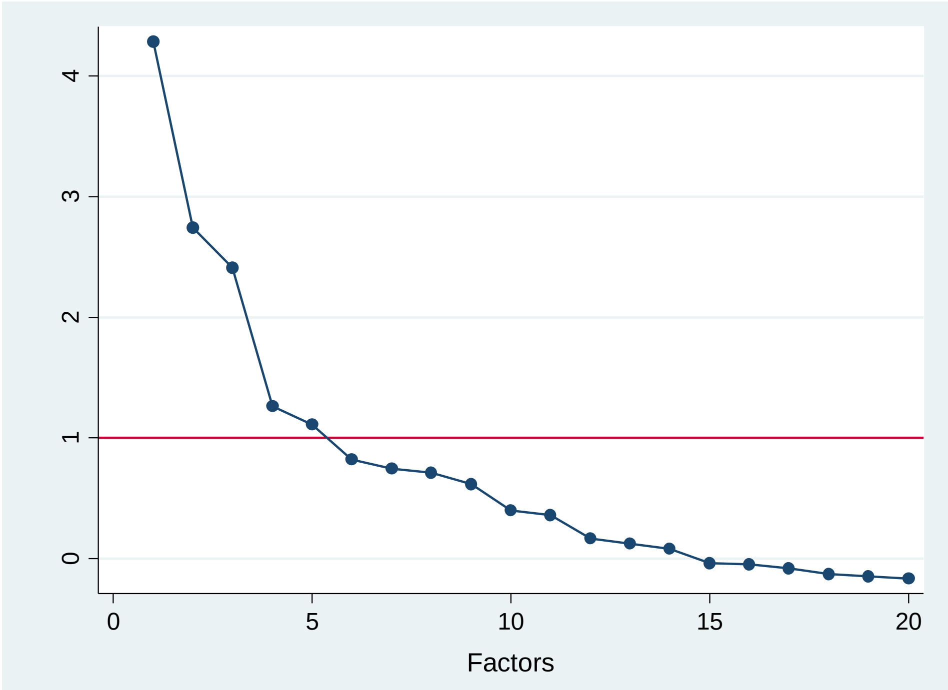

Figure 4. Scree plot of eigenvalues for each factor. The line drawn at y = 1, represents the cut-off point, only factors with eigenvalues above this line were retained.

RPQ items	Factor1	Factor2	Factor3	Factor4	Factor5	Uniqueness
Item 1	0.9029					0.1752
Item 2	0.5648					0.3552
Item 3				0.3760	0.5899	0.2323
Item 4				0.8081		0.2199
Item 5				0.6575		0.4010
Item 6					-0.4025	0.7527
Item 7		0.6349				0.4993
Item 8		0.8479				0.2412
Item 9		0.7085				0.3603
Item 10			0.3581	-0.3903		0.6160
Item 11			0.6344			0.4350
Item 12a			0.7796			0.3489
Item 12b	0.4761	0.5491				0.4611
Item 13	0.4769	-0.3764				0.5357
Item 14					0.7112	0.2984
Item 15			0.5272			0.6834
Item 16					0.6519	0.5159
Item 17	0.6555		-0.3435			0.4475
Item 18	0.3521	-0.3518	-0.4680	0.3608		0.3059
Item 19	0.7610					0.3033

Figure 5: Factor loadings after rotation.

Discussion

The aim of this study was to determine the test-retest reliability, internal consistency and construct validity of a falls risk perception questionnaire in older community-dwelling adults with type 2 diabetes mellitus. The test-retest reliability of the Risk Perception Questionnaire (RPQ) was good (ICC = 0.78 (0.58 – 0.89)) when administered in person and by phone (ICC = 0.82 (0.62 – 0.92)). The internal consistency of the RPQ was also good (Cronbach's alpha = 0.78). Exploratory factor analysis revealed the presence of 3 distinct factors namely: "movement, strength and fall-related self-efficacy," "education and knowledge dissemination," and "beliefs about internal and external risk factors for falls." Lastly, scores on the RPQ were moderately correlated with scores on the Falls Efficacy Scale International, r = 0.52 (0.20 – 0.74), p = 0.003.

The test-retest reliability of the RPQ was substantial and almost perfect when administered in person and by phone respectively. This RPQ also had substantial test-retest reliability, ICC= 0.66 (0.30 – 0.85), in women, > 45 years, following a distal radius facture (46). The falls efficacy scale international (FES-I) has also been used to assess perceived risk of falling in older adults (53). In this population, the test-retest reliability of the FES-I has been almost perfect, ICC= 0.94 (53). Acceptable reliability differs depending on whether the assessment is used in research or clinical practice (54). A minimum ICC of 0.70 is considered acceptable for research purposes whereas a minimum ICC of 0.90 is considered acceptable for clinical decision making (54). The main reason for this difference is that clinical decisions based on research findings are usually drawn from the cumulative findings of multiple replicated studies rather than a single study (54). Overall, the RPQ has demonstrated good test-retest reliability in research settings thus far.

Based on the literature, acceptable values for internal consistency (Cronbach's alpha) range from 0.70 – 0.95 (15). However, caution should be exercised when interpreting alpha values because extremely high values (> 0.90) may indicate that the test has redundant items and therefore should be shortened (15). We therefore conclude that the internal consistency of the Risk Perception Questionnaire was good (Cronbach's alpha = 0.78). Other risk perception measures such as the FES-I have also shown good internal consistency in older adults, Cronbach's alpha= 0.97 (53). The 3 factors identified through exploratory factor analysis are consistent with many of the factors identified in the risk perception literature such as knowledge, internal and external factors and self-efficacy.

There was a moderate positive correlation between scores on the RPQ and scores on the FES-I, r= 0.52 (0.20 – 0.74), p = 0.003. The theoretical bases of perceived risk of falling and fear of falling are similar. For example, self-efficacy is considered an important component of both constructs (43). We conclude that the moderate correlation between perceived risk of falling and fear of falling demonstrates that both constructs measure shared components such as self-efficacy and are theoretically similar in nature. We also conclude that the RPQ has good construct validity.

Perceived risk of falling

It is important to examine perceived risk of falling because of its implications for fall prevention. In order for older adults to consider fall prevention strategies, they must first perceive that they are at risk for falling. A review of older adults' perceptions, beliefs and behaviours regarding fall prevention stated that some older adults do not believe that they are at risk for falling because they feel healthy and confident (57). This review also stated that some older adults believe they are at risk for falling but do not admit it publicly because they are afraid that other people will label them as old, incompetent or frail (57). Older adults also believe that external factors such as environmental hazards cause more falls than internal factors such as dizziness or muscle weakness (57). Additionally, many older adults who have fallen in the past do not perceive that they are at risk for future falls because they attributed their fall to a temporary illness, a temporary lapse in attention or simply bad luck (57). There is some evidence that suggests that older adults' perceptions about falling can be changed which changes individuals' attitudes towards fall prevention. Hughes et al (2008) examined older adults' perceptions of risk for falling and the implications for fall prevention (56). Hughes et al. interviewed older adults from Australia (n= 3202) to assess perceived risk of falling; 1601 participants were recruited from a previous fall prevention program and 1601 were recruited for comparison (56). Individuals from the fall prevention program were less likely than individuals from the comparison group to agree with the statement "older people fall, and there is nothing that can be done about it," $\chi^2 = 17.1$, $p < 0.001$ (56). Additionally, individuals from the fall prevention program were more likely to rate fall prevention as a high or very high priority compared with individuals from the comparison group ($\chi^2 = 11.4$, $p < 0.01$) (56).

Perceived risk and behaviour

Falls risk assessment is an important part of clinical care for older adults. Balance (a measure of an individual's risk of falling) is assessed using standardized tests such as the Tinetti Balance and Gait Test, the Timed up and Go Test and the Berg Balance Scale (50). These tests determine whether individuals have any impairments in gait and balance that may predispose them to falling (50). These tests are also easy to administer as well as time and cost effective and have demonstrated excellent reliability and validity in various populations (50). Balance in older adults is well understood by both researchers and clinicians however, perceived risk of falling is not well understood (51). It is important to better understand and assess perceived risk of falling because it influences individuals' willingness to engage in fall prevention behaviours (51). A moderate level of perceived risk that is not too high or too low is considered optimal (51, 55). For example, if individuals' perceived risk is too low they will be less likely to engage in fall prevention behaviours (51). On the other hand, if individuals' perceived risk is too high, they may restrict participation in activities that promote muscle strength, balance, confidence and self-esteem, which not only increases their risk for future falls but also reduces their quality of life (55).

The risk perception literature suggests that perceived risk shapes health behaviour. For example, a meta-analysis of 34 studies which assessed the relationship between adult vaccination and perceived illness likelihood, perceived illness susceptibility and perceived illness severity demonstrated that individuals with higher perceived illness likelihood, susceptibility and severity were significantly more likely to get vaccinated (31). Additionally, a survey of 178 women, ≥ 50 years, examined predictors of Coronary Heart Disease (CHD) preventive behaviours using an adapted form of the Health Belief Model (HBM) (32). The HBM predictors examined were perceived susceptibility of CHD, perceived severity of CHD, general health motivation, social support and knowledge of CHD risk factors (32). In this study, perceived susceptibility, perceived severity, general health motivation and knowledge of risk factors accounted for 76% of the variance in CHD preventive behaviours (e.g. low fat and low cholesterol diets, adequate physical activity and limiting alcohol consumption) (32). There were also positive moderate to higher correlations between the CHD predictors and the CHD preventive behaviours ($r = 0.44 – 0.84$) (32). Although there seems to be a positive relationship between risk perception and health behaviour, this relationship is quite complex and involves many mediating factors. According to the Health Action Process Approach (HAPA), risk perception itself is not sufficient for the formation of behavioural intentions, rather it jump starts the contemplation and elaboration of thoughts, consequences and competencies needed to initiate behaviour change (33). Perceived self-efficacy is another factor that mediates the relationship between perceived risk and health behaviour. For example, Rimal (2001) measured perceived risk of Cardiovascular Diseases (CVDs) by asking participants to rate, on a 7 point scale, their likelihood of acquiring CVDs and CVD-related self-efficacy by asking participants to rate, on a 9 point scale, their confidence in their ability to engage in CVD-prevention behaviours such as exercising regularly and consuming a healthy diet (42). Rimal (2001) identified four distinct groups of individuals: responsive, proactive, avoidant and indifferent (42). Responsive individuals: high perceived risk + high self-efficacy, proactive individuals: low perceived risk + high self-efficacy, avoidant individuals: high perceived risk + low self-efficacy and indifferent individuals: low perceived risk + low self-efficacy (42). Rimal (2001) also found that individuals classified as responsive or proactive were significantly more likely to think about and use CVD-related information than individuals classified as avoidant or indifferent (42).

Limitations

This study had several limitations. In order to increase the generalizability of our results, we intended to recruit equal numbers of older adults from different age cohorts however, this was not achieved. For example, the majority of our participants were 66 – 75 years (50%), while only 36.67% of participants were 55 – 65 years, 10% of participants were 76 – 85 years and no participants were 86 – 95 years. Therefore, our results may be more applicable to the two younger cohorts and less applicable to the two older cohorts. Secondly, our sample size of 30 participants is relatively small and therefore further psychometric testing of this questionnaire should be done using larger samples. Lastly, the missing data is also a limitation of this study. Missing data presents several challenges including: a reduction in the power of the statistical tests, introduction of potential bias in parameter estimation and reduction in the representativeness of the study sample (47).

Conclusion

This is the first time that perceived risk of falling has been measured in older adults with type 2 diabetes mellitus. Physical function of older adults with an increased risk for falling due to chronic conditions such as type 2 diabetes mellitus should be closely monitored. Measures of balance such as the Berg Balance Scale are widely used by clinicians to assess their patients' physical function. However, clinicians should also measure individuals' perceived risk of falling because perceived risk determines whether or not individuals will be motivated to engage in fall prevention behaviours. This Risk Perception Questionnaire has demonstrated good test-retest reliability, internal consistency and construct validity in older adults with type 2 diabetes mellitus. Further testing is required to determine whether the RPQ can be used with confidence in clinical settings.

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Appendix A

Sample size calculation

Parameters:

- Type I error = 0.05
- Type II error = 0.20
- k = 2
- hypothesized ICC = 0.80

$$n = \frac{0.5\ k\ (Z\alpha + Z\beta)^\wedge 2}{\sigma 2\ (k-1)} + 2$$

$Z\alpha = 1.645$

$Z\beta = 0.842$

$R_{expected} = 0.80$

$Z_{Rexpected} = 0.5$ natural log $\frac{1+(k-1)Rexpected}{1-Rexpected}$

$Z_{Rexpected} = 1.0986$

$R_{lowerlimit} = 0.80 – 0.10 = 0.70$

$Z_{Rnull} = 0.5$ natural log $\frac{1+(2-1)0.70}{1-0.70}$

$Z_{Rnull} = 0.867$

$\sigma^2 = Z_{Rexpected} - Z_{Rnull}$

$\sigma^2 = 0.2316$

$$n = \frac{0.5\ k\ (Z\alpha + Z\beta)^2}{\sigma 2\ (k-1)} + 2$$

n = 28.706

Sample size = 29 participants round to 30 participants

Appendix B

Risk Perception Questionnaire

McMaster
University

Risk Perception Questionnaire

Please respond to the following questions to the best of your ability. Please indicate your response to each question by circling the most appropriate number on the scale that follows each question.

Risk-perception of falling

1. I feel that I am at risk for having a fall

1 2 3 4 5 6 7
strongly disagree strongly agree

Risk factors

Please rate if you feel that the following factors may increase your risk for falling.

2. A fall in the past year

1 2 3 4 5 6 7
strongly disagree strongly agree

Please rate if you feel that the following factor may increase your risk for falling.

3. Weakness in your legs

1 2 3 4 5 6 7
strongly disagree strongly agree

Please rate if you feel that the following factor may increase your risk for falling.

4. Difficulty moving around the house or community

1 2 3 4 5 6 7
strongly disagree strongly agree

Please rate if you feel that the following factor may increase your risk for falling.

5. Using a cane or a walker

1 2 3 4 5 6 7
strongly disagree strongly agree

Please rate if you feel that the following factor may increase your risk for falling.

6. Being physically active (*beyond* your regular daily activity) twice a week or more

1 2 3 4 5 6 7
strongly disagree strongly agree

Internal/external factors

I believe that my risk of falling is influenced by:

7. Information given to me by my friends and family

1 2 3 4 5 6 7
strongly disagree strongly agree

I believe that my risk of falling is influenced by:

8. Information given to me by the media (i.e. TV, radio, newspaper, etc.)

1 2 3 4 5 6 7
strongly disagree strongly agree

I believe that my risk of falling is influenced by:

9. Information given to me by my doctor, physiotherapist or health care worker

1 2 3 4 5 6 7
strongly disagree strongly agree

I believe that my risk of falling is influenced by:

10. My cultural and religious beliefs

1 2 3 4 5 6 7
strongly disagree strongly agree

---

11. I feel that getting older increases my risk of falling

1 2 3 4 5 6 7
strongly disagree strongly agree

Individual perceptions

12. a. I feel that people my age are more likely to fall than people who are younger

1 2 3 4 5 6 7
strongly disagree strongly agree

b. I am less likely to fall when compared to other people my age

1 2 3 4 5 6 7
strongly disagree strongly agree

13. I feel that I am able to protect myself from falling

1 2 3 4 5 6 7
strongly disagree strongly agree

14. If I had a fall, it would result in serious consequences

1 2 3 4 5 6 7
strongly disagree strongly agree

15. My attitude about aging influences my risk of falling

1 2 3 4 5 6 7
strongly disagree strongly agree

16. Avoiding a fall is just as important as my other health concerns

1 2 3 4 5 6 7
strongly disagree strongly agree

Self-efficacy

17. I feel confident that I can maintain my balance when I walk outside in the community

1 2 3 4 5 6 7
strongly disagree strongly agree

18. I feel confident that I will not fall when walking outside in poor weather

1 2 3 4 5 6 7
strongly disagree strongly agree

19. I feel confident that I will not fall when moving around in my house

1 2 3 4 5 6 7
strongly disagree strongly agree

Falls-Efficacy Scale- International

SUPPLEMENTARY DATA

Translators'/Interviewers' notes for FES-I

The text of the FES-I below is the final version agreed by the authors on completion of the development study, prior to subsequent translation and validation in different languages. It became clear during the process of translation that there was no wording of the questionnaire that would translate easily into every EC language using exactly the same words and phrases. Consequently, these notes are intended to assist translators of the FES-I to express the same *meaning* of items, even if they cannot use quite the same words in their language. They may also assist interviewers who are asked for clarification of the meaning of items when the FES-I is administered by interview.

Instructions
Participants should answer items thinking about how they usually do the activity – for example, if they usually walk with an aid they should answer items about walking to show how concerned they would be about falling when using that aid. Some translators may find it helpful to clarify in the instructions (after the sentence on circling an opinion) 'The opinions you can choose from are: 1 = not at all concerned 2 = somewhat concerned 3 = fairly concerned 4 = very concerned.' In some languages it is better to translate the word 'opinion' as 'statement'.

Response categories
The word 'concerned' expresses a cognitive or rational disquiet about the possibility of falling, but does not express the emotional distress that would be expressed by terms such as 'worried', 'anxious' or 'fearful'. It is important to use a similar unemotional term, as respondents may be less willing to admit to emotions, which might be viewed as signs of weakness.

Item 3. In some EC languages 'simple' meals are best translated as 'everyday' meals, but the intention is to refer to a meal that does not require complex preparation, rather than one that is prepared every day.

Item 5. This item is intended to refer to shopping that is not extensive or recreational. In some languages the best translation is 'shopping for groceries'.

Item 7. This item refers to *any* stairs, not necessarily the flight of stairs in one's own house.

Item 8. In some languages 'neighbourhood' may be difficult to translate, and so 'walking around outside' can be used instead.

Item 12. In some languages it is necessary to add the term 'acquaintances' to friends and relatives, since this is a more common and casual category of relationship than friends. (see also comment on items 12, 13 and 16 below)

Item 13. 'Crowds' can be translated as 'many people' if necessary. (see also comment on items 12,13 and 16 below)

Item 14. It was found to be necessary to give examples of what is meant by uneven ground, but no examples could be found that were appropriate for all countries. Consequently, translators should choose any TWO examples from the following: cobblestones; poorly maintained pavement; rocky ground; unpaved surface.

Items 12, 13, 16. These items contain a greater element of ambiguity than many of the items assessing functional capabilities, because the physical activities involved in these social events may differ greatly for different respondents. However, it was decided that this ambiguity was acceptable because it is important to assess effects of fear of falling on social activities.

Now we would like to ask some questions about how concerned you are about the possibility of falling. For each of the following activities, please circle the opinion closest to your own to show how concerned you are that you might fall if you did this activity. Please reply thinking about how you usually do the activity. If you currently don't do the activity (e.g. if someone does your shopping for you), please answer to show whether you think you would be concerned about falling IF you did the activity.

		Not at all concerned 1	*Somewhat concerned 2*	*Fairly concerned 3*	*Very concerned 4*
1	Cleaning the house (e.g. sweep, vacuum or dust)	*1*	*2*	*3*	*4*
2	Getting dressed or undressed	*1*	*2*	*3*	*4*
3	Preparing simple meals	*1*	*2*	*3*	*4*
4	Taking a bath or shower	*1*	*2*	*3*	*4*
5	Going to the shop	*1*	*2*	*3*	*4*
6	Getting in or out of a chair	*1*	*2*	*3*	*4*
7	Going up or down stairs	*1*	*2*	*3*	*4*
8	Walking around in the neighbourhood	*1*	*2*	*3*	*4*

9	Reaching for something above your head or on the ground	*1*	*2*	*3*	*4*
10	Going to answer the telephone before it stops ringing	*1*	*2*	*3*	*4*
11	Walking on a slippery surface (e.g. wet or icy)	*1*	*2*	*3*	*4*
12	Visiting a friend or relative	*1*	*2*	*3*	*4*
13	Walking in a place with crowds	*1*	*2*	*3*	*4*
14	Walking on an uneven surface (e.g. rocky ground, poorly maintained pavement)	*1*	*2*	*3*	*4*
15	Walking up or down a slope	*1*	*2*	*3*	*4*
16	Going out to a social event (e.g. religious service, family gathering or club meeting)	*1*	*2*	*3*	*4*

Rapid Assessment of Physical Activity (RAPA)

How Physically Active Are You?

An assessment of level and intensity of physical activity

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http://depts.washington.edu/hprc/rapa

Rapid Assessment of Physical Activity

Physical Activities are activities where you move and increase your heart rate above its resting rate, whether you do them for pleasure, work, or transportation.

The following questions ask about the amount and intensity of physical activity you usually do. The intensity of the activity is related to the amount of energy you use to do these activities.

Examples of physical activity intensity levels:

Light activities • your heart beats slightly faster than normal • you can talk and sing	 Walking Leisurely  Stretching  Vacuuming or Light Yard Work
Moderate activities • your heart beats faster than normal • you can talk but not sing	 Fast Walking  Aerobics Class  Strength Training  Swimming Gently
Vigorous activities • your heart rate increases a lot • you can't talk or your talking is broken up by large breaths	 Stair Machine  Jogging or Running  Tennis, Racquetball, Pickleball or Badminton

How physically active are you? *(Check one answer on each line)*

			Does this accurately describe you?	
			Yes	No
RAPA 1	1	I rarely or never do any physical activities.	☐	☐
	2	I do some **light** or **moderate** physical activities, but not every week.	☐	☐
	3	I do some **light** physical activity every week.	☐	☐
	4	I do **moderate** physical activities every week, but less than 30 minutes a day or 5 days a week.	☐	☐
	5	I do **vigorous** physical activities every week, but less than 20 minutes a day or 3 days a week.	☐	☐
	6	I do 30 minutes or more a day of **moderate** physical activities, 5 or more days a week.	☐	☐
	7	I do 20 minutes or more a day of **vigorous** physical activities, 3 or more days a week.	☐	☐
RAPA 2 (3 = Both 1 & 2)	1	I do activities to increase muscle **strength**, such as lifting weights or calisthenics, once a week or more.	☐	☐
	2	I do activities to improve **flexibility**, such as stretching or yoga, once a week or more.	☐	☐

Scoring Instructions

RAPA 1: Aerobic

To score, choose the question with the highest score with an affirmative response. Any number less than 6 is suboptimal.

For scoring or summarizing categorically:

Score as sedentary:

1. I rarely or never do any physical activities.

Score as under-active:

2. I do some light or moderate physical activities, but not every week.

Score as under-active regular – light activities:

3. I do some light physical activity every week.

Score as under-active regular:

4. I do moderate physical activities every week, but less than 30 minutes a day or 5 days a week.
5. I do vigorous physical activities every week, but less than 20 minutes a day or 3 days a week.

Score as active:

6. I do 30 minutes or more a day of moderate physical activities, 5 or more days a week.
7. I do 20 minutes or more a day of vigorous physical activities, 3 or more days a week.

RAPA 2: Strength & Flexibility

I do activities to increase muscle strength, such as lifting weights or calisthenics, once a week or more. (1)

I do activities to improve flexibility, such as stretching or yoga, once a week or more. (2)

Both. (3)

None (0)

Chapter 4: Classification of risk for falling in older adults with type 2 diabetes mellitus using perceived risk (self-report) and balance (performance-based test).

Abstract

Purpose: To determine: (1) whether individuals' ratings of their risk for falling (perceived risk) are correlated with their balance, (2) whether individuals' perceived risk of falling is influenced by receiving feedback about their balance and 3) whether perceived risk of falling can be explained by specific personal characteristics.

Methods: A prospective cohort of n=30 community-dwelling older adults, ≥ 55 years, with type 2 diabetes mellitus was assembled and data was collected about the duration of diabetes, diabetes-related complications and falls in the past year as well as perceived risk of falling, physical activity and fear of falling. At baseline demographic data such as age, gender, duration of diabetes, history of falling and presence of comorbid conditions was collected and the following assessments were administered : perceived risk of falling using a Risk Perception Questionnaire (RPQ), fear of falling using the Falls Efficacy Scale – International (FES-I) and physical activity using the Rapid Assessment of Physical Activity (RAPA). At time 2, approximately 2 days later, the Berg Balance Scale (BBS) was administered to determine participants' balance. Individuals were then given feedback about their balance. Participants were reassessed using the RPQ immediately after feedback and at 6 week follow up to determine whether they altered their perceived risk of falling after receiving feedback about their balance.

Results: There was a significant positive correlation between perceived risk of falling and fear of falling ($r = 0.52$, $p = 0.003$). Fear of falling explained 27.4% of the variation in perceived risk of falling. Sixteen participants (53.3%) displayed concordance between the hypothetical tense

(RPQ) and the experimental tense (BBS) whereas 21 participants (70.0%) displayed concordance between the hypothetical tense (RPQ) and the enacted tense (history of falling). There was a weak positive correlation between individuals' perceived risk of falling and balance, $r = 0.21$, $p = 0.27$. The change in perceived risk of falling was very small after individuals were given feedback about their balance, $t = 0.81$, $p = 0.42$ (immediately after feedback) and $t = 0.03$, $p = 0.98$ (6 weeks after feedback) was not statistically significant. Cohen's d effect sizes 0.15 and 0.005 and standardized response means 0.15 and 0.005 were also very small: immediately after feedback and at 6 week follow up respectively.

Conclusion: Risk perception is a complex concept consisting of many interacting factors. The weak correlation between perceived risk of falling and balance suggests that they are independent components of fall risk. Therefore, comprehensive fall risk assessment and prevention should include measures of perceived risk of falling and standardized performance-based tests.

1. Introduction

In 2008, approximately 2.4 million (6.8 %) Canadians had diabetes mellitus (DM) (1), 90% of these cases were type 2 diabetes mellitus (DM2) (2). It is projected that by 2018 the number of Canadians living with DM will rise to 3.7 million (1). In Canada, the highest rates of DM have been reported in Newfoundland and Labrador, Nova Scotia and Ontario (1). Risk factors for DM2 include: advancing age, ethnicity, physical inactivity, obesity and a family history of diabetes (1). Mortality rates among individuals with DM (type 1 & 2) are at least two times higher than those among individuals without DM (1). In 2010, health care expenditure due to DM was estimated at $12.2 billion, by 2020 this figure is projected to rise by $4.7 billion (7).

Type 2 diabetes mellitus (DM2) is associated with numerous complications such as diabetic peripheral neuropathy, diabetic retinopathy, autonomic neuropathy and diabetic foot ulcers which have all been linked to increased risk for falling (3). Diabetic peripheral neuropathy (DPN) causes reduced sensation in the lower extremities which results in impaired balance and increased risk for falling (4). More than 50 % of persons with diabetes ≥ 60 years have DPN, together with an associated fall risk that is a leading cause of mortality in this group ≥ 65years (5). Additionally, women with DM2 are 1.6 times more likely to have experienced a fall in the past year and are twice as likely to be injured when they fall compared to women without DM2 (6).

An individual's risk for falling is often assessed objectively using measures such as the Berg Balance Scale. The Berg Balance Scale (BBS) is a 14-item scale that quantitatively measures balance and fall risk in older community-dwelling adults (8). It has been recommended that 45 points should be used as the cut-off score for the BBS; individuals who score < 45 points are considered at risk for falling while individuals who score ≥ 45 points are not considered at risk for falling (9). With this cut-off score, the sensitivity is reported to be 64% and the specificity is 90% (9). In older community-dwelling adults, the BBS has demonstrated high inter-rater reliability, ICC = 0.88 – 0.98, high intra-rater reliability, ICC = 0.68 - 0.99 (36), moderate construct validity, r = -0.47 to -0.69, with the Timed up and Go Test (TUG) (36) and good internal consistency, Cronbach's $\alpha = 0.77$ (37).

Another important component of fall risk that is less frequently assessed is perceived fall risk. Perceived risk has been defined in various ways. A common theme among definitions is the idea that perceived risk is a multidimensional concept. One definition of perceived risk put forward by Satterfield et al. (2000) is a multidimensional concept that considers thoughts about the probability of disease and its potential consequences as well as judgments about the importance of the risk to the individual (10). Risk perception of various health outcomes has been conceptualized as consisting of several types of interacting factors which contribute to an individual's overall perceived risk. These factors include: external factors, individual/internal factors, self-efficacy in activities of daily living (ADLs) and instrumental activities of daily living (IADLs) as well as individual perceptions (11). External factors include health care practitioners, friends/family, media sources and level of education; individual factors include knowledge, age and gender (11). Individual perceptions include perceived severity and perceived control which is further divided into perceived susceptibility and exposure to risk (11). The last component of perceived risk is self-efficacy in ADLs and IADLs (11). A cross-sectional study of older adults, n= 387, ≥ 75 years, demonstrated that the strongest predictor of falls was low falls related self-efficacy in IADLs (34). Additionally, a prospective study of older adults, n= 528, revealed that older adults with low falls related self-efficacy had increased risk for falling, more difficulty performing ADLs and were at increased risk for admission to an aged care institution (35).

It is important to examine perceived risk of falling in addition to balance because these two different components of fall risk are often incongruent. Additionally, an individual's perceived risk influences how they react to the potential adverse health outcome; for instance, whether or not they engage in healthy behaviour change. One widely observed phenomenon is *risk denial* which refers to the fact that individuals often perceive their own risk (personal risk) as smaller than the risk of other people (general risk) (12). Risk denial has also been referred to as unrealistic optimism or optimistic bias (13). There are 3 types of risk denial: scapegoating, self-confidence and comparison between risks (13). *Scapegoating* occurs when individuals create a mental boundary between the stereotyped "them", people who engage in so called risky behaviour and "us", people who are cautious including themselves (13). "Them" is considered a deviant minority who are more likely to succumb to an unfavourable outcome due to their own risky behaviour (13). *Self-confidence* occurs when individuals distinguish themselves from "others" because they believe that their ability to avoid or control risky situations is superior to that of "others" (13). Finally, *comparison between risks* occurs when individuals compare a given risk to similar risks which are considered acceptable by most people (13). A major negative consequence of risk denial is failure to discontinue risky/unhealthy behaviours and/or failure to engage in behaviours that promote risk reduction (13). The phenomenon of risk denial begs the question: If individuals' perceived risk of negative health outcomes is often incongruent with their risk as measured by standardized outcome measures then, is it possible to change people's perceptions so that they become more congruent with standardized outcome measures or actual adverse health events such as falls? A prospective cohort study of n=732 men and women, 25 – 65 years, assessed individual's perceived and objective risk of heart attack or stroke; the findings of this study supported the risk denial phenomenon where the majority of participants perceived their risk of heart attack and stroke as lower than the average person (23). In this study, individuals were also given feedback based on their objective risk of heart attack and stroke; most participants did not change their perceived risk in response to this feedback (23). However, 21.8 % of individuals who were told that their risk of heart attack and stroke was higher than the average person increased their perceived risk after receiving feedback (23). This study provides evidence that objective feedback does have some effect on risk perception specifically for individuals who are told that their objective risk is high (23).

To date, no study has examined the relationship between perceived risk of falling and balance in older adults with type 2 diabetes mellitus and whether feedback about one's balance has any impact on one's perceived risk of falling.

Research Questions

1) Is there an association between perceived risk of falling as measured by the Risk Perception Questionnaire and balance as measured by the Berg Balance Scale in community-dwelling older adults with type 2 diabetes mellitus? 2) Can individuals' perceived risk of falling be explained by characteristics such as age, gender and fear of falling?

3) What is the optimal cut point for the Risk Perception Questionnaire determined by receiver operating characteristic curves?

4) What is the degree of concordance/ discordance between the 'tenses' of function i.e. the hypothetical and experimental tense as well as the hypothetical and enacted tense?

5) Do individuals alter their perceived risk of falling immediately after receiving feedback about their balance and at 6 week follow up?

2. Methods

2.1 Design

This is a prospective cohort study which followed 30 participants over 6 weeks.

2.2 Eligibility criteria

The eligibility criteria for this study were as follows:

1) A self-reported diagnosis of type 2 diabetes mellitus.

2) For this study we included people ≥55 years because persons with diabetes are at increased risk for falling and therefore would benefit from interventions aimed at prevention

3) Persons were living independently in the community

4) Persons were able to follow verbal instructions in English

5) Persons were able to provide written informed consent.

2.3 Participants

Convenience sampling was used to recruit participants. The sample size determined in chapter 3 was used as a pilot for this chapter. Participants were recruited from various exercise programs located at hospitals across Hamilton, Ontario (n= 14). In addition, participants were recruited through an advertisement in a local newspaper (n= 16).

2.4 Settings

Assessments were conducted at McMaster University and in two outpatient settings in Hamilton Ontario. Please refer to the timeline of assessments section (section 2.7) for information regarding: how, when and in what order assessments were administered.

2.5 Ethics

Ethics approval for this study was granted by the Hamilton Integrated Research Ethics Board (HIREB), REB: 15-346-S.

2.6 Procedures

Study Outcomes/ Assessments

Primary outcome: Perceived risk of falling

Perceived risk of falling was assessed using a Risk Perception Questionnaire (RPQ). The development of the RPQ has been described in detail elsewhere (Chapter 3); but in brief, the RPQ consists of 20 items and was formulated using a conceptual model which views an individual's risk perception as the combination of interacting factors namely: external factors, individual factors, self- efficacy in activities of daily living (ADLs) and instrumental activities of daily living (IADLs) and finally individual perceptions (11) (Please refer to the introduction of chapter 3 for a detailed description of each of these factors). The questionnaire is composed of 5 subscales: risk-perception of falling, risk factors, internal/external factors, individual perceptions and self-efficacy (11). Each item is rated on a 7-point Likert scale from strongly disagree to strongly agree (11). Individuals' scores from each of the 5 subscales are added to produce an overall score out of 140. Higher scores on the RPQ indicate higher perceived risk of falling. The

RPQ has demonstrated substantial test-retest reliability when administered in person (ICC = 0.78 (0.59 – 0.89)) and by phone (ICC = 0.82 (0.62 – 0.92)), good internal consistency (Cronbach's α = 0.78) and good construct validity with the Falls Efficacy Scale – International (r = 0.52, p = 0.003) in older adults with type 2 diabetes mellitus (Chapter 3).

Secondary outcome: Balance

Berg Balance Scale

Participants' balance was assessed using the Berg Balance Scale (BBS) which is a 14-item scale that quantitatively measures balance and risk for falling in older community-dwelling adults (8). Administration of the BBS by a trained assessor takes approximately 10 -20 minutes, during this time the individual's ability to maintain their balance either while stationary (static balance) or while moving (dynamic balance) is assessed (8). Each item on the BBS is scored from 0 – 4 with a score of 0 indicating inability to perform the task and a score of 4 indicating ability to perform the task independently (8). The maximum score that can be achieved on the BBS is 56 points (8). Individuals who score between 0 – 20 have impaired balance and are considered to be at high risk for falling, individuals who score between 21 – 40 have acceptable balance and are considered to be at medium risk for falling and individuals who score between 41 – 56 have good balance and are considered to be at low risk for falling (8).

Physical activity: Rapid assessment of physical activity (RAPA)

The Rapid Assessment of Physical Activity (RAPA) was administered at baseline to assess participants' physical activity levels. The RAPA is a questionnaire comprising nine items which asks persons to answer yes or no to questions about their performance of varying degrees of physical activity such as light, moderate or vigorous activity (16). The RAPA provides both written and pictorial examples of what constitutes light, moderate and vigorous activity (16). This questionnaire also assesses strength training and flexibility (16). During administration of the RAPA, individuals are read 7 statements in ascending order of amount and intensity of physical activity; individuals then respond yes or no to each statement depending on whether the statement accurately describes them or not (16). The RAPA is scored by choosing the highest statement (out of 7) with a 'yes' response; individuals receive one of seven possible scores: 1 = sedentary, 2 = underactive, 3 = underactive regular (light activities), 4 = underactive regular (moderate activities), 5 = underactive regular (vigorous activities), 6 = active (moderate activities) and 7 = active (vigorous activities) (16). The last two items on the RAPA assess strength and flexibility and are scored separately: 1 = strength training, 2 = flexibility training and 3 = both strength and flexibility training (16). The sensitivity and specificity of the RAPA in older adults has been reported at 81% and 69% respectively when the Community Health Activities Model Program for Seniors (CHAMPS) was used as the gold standard (19).

Fear of falling: Falls efficacy scale- international (FES-I)

The falls efficacy scale- international (FES-I) was also administered at baseline. The FES-I is a 16 item tool used to assess fear of falling in older adults while performing physical and social activities (17). Fear of falling is assessed on a 4 point scale with 1 indicating not at all concerned about falling to 4 indicating very concerned about falling (17). Total scores range from 16 to 64, a cut point of 23 points has been used to differentiate between individuals with low and high concern about falling, individuals who score 16 – 22 are considered to have a low concern about falling whereas individuals who score 23 – 64 are considered to have a high concern about falling (18). With the suggested cut point, the sensitivity and specificity of the

FES-I are 90.9% and 47.2% respectively (18). The FES-I has demonstrated high test-retest reliability, ICC = 0.96, as well as high internal consistency, Cronbach's alpha = 0.96 (17).

2.7 Timeline of assessments

At time 1 the risk perception questionnaire (RPQ) was administered to all participants to determine their baseline perceived risk of falling. At time 1, the Rapid Assessment of Physical Activity (RAPA) and the Falls Efficacy Scale- International (FES-I) were also administered to assess participants' baseline physical activity levels and fear of falling respectively. At time 2 (approximately 2 days later), the Berg Balance Scale (BBS) was administered to determine participants' balance. Following administration of the BBS, participants were given feedback about their balance based on their BBS score. Participants were told what their total score on the BBS was and what that score meant in terms of their balance and risk for falling. Participants who scored < 45 points on the BBS were told that they had impaired balance and therefore were at risk for falling; participants who scored ≥ 45 points were told that they had good balance and therefore were not at risk for falling. Following feedback, the assessor reviewed the Otago home exercise programme with each participant irrespective of fall risk. Participants are then advised on how to perform the exercises safely based on their level of functioning (based on their BBS score) in order to achieve optimal muscle strengthening and balance training. The Otago home exercise programme consists of leg muscle strengthening exercises, balance retraining exercises and a walking plan and was designed specifically to prevent falls in older adults (20). The exercises take approximately 30 minutes to complete. It is recommended that individuals perform the exercises three times per week and walk at least twice per week (20). This exercise programme has demonstrated effectiveness in reducing falls and fall-related injuries in older adults. For example, in a randomized controlled trial of 233 women, ≥ 80 years, this exercise programme reduced the risk of falling and fall-related injuries by 32% and 39% respectively at one year follow up (21). Another randomized controlled trial of 240 older men and women, ≥ 75 years, demonstrated a 46% reduction in the number of falls for individuals who received the exercise programme compared to individuals who received usual care (22). Following this feedback, the risk perception questionnaire was administered to determine whether participants altered their perceived risk of falling after receiving feedback about their balance. At time 3, approximately 6 weeks later, the Risk Perception Questionnaire was administered by phone to determine participants' perceived risk of falling 6 weeks post baseline (Figure 1).

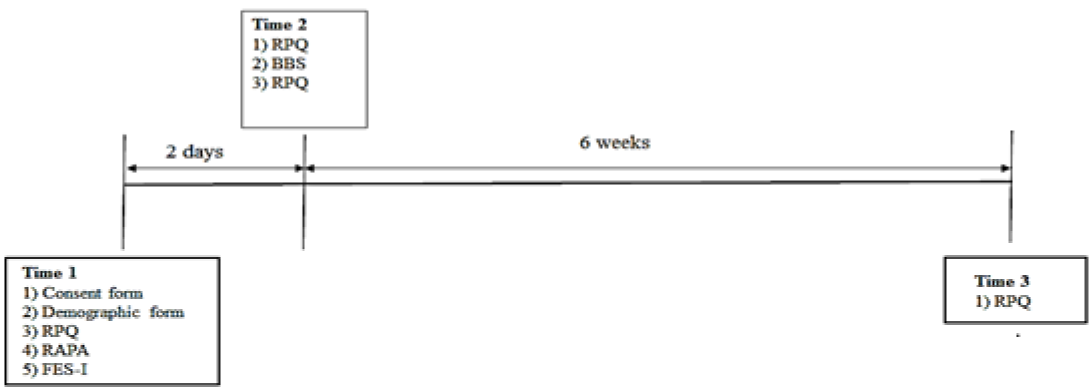

Figure 1: Timeline of assessments

2.8 Statistical Analyses

All statistical analyses were performed in STATA version 13 for Windows (38). Descriptive statistics were performed for demographic variables. Means and standard deviations were calculated for normally distributed data while medians were calculated for data that were not normally distributed. Minimum and maximum values as well as frequencies were also calculated for the appropriate demographic variables. The level of significance for each statistical test was set at $p < 0.05$. We summarized the statistical analyses performed to answer each research question below.

Research question 1

We examined the association between perceived risk of falling as measured by the Risk Perception Questionnaire (RPQ) and balance as measured by the Berg Balance Scale (BBS) in older community-dwelling adults with DM2 using Pearson's correlation coefficient.

Research question 2

Multiple linear regression was used to examine the relationship between perceived risk of falling as measured by the RPQ and potential explanatory variables including: gender, age, balance, duration of diabetes and fear of falling.

Research question 3

Receiver operating characteristic (ROC) curves were used to determine the cut point of the RPQ that can be used to distinguish between individuals who perceive that they are at risk for falling from individuals who do not perceive that they are at risk for falling. Receiver operating characteristic (ROC) curves are graphs used to evaluate the ability of tests to differentiate between individuals with and without a health outcome of interest (24). Additionally, ROC curves provide a visual representation of the trade-off between sensitivity and specificity when various cut points are chosen (24). The y axis of the ROC curve displays the sensitivity while the x axis displays 1 – specificity (24). In general, there are 3 main uses of ROC curves: 1) ROC curves are used to identify the cut point at which both sensitivity and specificity are optimized 2) they are used to determine the diagnostic accuracy of tests and 3) they are used to compare the usefulness of two or more diagnostic tests (24). The area under the ROC curve (AUC) provides an estimate of the test's ability to discriminate between individuals with and without the disease of interest (24). A "perfect" test will have an AUC of 1.0 whereas a completely useless test will have an AUC of 0.5. i.e., the diagnostic accuracy is no better than chance (24). Recommendations for interpreting the AUC state that AUC > 0.9 indicates a test with high accuracy, AUC: 0.7 – 0.9 indicates moderate accuracy and AUC: 0.5 – 0.7 indicates low accuracy (24). We constructed two ROC curves; for the first curve we used the BBS as the reference variable to determine the optimal cut point for the RPQ. Participants who scored ≥ 45 points were coded as 0 (not at risk for falling) whereas participants who scored < 45 points were coded as 1 (at risk for falling). For the second ROC curve we used history of falling as the reference variable to determine the optimal cut point for the RPQ. Participants who reported no falls in the past 12 months were coded as 0 (not at risk for falling) whereas participants who reported at least one fall in the past 12 months were coded as 1 (at risk for falling). For the RPQ we chose to maximize sensitivity at the cost of specificity.

Research question 4

We examined the degree of concordance/ discordance between the 'tenses' of function namely: the hypothetical tense (RPQ), the experimental tense (BBS) and the enacted tense (history of falling) using Glass's model.

Glass's Model

In the assessment of physical function, there is often discordance between the level of functioning adults report based on self-report, their level of functioning in the clinical setting as measured by performance-based tests and their level of functioning in the 'real world' (41). Glass (1998) proposed three 'tenses' in order to understand level of functioning in different contexts (41). The three ‘tenses’ of function are: the *hypothetical tense*, the *experimental tense* and the *enacted tense* (41). The hypothetical tense assesses what individuals can do in theory (hypothetically), individuals are asked questions about their ability to perform functional tasks, how difficult it is for them to perform these tasks and whether they need assistance in order to perform these tasks (41). The hypothetical tense is assessed by self-report (41). The experimental tense assesses function by asking individuals to demonstrate their functional capacity in a clinical or experimental setting (41). The experimental tense is assessed by performance-based measures such as the Berg Balance Scale (41). Lastly, the enacted tense refers to an individual’s functional capacity in the ‘real world’ (e.g. at home) outside the controlled conditions of the clinic or laboratory (41). Taken together, these three tenses of function provide a more comprehensive approach to studying function, however, aging research has almost exclusively focused on the hypothetical tense (41). To demonstrate the distinction between the tenses of function, Glass (1998) constructed a simple 2 by 2 table to compare how function could be assessed using the hypothetical tense (self-reported functional capacity) and the enacted tense (functional performance at home) (41). Glass (1998) classified individuals into four types (I - IV) based on the agreement between their function using both the hypothetical and enacted tenses (41). Individuals classified as type I or type IV display concordance between their hypothetical and enacted tenses of functioning. On the other hand, individuals classified as type II or type III display discordance between their hypothetical and enacted tenses of functioning (41). Glass refers to type II individuals as over-achievers, these individuals have higher levels of enacted function than would be predicted by the hypothetical tense alone (41). Type II individuals display high levels of functioning at home despite significant disability or diminished functional capacity (41). Lastly, Glass refers to type III individuals as underachievers, these individuals have lower levels of enacted function than would be predicted by the hypothetical tense alone (41). Despite the absence of significant disability, type III individuals do not perform tasks that they are capable of, these individuals often have sedentary lifestyles (41) (Figure 2). We used Glass' model to compare the three tenses of function in older adults with type 2 diabetes mellitus. We compared the hypothetical tense (Risk Perception Questionnaire) with both the experimental tense (Berg Balance Scale) and the enacted tenses (number of falls in the past year).

	Functional performance at home ("Enacted tense")	
	Low	**High**
Functional capacity (Hypothetical "tense") **Low**	**Type I** Low functioning	**Type II** Over-achievers
High	**Type III** Under- achievers	**Type IV** High functioning

Figure 2. Glass's cross-classification of "hypothetical" and "enacted" tenses of functioning.

Research question 5

Responsiveness refers to the ability of an outcome measure to detect change over time (29). We used paired t-tests and two indices of effect size namely: Cohen's *d* and standardized response means to determine the responsiveness of the RPQ immediately after individuals were given feedback about their balance as well as 6 weeks post feedback.

Effect size

An effect size quantifies the magnitude of the difference between groups (42). Specifically, effect size is the difference between mean outcomes of two groups, for example treatment vs. placebo or pre-treatment vs. post-treatment (42). One index used to estimate effect size is Cohen's *d*. Cohen's *d* is computed as follows: $d = t / \sqrt{N}$, where t is the test statistic from the paired t test and N is the sample size (42). Cohen recommends the following for interpreting effect sizes: 0.2 small, 0.5 moderate and 0.8 large (42). Another index of effect size is the standardized response mean (SRM). Standardized responsive means are calculated as follows: $SRM = (M_1 - M_2)/ S_{\Delta}$, where M_1 is the mean at follow-up, M_2 is the mean at baseline and S_{Δ} is the standard deviation of $(M_1 - M_2)$ (31). Recommendations for interpreting SRM are as follows: 0.2 low, 0.5 moderate and 0.8 high (31).

3. Results

3.1 Participant characteristics

A total of 30 community dwelling older adults with type 2 diabetes mellitus (DM2) were included in this study, 12 participants were male (40%) (Table 1). The mean age was 68.6 (6.9) years, mean duration of type 2 diabetes mellitus was 13.2 (8.2) years and the median number of falls in the last 12 months was 1 (Table 1). On average, participants reported a high fear of falling, median FES-I score 25 (Table 1). Twenty (66.7%) participants reported nerve pain in their fingers and toes (Table 1). Six (20.0%) of participants reported having diabetic peripheral neuropathy, 1 (3.3%) participant reported diabetic retinopathy, 2 (6.7%) participants reported diabetic foot ulcers and no participants reported autonomic neuropathy (Table 1). The most commonly reported comorbid conditions were hypertension (70.0%), arthritis (43.3%) and high cholesterol (33.3%) (Table 2). Other less common comorbid conditions reported were: stroke, cardiac bypass, asthma, glaucoma and depression (Table 2). On average, there were 2.3 comorbid conditions per person. Scores from the Rapid Assessment of Physical Activity (RAPA) indicated that the majority of participants were under active (60.0%) (Table 3A). It is possible that the individuals who were underactive were restricting their activity due to fear of falling. However, in our sample the correlation between fear of falling and physical activity was not significant (r = -0.28, p = 0.14). Lastly, there was a gender difference in perceived risk of falling where women reported higher perceived risk of falling than men, mean difference = -10.3, t = -1.91, p = 0.03.

Table 1: Demographic characteristics of participants

Variable	**All participants (N = 30)**
Age, Mean (SD)	68.6 (6.9)
Female n (%)	18 (60.0%)
Duration of diabetes in years, Mean (SD)	13.2 (8.2)
Falls Efficacy Scale – International score, median (IQR)	25 (22 - 37)
Falls in the past year, median (IQR)	1 (0 - 3)
Nerve pain in the extremities, n (%)	20 (66.7%)
Diabetes related complications, n (%)	
Diabetic peripheral neuropathy, n (%)	6 (20.0%)
Diabetic retinopathy, n (%)	1 (3.3%)
Autonomic neuropathy, n (%)	0 (0%)
Diabetic foot ulcers, n (%)	2 (6.7%)

*IQR stands for interquartile range, SD stands for standard deviation.

Table 2: Comorbid conditions

Comorbid condition	**Frequency (%)**
Hypertension	21 (70.0%)
Arthritis	13 (43.3%)
High Cholesterol	10 (33.3%)
Plantar Fasciitis	1 (3.3%)
Blood disorder	1 (3.3%)
Vascular disease	1 (3.3%)
Asthma	2 (6.7%)
Anaemia	1 (3.3%)
Stroke	1 (3.3%)
Glaucoma	1 (3.3%)
Cardiac bypass	3 (10.0%)
Heart attack	1 (3.3%)
Aneurysm	1 (3.3%)
Heart disease	1 (3.3%)
Osteoporosis	1 (3.3%)
Damaged spine	1 (3.3%)
Detached ribs	1 (3.3%)
Skull fracture	1 (3.3%)
Concussion	1 (3.3%)
Vertigo	1 (3.3%)
COPD	1 (3.3%)

Sleep apnea	1 (3.3%)
Depression	1 (3.3%)
Hypothyroidism	1 (3.3%)

Table 3A: Physical activity levels

Physical activity level	**Frequency (%)**
Sedentary	0 (0%)
Under-active	2 (6.7%)
Under-active regular (light activities)	5 (16.7%)
Under-active regular (moderate activities)	10 (33.3%)
Under-active regular (vigorous activities)	1 (3.3%)
Active (moderate activities)	10 (33.3%)
Active (vigorous activities)	2 (6.7%)

Table 3B: Strength and flexibility obtained from the Rapid Assessment of Physical Activity (RAPA).

Rapa score	**Strength/flexibility training**	**Frequency (%)**
0	No strength/flexibility training	5 (16.7%)
1	Strength training only	7 (23.3%)
2	Flexibility training only	7(23.3%)
3	Strength and flexibility training	11 (36.7%)

3.2 Missing data

There are several types of missing data, namely: missing completely at random (MCAR), missing at random (MAR) and non-ignorable responses (39). MCAR refers to missing data that does not depend on the dependent variable, the covariates or the study design (39). MAR also known as ignorable non-response occurs when the probability of the missing response depends only on the independent variables and not on the dependent variables (39). Lastly, non-ignorable response occurs when the probability of the missing response depends on the value of the response (the dependent variable) (39). The amount of missing data differed at each time point. At time 1 and time 2 there was no missing data (Table 4). However, at time 3 there was 10% missing data (Table 4). Little's MCAR test showed that our data were missing completely at random (Chi-Square= 0.00, DF= 140, p= 1.00). Missing data was imputed using expectation maximization (EM). Expectation maximization begins with the expectation step, during this step the parameters such as means and variances are estimated (40). Parameter estimates are then used to generate a regression equation which is then used to predict the missing data (40). During the maximization step, the regression equation is used to fill in the missing data (40). The expectation and maximization steps are repeated until the dataset stabilizes that is, when the covariance matrix of the previous iteration is virtually identical to that of the current iteration (40). Unlike other simple imputation methods such as mean substitution, EM does not change the relationship of the variable with missingness to other variables without missingness (40). Statistical analyses were performed two ways: without the missing data and with imputed data. However, the results obtained using both methods were not significantly different.

Table 4: Number of participants with missing data at each time point

Time 1	**Time 2**	**Time 3**
0 (0%)	0 (0%)	3 (10%)

3.3 Factors associated with perceived risk of falling

Multiple regression analyses were performed to examine the relationship between perceived risk of falling (total RPQ score) and potential explanatory variables including: gender, age, balance, duration of diabetes, history of falling and fear of falling. Table 5 summarizes the descriptive statistics and regression analyses. We conducted bivariate analyses to determine whether there was a linear relationship between each of the independent variables and the dependent variable (perceived risk of falling). There was no linear relationship between perceived risk of falling and the following independent variables: gender ($t = 1.91$, $p = 0.07$), age ($t = -1.03$, $p = 0.31$), balance ($t = 1.14$, $p = 0.27$), duration of type 2 diabetes ($t= -0.31$, $p = 0.76$) and history of falling ($t = 1.77$, $p= 0.09$). However, there was a linear relationship between perceived risk of falling and fear of falling ($t = 3.25$, $p = 0.003$). Therefore, we included fear of falling as an explanatory variable in our regression model. The multiple regression model with perceived risk of falling and fear of falling produced the following result: $R^2 = 0.27$, $F (1, 28) = 10.55$, $p = 0.003$. The R^2 value of 0.27 indicates that 27% of the variation in perceived risk of falling can be accounted for by fear of falling. Although age and gender were not significant explanatory variables in the bivariate analyses (possibly due to our small sample size), we forced them into the regression model based on evidence from the falls literature. For example, telephone interviews of 3202 older adults, > 60 years, found that men were 40% more likely than women to perceive their risk of falling as low (32). This study also found that younger individuals were more likely to perceive their risk of falling as low compared to older individuals. Individuals in their 60s were 70% more likely and individuals in their 70s were 50% more likely to perceive their risk of falling as low compared to individuals in their 80s (32). The multiple regression model with perceived risk of falling (dependent variable), fear of falling, gender and age produced the following result: $R^2 = 0.33$, $F(3, 25) = 4.07$, $p = 0.02$. The R^2 value of 0.33 indicates that 33% of the variation in perceived risk of falling can be accounted for by fear of falling, gender and age (see Table 6 for detailed results from the regression model).

Table 5: Summary statistics, correlations and results of regression analysis.

Variable	**Mean**	**Standard deviation**	**Correlation with perceived risk of falling**	**Regression coefficient**	**Beta coefficient**
Perceived risk of falling	78.93	15.15			
Fear of falling	3.32	0.31	0.52, p = 0.003	25.29	0.52

*Note: perceived risk of falling was measured by a Risk Perception Questionnaire (RPQ) and fear of falling was measured by the Falls Efficacy Scale – International (FES-I). FES-I scores were transformed to become consistent with a normal distribution. RPQ total scores were normally distributed and FES-I scores were positively skewed and therefore a logarithmic transformation was done before parametric statistics were performed.

Table 6: Summary statistics, correlations and results of regression analysis: full model.

Variable	**Mean**	**Standard deviation**	**Correlation with perceived risk of falling**	**Regression coefficient**	**Beta coefficient**
Perceived risk of falling	78.93	15.15			
Fear of falling	3.32	0.31	0.52, p = 0.003	25.29	0.52
Gender	N/A	N/A	N/A	1.42	0.05
Age	62.62	6.90	-0.19, p = 0.31	-0.47	-0.21

*Note: perceived risk of falling was measured by a Risk Perception Questionnaire (RPQ) and fear of falling was measured by the Falls Efficacy Scale – International (FES-I). FES-I scores were transformed to become consistent with a normal distribution. Total RPQ scores, age and gender were normally distributed. However, total FES-I scores were positively skewed and therefore a logarithmic transformation was done before parametric statistics were performed.

3.4 Cut point determination of the Risk Perception questionnaire

A receiver operating characteristic (ROC) curve was used to determine the cut point of the Risk Perception Questionnaire that can be used to distinguish between individuals who perceive that they are at risk for falling and individuals who do not perceive that they are at risk for falling. The Berg Balance Scale (BBS) was used as the reference variable to indicate the true status of each individual, at risk for falling versus not at risk for falling. As recommended, individuals with a BBS score < 45 were considered to be at risk for falling whereas individuals with a BBS score ≥ 45 were not considered at risk for falling (9). The area under the curve (AUC) was 0.65 (0.43 – 0.88) (Figure 3). The cut point chosen was 78 points. Individuals who scored < 78 points on the RPQ were considered to have low perceived risk of falling whereas individuals who scored ≥ 78 points on the RPQ were considered to have high perceived risk of falling. This cut point was chosen because it corresponds to the point closest to the upper left hand corner of the ROC curve, this point optimizes both the sensitivity and the specificity of the RPQ. With a cut point of 78 points, the sensitivity and specificity of the RPQ was 80% and 48% respectively. We also constructed an ROC curve using history of falling as the reference to indicate the true status of each individual; individuals with at least one fall in the past 12 months were classified as fallers and individuals with no falls in the past 12 months were classified as non-fallers. The AUC was 0.68 (0.48 – 0.88). The cut point chosen to distinguish between individuals with high perceived risk of falling and low perceived risk of falling was also 78 points. With this cut point, the sensitivity and specificity of the RPQ was 75.0% and 64.3% respectively (Figure 4). When choosing a cut point, researchers must decide whether to maximize sensitivity or maximize specificity (9). If the consequence of a false negative exceeds the cost of a false positive, sensitivity should be maximized (9). On the other hand, if the consequence of a false positive exceeds the consequence of a false negative, specificity should be maximized (9). For the RPQ we chose to maximize sensitivity at the cost of specificity. Increasing sensitivity causes the false positive rate to increase, this means that the RPQ will falsely classify some individuals as at risk for falling when they are not at risk for falling. One negative consequence of increasing the false positive rate is that telling individuals that they are at risk for falling may lead to increased anxiety and fear of falling which in turn may lead to activity restriction. However, the negative consequence of increasing the false negative rate is larger than increasing the false positive rate. If we chose to increase the specificity and false negative rate of the RPQ instead, we would falsely classify more individuals as not at risk for falling; this would result in missing individuals who would be benefit from fall prevention programs.

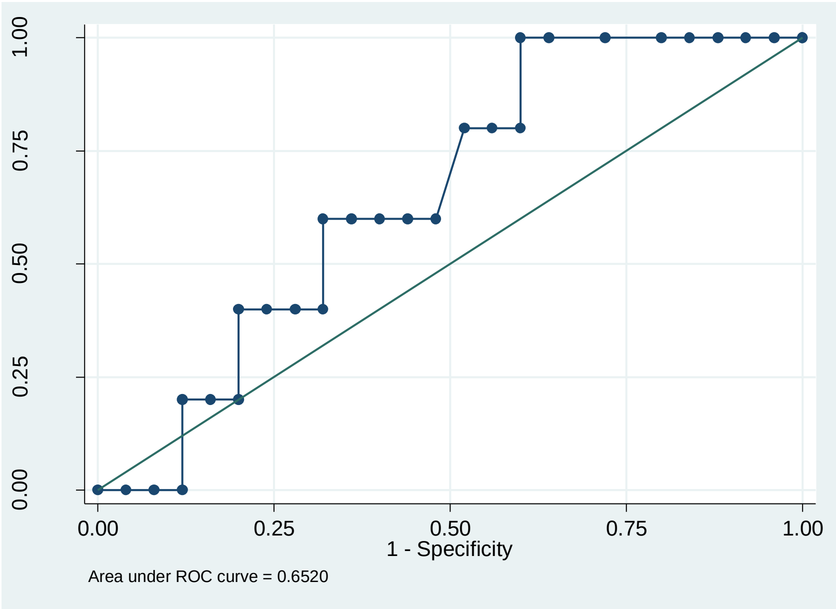

Figure 3: Receiver Operating Characteristic (ROC) curve used for cut-point determination of the Risk Perception Questionnaire using the Berg Balance Scale as the reference criterion.

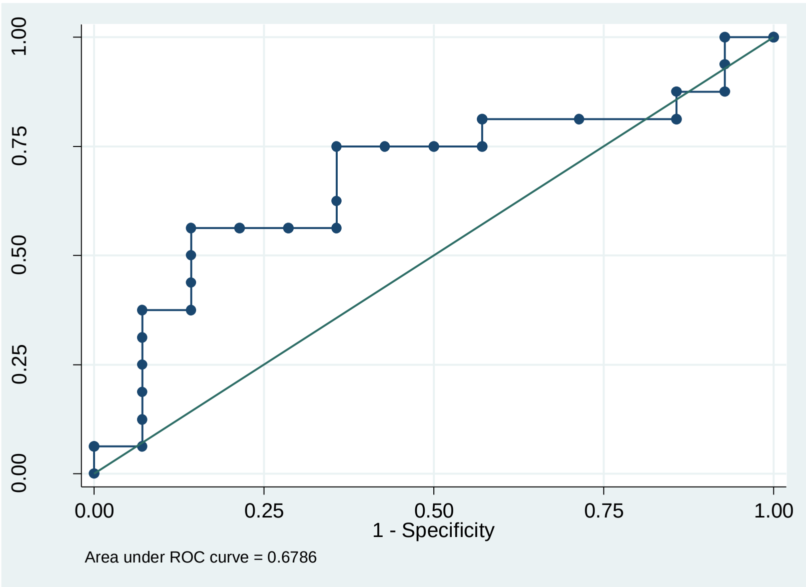

Figure 4: Receiver Operating Characteristic (ROC) curve used for cut-point determination of the Risk Perception Questionnaire using history of falling as the reference criterion.

3.5 Association between perceived risk of falling and balance

Perceived risk of falling was assessed by a Risk Perception Questionnaire (RPQ) and balance was assessed by the Berg Balance Scale (BBS). The median Berg Balance Scale score was 50 points. Using the recommended cut-off score of 45 points for the BBS, 16.7% of participants were considered at risk for falling whereas 83.3% of participants were not considered at risk for falling. The median RPQ score was 78.5 points. Using a cut-off score of 78 points (determined above), 43.3% of participants had a low perceived risk of falling whereas 56.7% of participants had a high perceived risk of falling. The RPQ classified 3.5 times more people than the BBS as at risk for having a fall. Pearson's correlation coefficient was used to examine the association between perceived risk of falling (RPQ) and balance (BBS). Total RPQ scores were normally distributed however, total BBS scores were negatively skewed. Therefore, a logarithmic transform was performed on the BBS scores before Pearson's correlation coefficient was calculated. Recommendations for quantifying the strength of a correlation are as follows: $r = 0 – 0.19$ very weak correlation, $r = 0.20 – 0.39$ weak correlation, $r = 0.40 – 0.59$ moderate correlation, $r = 0.60 – 0.79$ strong correlation and $r = 0.80 – 1$ very strong correlation (25). At baseline, there was a weak correlation between perceived risk of falling and balance, $r = 0.21$, $p = 0.27$.

I also examined the association between perceived risk of falling and balance using Glass's model. At baseline, 16 participants' (53.3%) displayed concordance between perceived risk (hypothetical tense, RPQ) and balance (experimental tense, BBS) (Figure 5). On the other hand, 14 participants' (46.7%) displayed discordance between perceived risk of falling and balance. Thirteen participants (43.3%) overestimated their risk for falling, these individuals displayed higher levels of function (good balance) than would be predicted by self-report measures alone. Lastly, one participant (3.3%) underestimated his/ her risk for falling, this individual displayed lower levels of function (impaired balance) than would be predicted by self-report measures alone (Figure 5). We also used Glass's model to compare the hypothetical tense (RPQ) and the enacted tense (we used history of falls as a proxy to estimate function in the real world). At baseline 21 participants (70.0%) displayed concordance between the hypothetical and enacted tense (Figure 6). Whereas 9 participants (30.0%) displayed discordance between the hypothetical and enacted tense; 5 participants (16.7%) overestimated their risk for falling, these individuals displayed higher levels of function than would be predicted by self-report measures alone and 4 participants (13.3%) underestimated their risk for falling, these individuals displayed lower levels of function than would be predicted by self-report measures alone (Figure 6).

	Balance (BBS), n = 30 Experimental tense	
	(+) **Type I** Low functioning 4 (13.33%)	(-) **Type II** Over-achievers 13 (43.33%)
Perceived risk of falling (+) (RPQ), n = 30 Hypothetical tense (-)	**Type III** Under- achievers 1 (3.33%)	**Type IV** High functioning 12 (40%)

Figure 5: Concordance/discordance between the hypothetical and experimental tense at baseline.

		History of falling (falls in the last 12 months), n = 30 Enacted tense	
		(+)	(-)
Perceived risk of falling (RPQ), n = 30 Hypothetical tense	(+)	**Type I** Low functioning 12 (40%)	**Type II** Over-achievers 5 (16.67%)
	(-)	**Type III** Under- achievers 4 (13.33%)	**Type IV** High functioning 9 (30%)

Figure 6: Concordance/discordance between the hypothetical and enacted tense at baseline.

We also examined the degree of concordance/ discordance between the hypothetical tense (perceived risk of falling) and the experimental tense (balance) by gender. At baseline 9 males (75.0%, figure 7) and 7 females (38.9%, figure 8) displayed concordance between the hypothetical tense (RPQ) and experimental tense (BBS). Three males (25.0%) and ten females (55.6%) overestimated their risk for falling. Finally, 0 males (0.0%) and 1 female (5.6%) underestimated her risk for falling. Additionally, we examined the concordance/ discordance between the hypothetical tense (perceived risk of falling) and the enacted tense (history of falling). At baseline, 6 males (50.0%, figure 9) and 15 females (83.3%, figure 10) displayed concordance between the hypothetical (RPQ) and enacted tense (history of falling). Three males (25.0%) and two females (11.1%) overestimated their risk for falling whereas 3 males (25.0%) and 1 female (5.6%) underestimated their risk for falling.

		Balance (BBS), n = 30 Experimental tense	
		(+)	(-)
Perceived risk of falling (RPQ), n = 30 Hypothetical tense	(+)	**Type I** Low functioning 2 (16.7%)	**Type II** Over-achievers 3 (25.0%)
	(-)	**Type III** Under- achievers 0 (0.0%)	**Type IV** High functioning 7 (58.3%)

Figure 7: Concordance/discordance between the hypothetical and experimental tense at baseline for males.

		Balance (BBS), n = 30 Experimental tense	
		(+)	(-)
Perceived risk of falling (RPQ), n = 30 Hypothetical tense	(+)	**Type I** Low functioning 2 (11.1%)	**Type II** Over-achievers 10 (55.6%)
	(-)	**Type III** Under- achievers 1 (5.6%)	**Type IV** High functioning 5 (27.8%)

Figure 8: Concordance/discordance between the hypothetical and experimental tense at baseline for females.

		History of falling (falls in the last 12 months), n = 30 Enacted tense	
		(+)	(-)
Perceived risk of falling (RPQ), n = 30 Hypothetical tense	(+)	**Type I** Low functioning 2 (16.7%)	**Type II** Over-achievers 3 (25.0%)
	(-)	**Type III** Under- achievers 3 (25.0%)	**Type IV** High functioning 4 (33.3%)

Figure 9: Concordance/discordance between the hypothetical and enacted tense at baseline for males.

	History of falling (falls in the last 12 months), n = 30 Enacted tense	
	(+)	(-)
Perceived risk of falling (RPQ), n = 30 Hypothetical tense (+)	**Type I** Low functioning 10 (55.6%)	**Type II** Over-achievers 2 (11.1%)
(-)	**Type III** Under- achievers 1 (5.6%)	**Type IV** High functioning 5 (27.8%)

Figure 10: Concordance/discordance between the hypothetical and enacted tense at baseline for females.

3.6 Responsiveness: Change in perceived risk

Paired t-test revealed no significant difference between individuals' perceived risk of falling at baseline and immediately after receiving feedback about their balance, t = 0.81, p = 0.42 (Table 7). There was also no significant difference between individuals' perceived risk of falling at baseline and 6 weeks post feedback, t = 0.03, p = 0.98 (Table 8).

Table 7: Paired t-test of RPQ scores at baseline and immediately after participants were given feedback about their balance.

Perceived risk of falling	**n**	**Mean**	**Standard deviation**	**t-statistic**	**p-value**
Baseline	30	78.93	15.15	0.81	0.42
Immediately after feedback	30	77.03	14.32		

Table 8: Paired t-test of RPQ scores at baseline and at 6 week follow-up

Perceived risk of falling	**n**	**Mean**	**Standard deviation**	**t-statistic**	**p-value**
Baseline	27	79.85	15.62	0.03	0.98
6 week follow-up	27	78.78	14.81		

We also calculated effect sizes to determine whether individuals changed their perceived risk for falling immediately after receiving feedback about their balance as well as 6 weeks post feedback to determine whether individuals needed more time to process and assimilate the feedback. The Cohen's *d* effect sizes immediately following feedback and at 6 week follow up were 0.15 and 0.005 respectively. Both Cohen's *d* effect sizes were < 0.2 and therefore would be considered very small. Additionally, standardized response means (SRMs) were calculated to determine whether individuals' perceived risk of falling changed after receiving feedback about their balance. The SRM was 0.15 immediately after receiving feedback and 0.005 6 weeks post feedback. Both SRMs were < 0.2 and therefore would be considered very small.

4. Discussion

The main objectives of this study were to determine the relationship between perceived risk of falling and balance in older community-dwelling adults with type 2 diabetes mellitus, to determine whether individuals ratings of their risk for falling are correlated with their balance, to determine whether individuals change their perceived risk after receiving feedback about their balance and to determine how knowledgeable older adults are about risk factors for falling. There was a weak correlation between perceived risk of falling and balance, $r = 0.21$, $p = 0.27$. Sixteen participants (53.3%) displayed concordance between perceived risk of falling and balance while 14 participants (46.67%) did not. Change in perceived risk of falling was very small after individuals were given feedback about their balance, $t = 0.81$, $p = 0.42$ (immediately after feedback) and $t = 0.03$, $p = 0.98$ (6 weeks after feedback). Additionally, the effect sizes for perceived risk were very small, 0.15 (immediately after feedback) and 0.005 (6 weeks after feedback). Standardized response means were also very small 0.15 (immediately after feedback) and 0.005 (6 weeks after feedback). Lastly, the mean change score for the RPQ was 1.9 points and 0.07 points immediately after feedback and at 6 week follow up respectively. It is possible that simply giving individuals feedback about their balance may not have been potent enough to alter their perceived risk of falling.

4.1 Perceived risk of falling and balance

At baseline, there was a weak correlation between perceived risk of falling and balance, $r = 0.21$, $p = 0.27$. Using the Berg Balance scale and the Risk Perception Questionnaire: 16 participants (53.3%) accurately estimated their risk for falling, 13 participants (43.3%) overestimated their risk for falling and 1 participant (3.3%) underestimated his/ her risk for falling. These categories of individuals have also been identified by other studies (48). A prospective cohort study (n = 500), 70 – 90 years also examined the relationship between perceived and objective risk for falling in older community-dwelling adults (48). In this study, 29% of participants had both low perceived and objective risk for falling and were labeled the “vigorous” group, 40% of participants had both high perceived and objective risk for falling and were labeled the “aware” group, 11% of participants overestimated their risk for falling and were labeled the “anxious” group and 20% of participants underestimated their risk for falling and were labeled the “stoic” group (48). The authors examined the psychological profiles of the “anxious” and “stoic” groups to determine why there was discordance between their perceived and objective risk for falling. In this study, individuals in the “anxious” group had high levels of irrational fear (neuroticism); the authors suggest that this neuroticism may have caused these individuals to overestimate their risk for falling (48). The authors also examined the psychological profiles of the “stoic” group who underestimated their risk for falling; these individuals had a positive attitude to life, were emotionally stable and had low reactivity to stress which may have caused them to underestimate their risk (48). This study (48) used the Falls

Efficacy Scale- International (FES-I), which was originally designed to measure fear of falling, as a measure of perceived risk of falling. In the following section we will discuss the association between perceived risk of falling and fear of falling.

4.2 Perceived risk of falling and fear of falling

Fear of falling has been defined as the negative psychosocial consequences associated with falling in older adults including: fear, anxiety, loss of confidence and impaired perception of one's ability to walk safely and prevent falling (27). On the other hand, perceived risk has been defined as a multi-dimensional concept that considers thoughts about the probability of disease (falling), and its consequences as well as judgements about the importance of the risk (fall risk) to the individual (10). We found a moderate correlation between perceived risk of falling and fear of falling, $r = 0.52$, $p = 0.003$ which suggests that these two constructs are similar. This moderate correlation raises the issue of whether the RPQ is a redundant outcome measure given that the FES-I already exists. The FES-I assesses older adults' fears/concerns about falling during a range of activities of daily living (ADLs) including: cleaning the house, taking a bath or shower, getting dressed or undressed and going up or down stairs (17). On the other hand, the RPQ covers a wider range of fall-related issues in addition to ADLs. For example, the RPQ assesses older adults' attitudes and beliefs about falling. Items on the RPQ that illustrate this include: "I feel that getting older increases my risk of falling," "My attitude about aging influences my risk of falling" and "Avoiding a fall is just as important as my other health concerns."

Another distinction between the FES-I and the RPQ is the fact that the FES-I only examines the impact of the individuals' physical environment on their risk for falling whereas the RPQ examines the impact of individuals' physical, social and cultural environment on their risk for falling. For example, the RPQ examines the impact of the media as well as family, friends and healthcare professionals on individuals' risk for falling. Additionally, the RPQ also examines the impact of individuals' cultural and religious beliefs on their risk for falling. Another feature of the RPQ that makes it different from the FES-I is the fact that it can also be used to assess individuals' opinions about known risk factors for having a fall. For example, the RPQ includes the following; instruction: "Please rate if you feel that the following factors may increase your risk for falling": "A fall in the past year", "weakness in your legs" and "Difficulty moving around the house or community." As a result, the RPQ has the potential to be used to assess knowledge gaps in order to design tailored falls education materials. Lastly, the FES-I and the RPQ may have different scopes; the FES-I has been validated in the clinical setting, while the RPQ may have public health and community health applications. We therefore conclude that the FES-I and the RPQ are distinct outcome measures and should be used to complement each other.

4.3 Gender differences

Previous research has also found gender differences in both risk perception (43, 44, 45) and fear of falling (47, 49). In general, research has found that women worry significantly more than men (43). Differences in social roles between men and women is believed to partly explain the gender difference in risk perception commonly reported (43). In general, women are the primary nurturers and caregivers for their loved ones; as such women are more concerned about health and safety risks such as falling which are linked to their ability to care for others (43). Higher concerns about falling among women compared to men may also be associated with the greater risk of serious fall-related injuries including fractures (46). For instance, bone mass starts to decline after age 30, however, this decline is more rapid in women (1% per year) than men (0.5% per year) which results in a higher fracture risk among older women than older men (46).

Another possible explanation for the higher perceived risk seen in women than men is the fact that traditionally masculinity has been associated with being physically strong and fearless and therefore men may be less likely to admit that they are concerned about falling for fear of being viewed as "less masculine" (47). Gender differences in risk perception have also been found for other health risks including cardiovascular disease (CVD) (28). A cross-sectional study, n = 211, 18 – 85 years, of individuals with type 2 diabetes mellitus who had a 10% or higher risk for CVD based on the Framingham risk index also observed gender differences in risk perception (28). In this study, women reported significantly higher perceived risk for CVD than men (perceived risk score = 0.68 ± 1.3 for women and 0.31 ± 1.4 for men, $p< 0.05$) although there was no significant gender difference in objective risk for CVD based on the Framingham risk index (28).

4.4 Change in perceived risk for falling

In our study, participants' perceived risk for falling did not change immediately after feedback or 6 weeks after feedback, $t = 0.81$, $p = 0.42$ and $t = 0.03$, $p = 0.98$ respectively. Additionally, effect sizes were very small, 0.15 and 0.005 respectively. It is possible that 6 weeks may not have been enough time to detect a change in individuals' perceived risk for falling. Moreover, simply giving individuals feedback about their balance may not have been potent enough to produce a significant change in perceived risk for falling. Hughes et al. (2008) conducted a survey (n= 3202) to examine older adults' attitudes about falls and its implications for fall prevention (32). In this study 50% of individuals were recruited from a previous fall prevention program and 50% were recruited as a control group (32). This study found no difference in perceived risk of falling between the two groups suggesting that the fall prevention program did not change individuals' perceptions (32). Although this study did not find a change in perceived risk, individuals from the fall prevention program were less likely than individuals in the control group to agree that falls are not preventable, OR = 0.76 (0.65 – 0.90) (32). Additionally, individuals from the fall prevention group were more likely to rate fall prevention as a high priority, OR = 1.31 (1.09 – 1.57) (32). These results suggest that falls education may be effective in changing some attitudes and perceptions even though no change was observed in overall perceived risk.

4.5 General comments about the RPQ

The assessor read each statement (item) aloud and participants were asked on a scale of 1 to 7 to rate the degree to which they agreed or disagreed with the statement. Participants were able to say whether they agreed or disagreed with each statement however, many participants had difficulty rating their response on the numbered scale. One suggestion to address this problem is to attach a descriptor to each number on the scale. For example 1) strongly disagree 2) disagree 3) somewhat disagree 4) neither agree nor disagree 5) somewhat agree 6) agree 7) strongly agree. Additionally, some participants forgot the direction of the scale: strongly disagree to strongly agree (left to right). Therefore, re-orienting participants at the beginning of each item may help to ensure their true perception is recorded. Lastly, participants had difficulty with statements that did not personally apply to them. For example, participants who had not fallen in the past 12 months had difficulty with the following statement: please rate if you feel that the following factor may increase your risk of falling: A fall in the past 12 months. One suggestion to address this problem is to ask participants to imagine statements that do not personally apply to them and then ask them to respond based on the imagined scenario. This has been done with other outcome measures such as the falls efficacy scale-international (FES-I) (18).

4.6 Limitations

This study had several limitations. In order to increase the generalizability of our results, we intended to recruit equal numbers of older adults from different age cohorts however, this was not achieved. For example, the majority of our participants were 66 – 75 years (50%), while only 36.7% of participants were 55 – 65 years, 10% of participants were 76 – 85 years and no participants were 86 – 95 years. Therefore, our results may be more applicable to the two younger cohorts and less applicable to the two older cohorts. Additionally, we only observed a very small change in perceived risk of falling after individuals were given feedback about their balance. It is possible that simply giving individuals feedback about their balance may not have been potent enough to change their perceived risk of falling. Lastly, the missing data further reduced our small sample size leading to loss of information and reduced statistical power.

5. Conclusion

Risk perception is a complex concept consisting of many interacting factors. In this study, some individuals displayed concordance between their perceived risk of falling and balance (53.3%) while others displayed discordance between their perceived risk of falling and their balance (46.7%). Discordance between perceived risk of falling and balance can have adverse consequences. For instance, overestimation of perceived risk could lead to excessive fear of falling which may lead to unnecessary activity restriction. On the other hand, underestimation of perceived risk may lead to a false sense of security which in turn may result in failure to engage in fall prevention behaviours. We recommend that fear of falling and perceived risk of falling should be assessed in conjunction with each other in order to gain a more comprehensive understanding of individuals' concerns about falling during ADLs (FES-I), their attitudes and beliefs about falling as well as their attitudes towards fall prevention (RPQ). In conclusion, clinicians should assess fear of falling, perceived risk of falling and balance in order to design appropriate, tailored fall risk management strategies.

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Chapter 5: Discussion and implications

Summary

The overall objective of this thesis was to explore the perceived risk of falling and balance in older community-dwelling adults with type 2 diabetes mellitus. This thesis was made up of three related studies. The first study was a systematic review on identification of non-pharmacological risk factors for falling in older adults with type 2 diabetes mellitus (DM2). This study found that the most common risk factors for falling were: impaired balance, reduced walking velocity, peripheral neuropathy and comorbid conditions. However, the risk factors with the greatest impact on risk for falling were: lower extremity pain, being overweight, and the presence of comorbid conditions as measured by odds ratios and hazard ratios. Therefore, the risk factors with the greatest impact on fall risk should be targeted when designing fall prevention interventions for older adults with DM2. The second study was a prospective cohort study to determine the measurement properties of a falls risk perception questionnaire. The goal of this study was to determine the test-retest reliability, internal consistency, construct validity and the factor structure of a Risk Perception Questionnaire (RPQ) in older adults with DM2. The RPQ demonstrated substantial test-retest reliability when delivered in person and by phone as well as good internal consistency and good construct validity. Additionally, exploratory factor analysis of the RPQ revealed a five factor structure namely: self-efficacy, effect of information/ education on risk for falling, attitudes and beliefs about falling in relation to aging, risk factors and importance of fall prevention. These results suggest that the RPQ is a useful tool for assessing perceived risk of falling however, further testing should be done on a larger scale. The final study was also a prospective cohort study. The main objectives of this study were to determine the association between perceived risk of falling and balance in older adults with

DM2, to determine whether individuals' ratings of their risk for falling are correlated with their balance and to determine whether individuals' perceived risk of falling is influenced by feedback about their balance. This study revealed that only 53.3% of participants displayed concordance between their perceived risk of falling (RPQ) and their balance (BBS) as determined by Glass's model. Additionally, there was a weak positive correlation between perceived risk of falling and balance however this correlation was not statistically significant possibly due to low statistical power. Lastly, there was a very small change in perceived risk of falling after individuals were given feedback about their balance. The weak correlation between perceived risk of falling and balance suggests that they are independent components of fall risk. Therefore, comprehensive fall risk assessment should include both perceived measures and standardized performance measures.

Main contributions

This thesis has made several substantive contributions to the falls and risk perception literature respectively. This is the first time that the psychometric properties of the RPQ have been evaluated. Further psychometric testing of this questionnaire should be done on a larger scale to confirm the findings of this thesis. For example, the RPQ should be tested using larger sample sizes to increase statistical power, in different settings including clinics and residential aged care institutions as well as in different populations including individuals with other chronic conditions example, post-stroke populations and individuals who have undergone hip or knee arthroplasty. Further testing of the RPQ will also help to clarify its usefulness as a tool for falls risk assessment and management. After further testing of the RPQ has been done, it has the potential to be used on a large scale to assess perceived risk of falling in the field of rehabilitation which is currently dominated by standardized performance-based measures of fall risk. The RPQ may also help us to better understand individuals' attitudes, beliefs and behavioural responses to their risk for falling. The use of both perceived measures and standardized performance-based measures will provide a more comprehensive approach to fall risk assessment and management than the use of performance-based measures alone. Additionally research is needed to link risk assessment using the RPQ to fall management and prevention.

Perceived risk of falling and fear of falling

This thesis has also contributed substantively to our knowledge of the link between perceived risk of falling and fear of falling. Fear of falling has been defined as the negative psychosocial consequences associated with falling in older adults including: fear, anxiety, loss of confidence and impaired perception of one's ability to walk safely and prevent falling (1). On the other hand, perceived risk has been defined as a multi-dimensional concept that considers thoughts about the probability of disease (falling), and its consequences as well as judgements about the importance of the risk (fall risk) to the individual (2). In the falls literature, fear of falling instruments such as the Falls Efficacy Scale- International (FES-I) have been used to assess perceived risk of falling (3). However, is it really appropriate to use the FES-I as a measure of perceived risk of falling? My answer is no. On one hand, there was a moderate correlation between fear of falling and perceived risk of falling ($r = 0.52$, $p = 0.003$) which suggests that these two constructs are similar. Though similar, fear of falling and perceived risk of falling are two distinct constructs. Fear of falling has a larger emotional/ affective component than perceived risk of falling. For example, fear of falling involves emotions such as fear and anxiety (1). On the other hand, perceived risk of falling has a larger evaluative component than fear of falling. For example, perceived risk of falling considers judgments about the importance of fall risk to the individual (2). One distinction between the FES-I and the RPQ is that the FES-I assesses older adults' fears/concerns about falling during a range of activities of daily living (ADLs) including: cleaning the house, taking a bath or shower, getting dressed or undressed and going up or down stairs (14) whereas the RPQ covers a wider range of fall-related issues in addition to ADLs. For example, the RPQ assesses older adults' attitudes and beliefs about falling. Items on the RPQ that illustrate this include: "I feel that getting older increases my risk of falling," "My attitude about aging influences my risk of falling" and "Avoiding a fall is just as important as my other health concerns." Another distinction between the FES-I and the RPQ is the fact that the FES-I only examines the impact of the individuals' physical environment on their risk for falling whereas the RPQ examines the impact of individuals' physical, social and cultural environment on their risk for falling. For example, the RPQ examines the impact of the media as well as family, friends and healthcare professionals on individuals' risk for falling. Additionally, the RPQ also examines the impact of individuals' cultural and religious beliefs on their risk for falling. Therefore, we suggest that using measures such as the FES-I alone will not provide a complete picture of an individual's perceived risk of falling.

Perceived risk of falling and balance

This thesis also highlighted the concordance/ discordance observed between individuals' perceived risk of falling and their balance. Only half (53.3%) of the participants displayed concordance between their perceived risk of falling and their balance (Chapter 4). The remainder of the participants either over-estimated (43.3%) or under-estimated their risk for falling (3.3%). There are dangers associated with both over estimating and under estimating one's risk for falling. Individuals who over-estimate their risk for falling also tend to have high levels of fear of falling, this is based on the moderate correlated between perceived risk for falling and fear of falling. High levels of fear of falling, due to overestimation of fall risk, is often associated with a range of negative consequences including: falling, decrease in physical activity, reduced participation in social activities, depression and decreased quality of life (4). On the other hand individuals who under-estimate their risk for falling may have a false sense of security and therefore may be less motivated to engage in fall prevention behaviours (5). Moreover, the Health Action Process Approach (HAPA) states that perceived risk jump starts the contemplation and elaboration of thoughts, consequences and competencies needed to initiate behaviour change (7). Additionally, some individuals accurately estimate their risk for falling but choose to ignore their risk. For example, some individuals acknowledge that they are at risk for falling due to changes in physical function but decide not to modify their activities to match their level of function. It is important to keep in mind that behaviour is complex and largely self-determined. Therefore, clinicians can make recommendations but it is up to the individual consider and act upon them. Additionally, clinicians and patients may need tools to support behaviour change. For example, smartphone and computer applications (apps) can be used to administer fall prevention interventions. Apps allow individuals to record their goals and track their progress towards their goals (11). Moreover, apps allow the sharing of health information between patients and clinicians (11)

Use of the Risk Perception Questionnaire to tailor falls education

The RPQ contains items that assess individuals' knowledge about known risk factors for falling including: history of falling, muscle weakness and difficulty moving around the house or community. Using individuals' responses to items on the RPQ, we can determine what individuals know about risk factors for falling and as well as the gaps in their knowledge. We can then use this information to develop tailored fall education campaigns for individuals.

Tailoring refers to "any combination of information or change strategies intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and have been derived from an individual assessment" (7, p.1). Research suggests that tailored health information is viewed more favourably and is more likely to lead to behaviour change than untailored health information (8, 9, 10). A randomized controlled trial randomly assigned n=198 overweight adults to one of three types of weight loss information: computer generated pamphlets tailored to the unique needs of the individual based on the individual's enrollment interview, preprinted pamphlets from the American Heart Association (AHA) or preprinted pamphlets from the AHA which were formatted to look like the tailored pamphlets (8). Participants who received the tailored information had more positive thoughts about the information and positive behavioural intentions than individuals who received the untailored information (8). Another randomized controlled trial, n = 53, also provided some support for the efficacy of tailored health information (9). In this study, participants were assigned to one of two intervention groups (tailoring by authenticity and tailoring by motivation) or a control group (9). The goal of tailoring by authenticity was to improve the realism of the information to the learner; for example, vignettes were individualized to each participant based on his or her lifestyle including: living situation and use of mobility aids (9). On the other hand, the goal of tailoring by motivation was to highlight the program goals and benefits (9). Tailoring by motivation consisted of: 1) a clear statement about the goals of the fall prevention program, 2) an emphasis on the benefits of completing the program and 3) participant selection of information to be addressed during the program (9). The program goals and benefits were framed in a way that was personally relevant to each participant (9). For example one goal was "to assist you in establishing your own fall prevention strategies" (9 p. 705). One example of a benefit was: "by developing your own strategies and personal plan now, you may be able to remain active in the environments that are important to you and maintain your independence for your future" (9 p. 705). Lastly, the participants were asked to choose 4 – 10 situations from a list of 20 situations that were most relevant to their lives (9). Research has shown that tailoring content to the person's needs and values increases personal motivation which leads to improved outcomes (15, 16, 17). At 1 month follow up, individuals from both intervention groups gained more knowledge than individuals from the control group (9). Additionally, individuals in the tailoring by motivation group engaged in more fall prevention behaviours than individuals from the other two groups (9). These studies indicate that when health information is tailored to the individual, it is more likely to be considered as well as produce behavioural intentions and behaviour change.

Conceptual model

We also propose a conceptual model in an effort to integrate the various factors that influence falls risk perception and fall prevention. Older age is associated with changes in physical function; some individuals acknowledge these changes, perceive that they are at risk for falling, educate themselves about risk factors for falling and modify their activities in order to mitigate their risk. Some individuals acknowledge these changes, perceive that they are at risk for falling, educate themselves about risk factors for falling but choose not to modify their activities. These individuals take calculated risks knowing that may be predisposing themselves to falling. Lastly, some individuals deny their changes in function, do not perceive that they are at risk for falling, do not educate themselves about risk factors for falling and do not modify their activities which predisposes them to falling (Figure 1).

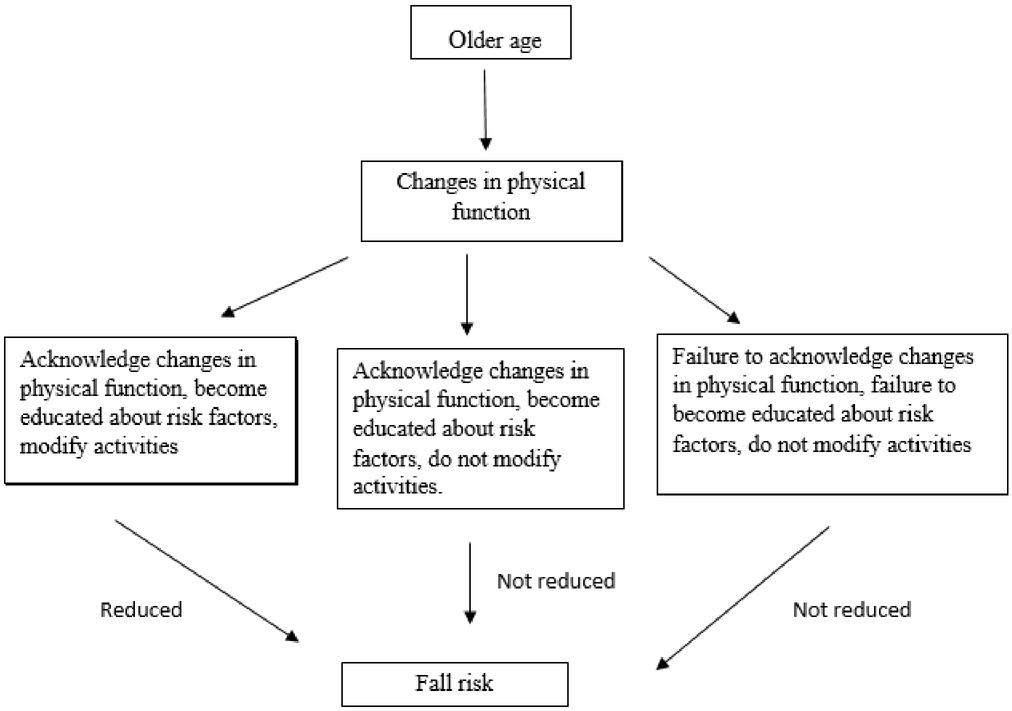

Figure 1. Visual representation of the conceptual model.

Strengths, limitations and future directions

To our knowledge this is the first falls risk perception questionnaire. We provided preliminary evidence which shows that this RPQ has substantial test-retest reliability, internal consistency and construct validity. Although we were able to reach our minimum required sample size of 30 participants, attrition reduced our sample size which reduced our statistical power. Our small sample size also may have resulted in failure to observe associations that have been previously observed in other studies such as the association between gender and perceived risk. For example, previous research has found that women are more concerned than men about health and safety risks including falling (12). Larger samples are also more likely than smaller samples to represent the characteristics of the population from which the sample was derived (13). Additionally, our small sample size reduced the robustness of our regression model. A rule of thumb is that a minimum of 10 participants is required for each independent variable in the regression model (13). With a sample size of 30 participants we were restricted to a maximum of 3 independent variables. Future research should be done with larger samples to address the statistical issues mentioned above. In study three we only observed a very small change in individuals' perceived risk of falling after receiving feedback about their balance. It is possible that the feedback given was not potent enough to alter individuals' perceptions. Future research should also determine the amount and type of feedback needed to alter perceived risk of falling, particularly for individuals who overestimate or underestimate their risk.

Concluding thoughts

Rehabilitation researchers and clinicians should use both perceived measures and standardized performance-based measures in order to gain a better understanding of individuals' overall risk for falling. Additionally, individuals' perceived risk of falling should be used in addition to their balance and history of falling in order to develop comprehensive, tailored fall prevention strategies. This RPQ shows promise as a useful measure of perceived risk of falling but further testing should be done on a larger scale before it can be used with confidence in clinical settings.

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