Evaluation of footwear worn at the time of fall in a Maltese long-term elderly facility

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PHMSC12

A dissertation presented to the Faculty of Health Sciences of the University of Malta in part fulfilment of the requirements for the degree of Masters of Science (by research) in Podiatry at the University of Malta

June 2024

Abstract

Evaluation of footwear worn at the time of fall in a Maltese long-term elderly residence.

Aim

The aim of this study was to investigate the relationship between footwear design and risk of falling in a sample of older adults living in a long-term care facility.

Research Design and Method

A quantitative, post-positive study was conducted in Malta's largest long-term care residence. This study consisted of 3 phases. Phase 1 evaluated footwear characteristics and fit worn by residents to provide an overview of the typical footwear worn in this population. A non-experimental approach was utilised with 135 residents selected through random sampling. The most commonly worn footwear was analysed using the Footwear Assessment Form, and its fit was assessed by measuring the footwear's length and width and comparing these to the participants' foot measurements. Phase 2 focused on evaluating the footwear worn at the time of falls. Employing a prospective design, this phase recorded any falls sustained over a period of 9 months, resulting in 76 eligible falls. Details about each fall and the footwear worn at the time were documented using the same methodology as in Phase 1. Phase 3 aimed to evaluate the functional stability and balance of participants when wearing the footwear worn at the time of fall versus 'adequate' footwear as recommended by the literature. An experimental design was used, involving 41 eligible participants from Phase 2. Participants completed two clinical balance and stability tests, the Functional Reach Test (FRT) and Time Up and Go (TUG), with both sets of footwear. The goal was to determine if adequate footwear provided better balance and stability than the footwear worn at the time of fall.

Results

Participants who sustained a fall were more likely to wear footwear with sub-optimal features such as heel height of more than 2.5cm and footwear having no fixation. Sandals were the most common type of footwear worn. Only 9.2% of participants who fell were wearing well-fitted footwear in terms of length and width. Participants performed significantly better in the TUG test when wearing 'adequate' footwear compared to the footwear worn at the time of fall. However, there was no significant difference in the FRT between the two types of footwear. Furthermore, none of the footwear characteristics were found to significantly impact the FRT and TUG test results.

Conclusion

This study demonstrates that inadequate footwear increases the risk of falling among a geriatric population living in a long-term care facility. Footwear worn at the time of fall negatively affected the participants' balance during walking, as evidenced by the TUG test. However, participants' stability over a fixed base of support, measured by the FRT test, was not affected when wearing 'adequate' footwear highlighting the importance of appropriate footwear for walking stability. None of the footwear characteristics significantly impacted changes in stability and balance during clinical balance tests. A plausible explanation for this, is that these tests are capable of detecting major changes between different types of footwear (e.g. adequate vs inadequate) but may not be capable of identifying subtle modifications in footwear design. Therefore, more research is required to better understand the impact of footwear on fall risk.

Keywords: Falls, footwear, older adults, residential care, footwear characteristics, footwear fit, balance and stability.

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As a Master's student, as per Regulation 77 of the General Regulations for University Postgraduate Awards 2021, I accept that should my dissertation be awarded a Grade A, it will be made publicly available on the University of Malta Institutional Repository.

Acknowledgements

I would like to show my gratitude for all the help and guidance that my Primary Supervisor, Dr. Stephen Mizzi, and Co-Supervisor Prof. Cynthia Formosa have given me throughout my journey in completing this study. I would like to thank them for the time, encouragement, and support they have always shown me.

My gratitude also goes to all those individuals who have willingly agreed to participate in this study. These elderly residents have been a big inspiration behind this study. I would also like to extend my acknowledgements to all study intermediaries who have helped me to recruit participants and also guided me in this study.

A depth of gratitude is also owed to Prof. Liberato Camilleri and Mr. Dylan Mercieca for their contributions towards statistical analysis of this study. Their help and guidance were instrumental to this study.

I would also like to thank all my colleagues and close friends who have always been helpful, supportive and encouraging throughout my journey in this study.

Last, but surely not least, I would like to show my appreciation towards my husband, Terence and the rest of my family, for constantly believing in me and pushing me to reach my potential. Thank you for always inspiring me and for providing me a shoulder to lean on during times of difficulty.

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Chapter 1:

Introduction

This chapter provides a brief overview of falls amongst the older population residing in a long-term facility. It also explores the relationship of footwear with falls in older adults, laying a contextual background to the study. In addition, it outlines the specific aims and objectives of the research, while also providing a clear outline of the dissertation's structure.

1.1 Background

1.1.1 Local Context on Long-Term Facility Care in Malta

Population ageing imposes great challenges to the quality of life and the well-being of a population, with increased demands and burdens on long-term care and institutionalisation (Luppa, et al., 2010). In Malta, the burden of institutionalization may be exacerbated by the arrival of the baby boomers who are now 65 years and over (Formosa, 2014). Baby boomers are those individuals born in the post-World Ward 2 era, when there was a temporary marked increase in the birth rate (Barnier, 2021). This can be observed in data published by NSO (2022) where the old age dependency ratio (the proportion of individuals aged over 65 compared to the working-age population) of Malta rose from 23.7 in 2011 to 27.6 in 2021.

In Malta, a network of services have been made available in the past years by the Active Ageing and Community Care in order to assist the older population with the aim of encouraging older people living in the community. Such services include Telecare Service, Telephone Rebate Scheme, Incontinence service, Night shelters, Home Help service, and Active Ageing Learning Hubs. Besides these services, a number of health care services targeting the older population living at home include Phlebotomists and Allied Health services, community Geriatricians and Dementia Intervention Teams (Active Ageing and Community Care, 2021).

For those needing more extensive care, a wide range of options for long-term care like nursing homes and skilled nursing facilities are also available. These facilities provide assisted living care for adults who cannot live independently and frequently require medical assistance. The goal of this service is to provide residential care for older adults who can no longer live independently, ensuring a physically and emotionally safe and secure environment (European Commission, 2023)

The 2021 census has noted that there are 5,456 individuals aged over 65 living in long-term facilities in Malta, with the majority being females (NSO, 2022). The average age of people living in long-term care is of 82.6 years (NSO, 2022). In Malta, both the public and private sectors are responsible for the care of older people. The share of responsibility is within the public sector and complimented by the private and church institutions. When older people require private facilities, the Catholic Church and the government provide most facilities designed to provide long-term care for the older population (Active Ageing and Community Care, 2021). At the moment there are 8 governmental run residential homes, and 31 private residential homes, which are financially assisted by the government (Government of Malta, 2023). Lately, there has been an extensive increase in private residential homes, accounting for the high demand in the country. Hospice Malta also provides palliative care to older individuals with terminal diseases (Active Ageing and Community Care, 2021).

The biggest medical care geriatric facility maintained by the government is St. Vincent De Paul Residence (Active Ageing and Community Care, 2021). This residence provides extensive medical care to the most vulnerable older adults on the island, who require complex and chronic long- term care. Its construction started in June 1886 and the land is spread over $122km^2$. Lately, this residence has been renovated and enlarged to incorporate new wards and clinics to accommodate the increasing number of older individuals seeking institutionalisation (Active Ageing and Community Care, 2021).

These long-term care facilities are essential for addressing the challenges of an aging population, which is a prominent demographic trend in the 21st century (Ismail et al., 2021).

1.1.2 Prevalence of falls in the older population

Increasing longevity, declining fertility, migration and improved medical care are all causes of why the older population continues to rise worldwide (Bloom & Luca, 2016). In fact, it is expected that by 2030, 1 in 6 individuals will be aged 60 years or over (WHO, 2021). In Malta, in 2020, it was estimated that the population of individuals aged 65 and over, stood at 94,160 people, which is 18% of the total population (Eurostat, 2021). Although population ageing is seen as a great triumph for humankind, at the same time, it imposes great challenges on the quality of life and the well-being of this specific population (WHO, 2021).

Falls amongst the older population is an example of this, as it is a main cause of morbidity and disability, with old age being a key factor for such falls (WHO, 2021). WHO (2021) defined a fall as an event that results in a person coming to rest accidentally on the ground or floor. It has been reported that in the United States, every second, an older adult suffers a fall, making falls the leading cause of injury and fatalities in this age group. One out of four older adults are estimated to fall each year across the U.S. (CDC, 2020). A similar trend is also observed in the United Kingdom where approximately a third of individuals aged 65 and over, and approximately half of the individuals aged 80 and over, fall at least once a year (England Public Health). It is worth noting that the incidence of falls has been found to be higher in long-term facilities for older people, with an estimated prevalence ranging between 34% and 67% (Teresi, et al., 2013; Baixinho & Dixe, 2015). This was further confirmed in a research paper published by Acker & Elliot (2017) who stated that older adults living in institutions fall at about twice the rate of age-matched cohorts living in the community. In the U.S. it is estimated that 1,800 older adults living in long-term institutions die each year from fall-related injuries (CDC, 2015). After road traffic accidents, falls emerge as the second leading cause of accidental fatalities, making them a major public health concern (WHO, 2021). Each year, falls result in an estimated 684,000 deaths globally, primarily impacting individuals over 60 years of age. In 2017, falls were responsible for 54,504 deaths amongst older adults in the Western European region. The highest incidence and fatalities occurred in those aged over 70 years in Norway, while the lowest were in Greece. Malta ranked 11th out of 22 countries in terms of fall-related facilities (Haagsma et al., 2020).

Fatalities from falls amongst older adults are always on the rise, in fact, the Centres for Disease Control and Prevention (CDC) estimated that in the U.S., fall death rates from 2007 to 2016 increased by 30%. It was further stated that if rates continue to increase, it is expected that 7 fall-related deaths will be reported every hour by 2030 (CDC, 2020).

Apart from fatalities, fall-related injuries amongst older people are a major cause of pain, disability, and loss of independence. It is estimated that globally approximately 37.3 million falls are severe enough to require medical attention each year. Hip fractures and head injuries are commonly sustained following falls, which often result in permanent disabilities and reduced quality of life (Teixeria et al., 2019). In 2017, in the Western European area, 11.7 million adults aged 70 and older sought medical care due to an injury, of which 8.4 million of these cases being fall-related (Haagsma et al., 2020). In the E.U., falls are the commonest cause of hospital attendance in older adults, accounting for more than 50% of emergency attendance in people over the age of 65 (Sant, 2018).

A common measure used by a number of countries to determine the burden of falls on the society is the DALY. The Disability-Adjusted Life Year (DALY) is a complex metric that combines premature mortality and disability into one measure. It provides a more comprehensive evaluation of the overall health impact of public health issues compared to mortality or incidence statistics alone (World Bank, 2013). It has been estimated that globally, 38 million DALYs (equivalent to 38 million years of full health) are lost each year due to falls. This can be observed in the U.K., with falls reported as the ninth- highest cause of DALYs lost in 2013, and the leading cause of injury (Haagsma, et al., 2020). Hip fractures are a common injury following falls, and short and long-term outlooks for patients are generally poor (Public Health England, 2020). An increased one-year mortality of between 18% to 33% is commonly observed in such instances, along with negative effects on daily living activities such as shopping and walking (Public Health England, 2020).

Locally, there is a lack of comprehensive data on the frequency of falls among the older population and related hospital admissions. The National Mortality Register is the only source of information on fall-related deaths for individuals aged 65 and over, reporting 42 deaths in 2013, 36 in 2014, 31 in 2015, and a peak of 46 fatalities in 2016. The number of fatalities decreased in 2017 and 2018 with 34 and 31 deaths recorded respectively (Directorate of Information and Research, 2021). No information is available on whether these falls occurred in long-term residences or in the community. No data has been recorded on the number of falls occurring amongst the older population or the number of hospital admissions following falls from 2019 to date. However, during a recent conference it was reported that in 2022 there were 62 fall-related hospital admissions, which mostly resulted in fractures (Vassallo, 2024). Moreover, Callus (2024) conducted a study on hospital emergency admissions in Malta in July 2022, revealing an average of 17 cases per day attributed to falls and syncope. The most prevalent age affected was 75 years, with 31% of cases identified as genuine accidental falls resulting from slips and trips. These numbers tend to be higher during the summer months, due to dehydration and may be lower during the rest of the year (Hussain Itthadi, 2022). Furthermore, it was disclosed that falls and syncope incur costs ranging from 2,400 to 4,000 euros per patient and a total of 9.6 million euros annually for the government of Malta. This information was presented during the latest legislative update in 2004, suggesting that these costs are likely much higher at present (Parlament of Malta, 2022).

1.2 Causes of falls in long-term institutions

Falls among older adults can be caused by various factors. Although there is no single risk factor identified as the cause of all falls, it is well known that the greater the number of risk factors a person has, the more likely they are to fall (Baixinho & Dixe, 2015).

Therefore, a multifactorial intervention is often essential in reducing falls in geriatric care. This was shown in various fall prevention programmes (Cockayne, et al., 2017; Wylie et al., 2019).

An example of this is a study conducted by Logan et al. (2021) to determine the clinical and cost effectiveness of a multifactorial fall prevention programme based on NICE falls guidelines in 2013, compared with usual care in long term care homes. This programme consisted of educating all health and non-health workers in UK care homes on multiple fall risk assessments and interventions such as footwear, exercise, and vision. This programme saw a 43% reduction in falls and a significant reduction in costs, suggesting the importance of a multi-factorial intervention in falls management.

Risk factors related to falls have been categorised into three: internal, external, and behavioural factors:

- Internal Risk Factors

Internal factors include increased frailty and dependence, higher numbers of chronic diseases such as Diabetes and urinary incontinence, polypharmacy (taking more than 4 medicines), and lack of physical activity (Woolcott et al., 2009; Tsai, et al., 2020). Increased fall risk in older adults can be partly explained by brain and cognitive ageing, in addition to muscle weakness and frailty (Rosso, et al., 2017; Woolcott, et al., 2009). Moreover, motor automaticity often reduces with increasing age; thus, making once seemingly simple and automatic tasks, such as walking, become more challenging or requiring greater conscious control (Fasano, et al., 2012).

The probability of falling increases when older adults are required to rapidly generate a postural reaction without a pre-planned motor response. Having to stop quickly, is an example of this (Liu Chan & Yan, 2014). The walking stability of older people is usually compromised, thus making a sudden change in momentum difficult (Oates et al., 2005). Moreover, differences in gait are also observed with increasing age, such as higher body sway, an increase in cadence and a shuffling gait, thus increasing the risk of falling (Mak, Young, & Wong, 2020)

- Behavioural risk factors

Behavioural fall risk factors include history of falls and fear of falling (Sharif, et al. 2019). These often lead to inactivity and a sedentary lifestyle which are risk factors for falls (Baixinho & Dixe, 2015). Poor nutrition and hydration are also risk factors for falls (Tsai et al., 2020).

- External/ Environmental risk factors

Various environmental factors are known to contribute to falls including poor lighting, uneven or slippery surfaces and loose rugs. Some older people tend to move to nursing homes, in order to feel safer due to these modified factors, which might not be present in their houses (Kumar et al., 2013). However, living in an institutional setting is an external risk factor for falls. This is because, in such settings, the nature of the physical environment, accessibility, and presence of medical professionals distinguish institutional settings from private homes. Furthermore, the suffering caused by the absence of families can by itself pose an additional risk factor (Dhargave & Sendhilkumar, 2016).

Inadequate footwear, especially when accompanied with gait irregularities, has also been identified as an environmental risk factor to falls (Liu, Chan & Yan, 2014; Davis, Haines & Williams, 2019).

1.3 The influence of footwear on balance and falls

Several studies suggested that inadequate footwear may be an additional contributing factor to falls in older adults by altering balance and stability (Kelsey et al., 2010; Davis et al., 2016; O'Rourke et al., 2020).

Footwear should enhance sensory feedback to the foot and aid in controlling postural stability through the tactile and proprioceptive systems. The cutaneous mechanoreceptors located in the plantar surface of the feet detect tactile stimulation and give information on plantar pressure distribution to the central nervous system (Liu, Chan & Yan, 2014). Conversely, inappropriate footwear can alter the somatosensory feedback to the foot and ankle, thus influencing postural stability and subsequently, the risk of falls (McLeod, 2016).

Several studies have identified footwear characteristics that affect foot sole sensitivity and gait measures and their role in balance and stability with fall prevention for older adults, under both static and dynamic conditions (Aboutorabi et al., 2016; O'Rourke et al., 2020). Many authors suggested a low heel height, good sole tread, and hard and thin midsole cushioning, as ideal footwear characteristics in the prevention of falls (Davis, Haines & Williams, 2019; Lopez Lopez & Becerro de Bengoa Vallejo, 2015).

Shoe fit is also an important consideration in the management of falls in older people. A good shoe fit is considered as having footwear with a gap of 10 to 15mm between the longest toe and the front of the shoe (Menant, et al., 2008). Although there is a general consensus that ill-fitting footwear (in terms of length and width) does affect balance and increase the risk of falling, to date, studies investigating the association between ill-fitting shoes, with balance and falls are meagre (O' Rourke et al., 2020). Lopez- Lopez et al. (2015) argued that good fitting footwear increase the stability of the foot and helps prevent slips. Ill-fitting footwear can cause functional limitations and impaired walking mobility. Moreover, ill-fitting footwear negatively influences the pressure distribution between the feet, causing imbalance (Lopez- Lopez et al., 2015).

In 2013, Borland, Hollins Martin & Locke proposed guidelines to educate nurses in nursing homes regarding appropriate footwear; nevertheless, studies have revealed that individuals residing in long-term care facilities still tend to wear inadequate footwear in terms of characteristics and fit (Barwick et al., 2019), thereby introducing an additional risk factor for falls.

1.4 Justification of the study

Working closely with older adults and frequently witnessing the consequences of falls has motivated the researcher to take a keen interest in reducing falls from a podiatric perspective. Moreover, most fall- intervention programmes often include the multidisciplinary intervention of doctors, nurses, physiotherapists, and occupational therapists (Lee & Yu, 2020). Podiatry is sometimes overlooked in falls interventions programmes; however, it has been proven to be effective in prevention of falls in older people (Najafi et al., 2013). Thus, this study attempts at providing an in-depth analysis of the relationship, if any, between footwear design and falls amongst older Maltese adults residing at a long-term facility. It is hoped that findings from this study will identify any relationships between footwear and falls, with the aim of reducing the number of falls in older adults.

Various footwear characteristics have been studied in the management of falls in older people (Jellema, et al., 2019). Although there seems to be a general consensus among researchers that a number of footwear characteristics such as heel height and inadequate fastening are detrimental to falls (Lopez-Lopez et al., 2018), research studies related to other footwear characteristics namely sole flexion point and longitudinal sole rigidity are scarce and at times conflicting and have been poorly investigated (Horgan, et al., 2009; Jellema et al, 2019).

Moreover, the effect of ill-fitting footwear (having appropriate length and width) on balance and stability in the older population still needs to be investigated, since to date, published research related to ill-fitting footwear tends to be more focused on the Diabetic population (Jones et al., 2019). Furthermore, most studies investigating the relationship between ill-fitting footwear and falls are mostly focused on measuring footwear in terms of length. While width is frequently overlooked in many studies, its significance should not be underestimated. This was demonstrated by Doi et al. (2010), where both shoe length and width were found to influence the mobility and stability of older adults. Therefore, this study will comprehensively address shoe fit in both length and width to gain a more holistic understanding.

Most research related to falls and footwear has been conducted among community-dwelling older individuals (Aboutorabi, et al., 2016; O'Rourke, et al., 2020). Research on the most vulnerable elderly living in long-term facilities is still limited. International guidelines on footwear assessment for people living in geriatric homes are limited, especially when compared to guidelines for community-dwelling older adults (Montero- Odasso et al., 2022). This gap in research is addressed in this study considering that older adults living in long-term facilities are at the most risk of falls (Baixinho & Dixe, 2015).

To this date, no studies have been conducted in Malta investigating falls related to footwear in the older population. Moreover, no information is available on footwear commonly worn by residents living in long-term residential care in Malta, and no local guidelines are available to guide healthcare workers on adequate footwear for older people. It is hoped that findings from this study will provide recommendations on the importance of adequate footwear in the prevention of falls inside Malta's largest long-term residential care.

1.5 Research Question

Does footwear design affect the risk of falling in a geriatric population at a long-term care facility?

1.6 Aims and Objectives

Aim:

To investigate the impact of footwear on the risk of falls amongst geriatric residents in a long-term care facility.

Objectives:

● To assess shoe fit and footwear characteristics typically worn among residents at a long-term elderly residence.

● To identify the prevalent risk factors for falls in a Maltese long-term care facility for older adults.

● To analyse shoe fit and footwear characteristics among elderly residents who sustained a fall during the study period.

● To evaluate the functional stability and balance of participants who sustained a fall while wearing the footwear used at the time of the incident.

1.7 Hypothesis and Null Hypothesis

A hypothesis is a tentative explanation that relates to a set of facts and is subject to testing through additional investigations (Dewitt Wallace Library, 2021). There are two types of hypotheses, namely the alternative hypothesis and the null hypothesis. The latter states that there is no significant relationship or effect between variables, which opposes the investigator's prediction. On the other hand, the alternative hypothesis proposes a specific outcome or relationship that the investigator expects or hypothesizes (Statistics Solutions, 2022).

In this study the null and alternative hypothesis were:

Alternative Hypothesis (H1): There is an association between footwear design and risk of falls in the geriatric population residing at a long-term facility.

Null Hypothesis (H0): There is no association between footwear design and risk of falls in the geriatric population residing at a long-term facility.

1.8 Dissertation Layout

• The first chapter provides an overview on falls, and the effect of footwear on balance and stability in older adults. It then leads to the rationale of this study together with its aims and objectives (Chapter 1).

• The literature review chapter provides a review of the current literature related to fall risk factors including footwear. Footwear characteristics and fit and their relationship with balance and falls amongst the older population are reviewed in this chapter. Current guidelines on fall prevention both nationally and internationally are discussed. The tools commonly used to evaluate footwear for its susceptibility to falls are also reviewed (Chapter 2).

• Research design and method chapter includes discussions on the underlying philosophical tenets guiding the research method, descriptions of participants, and ethical considerations. It also outlines the tools used and the protocols for data collection. (Chapter 3).

• Representation of participants, results displayed in tables and graph formats, along with statistical analysis are presented in Chapter 4.

• The study findings are discussed in relation to the current literature. Limitations of the study and recommendations for future research and the clinical implications of the findings are also highlighted (Chapter 5).

• A summary of significant findings and a conclusion for this study is provided in the last chapter (Chapter 6).

Chapter 2:

Literature Review

2.1 Search Strategy

A search strategy is a structured organization of key terms used to search a database. It links the vital concepts of the research question to retrieve precise and relevant results. (University of Leeds, 2023). This chapter project includes a literature search that was carried out electronically with the help of databases and search engines such as Google Scholar, HyDi, ScienceDirect, Pubmed and Cochrane Reviews. Other supporting literature such as textbooks related to statistical analysis and research methods were used to help conduct the study. Textbooks on footwear and falls in older people were also used in this study.

Reviewed studies consisted of peer-reviewed journals in their original source about falls, geriatrics and footwear. The most common searched phrases were 'footwear', 'falls', 'geriatrics', 'nursing homes', 'falls guidelines' and 'management of falls'. All original articles were read for relevance in relation to footwear in older people and their relationship with falls. When possible, studies that were outdated or were opinion based were avoided.

2.2 Introduction

This chapter begins with a comprehensive analysis of the footwear typically worn by this specific population. Subsequently, it delves into an in-depth examination of the existing literature, exploring the influence of specific footwear design including characteristics and fit on balance and fall incidents in older adults. Current studies investigating the role of footwear in fall prevention guidelines are also presented and discussed. Finally, various tools used to measure the effect of footwear on balance and stability are highlighted.

2.3 Footwear commonly worn by the older population

Understanding older people's choice of footwear is crucial in the management of falls in older people. Their choice of footwear is often complicated by contextual and personal factors (Nicholls, et al., 2018). Aesthetic preferences and financial priorities are two common influencing factors in footwear decision-making in this specific population (Davis, Murphy & Haines, 2013; Tehan, et al., 2019). Older people's choice of footwear is also prioritised differently when wearing footwear for inside the home, compared to wearing footwear outside the home. For instance, people are inclined to spend more money on their outdoor footwear than on their indoor shoes (Munro & Steel, 1999).

Numerous studies have assessed the footwear habits of older people. Bed slippers appear to be the indoor footwear of choice (Vass et al., 2015; Chari et al., 2016). Davis, Murphy & Haines

(2013) found that 48% of women aged between 60 and 80 years preferred wearing bed slippers when indoors. In their cross-sectional study, Barwick et al., (2019) found a strong association between old age and non-protective footwear such as backless slippers, flip-flops, and sandals, with odds increasing by 3% per year of age. Similarly, Barwick et al. (2019) observed that bed slippers were the most common non-protective footwear worn, however, they found a lower incidence of participants wearing bed slippers than the previously mentioned studies. A study by Tan et al. (2014) also revealed that slippers are the footwear of choice amongst people over the age of 65 years. This was followed by walking shoes, sandals, athletic footwear, and high heels. This predisposes older people to greater risks of falls, since many studies found bed slippers to be one of the factors that causes falls (Tsur et al., 2014; Jellema et al., 2019).

The likelihood of older people predominantly wearing slippers rises among older adults living in long-term facilities and hospitals (Menant, et al., 2008). As a matter of fact, about 36% of nursing home residents and 66% of patients in a subacute aged-care hospital were osberved wearing slippers indoors (Kerse, et al., 2004; Jessup, 2007). Munro & Steel (1999) explained that older people typically opt for slippers due to their soft materials and flexible structure, which can comforatably accommodate painful feet and foot deformites. However, this puts the residents at greater risk of falls, as bed slippers tend to lose their shape are associated with falls by tripping and provide an insecure base for gait (Sherrington & Menz, 2003).

The choice of footwear might also be influenced by comfort or the need to accommodate painful or swollen feet (Mickle, et al., 2007). In fact, Mickle et al. (2007) explain that for this reason, a substantial proportion of older people wear shoes that are excessively flexible or too wide or too long for their feet, which may cause slippage inside the shoe leading to falls (Doi et al., 2010).

One other aspect that determines the choice of shoe style in the older populations is practicality. Mickle et al., (2011) observed that older people prefer shoes without fixation, so as to eliminate the need to bend down to tie laces or remove straps. This can be a potential risk factor to falls, since Davis et al. (2016) found that footwear with poor fixation can lead to greater heel slippage and inadequate foot clearance during gait, which predisposes to trips.

Vass et al., (2015) observed that over 50% of older inpatients had footwear that provided minimal structure, stability and support. More than 60% had no method of fixation, and approximately 60% of footwear was more than a year old, showing signs of moderate to excess wear. When interviewed, the patients said that they opted for their current footwear as they valued the comfort and its fit (Vass, et al., 2015).

In conclusion, many older adults tend to wear inadequate footwear both indoors and outdoors. Shoes are not replaced frequently enough, probably due to a lack of awareness about the importance of safe footwear and financial constraints (Menant et al., 2008). Additionally, older people are more inclined to wear non-protective footwear such as slippers, indicating a need for behavioural change regarding footwear choices in this demographic.

2.4 The Impact of Footwear on Balance and Stability

Numerous studies have investigated the effect of footwear on balance and stability when compared to being barefoot (Horgan et al., 2009). Studies have shown that no difference was observed in standing balance and stability between barefoot or shod (Whitney & Wrisley, 2004; Arnadottir & Mercer, 2000). However, footwear was found to enhance balance and stability during walking (Menant & Lord et al., 2013; Horgan et al., 2009), thus highlighting the importance footwear plays during gait. Gait performance and velocity also increase when wearing footwear (Arnadottir & Mercer, 2000; Grey & Heneghan, 2015). This was also observed by Hollander et al. (2022), who showed that gait stability and variability; mostly gait velocity and minimal toe clearance, in older adults, are positively influenced by footwear when compared to barefoot in both indoor and outdoor conditions. In fact, gait speed has been found to be a strong predictor of falls in older adults by multiple authors (Kyrdalen et al., 2019; Dyer, Lawlor, & Kennelly, 2020).

Wearing shoes also protects the foot from uneven walking surfaces and offers better traction than bare feet, thereby lowering the risk of slipping, especially indoors (Menant & Lord, 2013).

Various footwear features have been found to facilitate or impair balance and stability during standing and gait (Menant & Lord, 2013). Menz & Sherrington (2000) have developed a tool, the Footwear Assessment Form to analyse how these features can contribute to falls in older people. Wingwood et al., (2022) also developed a tool to screen for feet and footwear-related influences on falls in older adults identified at risk of falling. These footwear features will be discussed in detail below.

Both laboratory (Davis, et al., 2016) and case reports (Kelsey, et al., 2010) have been published highlighting the relationship between footwear and falls. Studies conducted in laboratory settings have investigated gait, balance and proprioception in relation to footwear, using participants under controlled conditions (Davis et al., 2016). For instance, Davis et al., (2016) observed that wearing bed slippers reduced minimum foot clearance during the swing phase of gait when compared to Oxford shoes. This suggests a potential higher risk of falls when wearing slippers compared to Oxford shoes (illustrated in Figure 2.1). However, these conditions may not reflect conditions in real life, and thus the results may be biased and not realistic (Samek, 2019).

Case reports and case series have documented the footwear worn during falls and the faller's perceptions of whether their shoes played a role (Kelsey et al., 2010; Haines et al., 2015). However, this information may primarily indicate the most frequently worn footwear among older adults. To determine if the distribution of shoe styles worn by fallers is atypical, it is essential to gather data on the footwear worn by controls who have not experienced falls. This was done in a study published by Koepsell et al., (2004) who generated a risk estimate of falls while controls were wearing different footwear without having a direct measure of exposure.

2.5 Shoe Styles that increase risk of falls.

Shoe style is a footwear characteristic analysed in various footwear assessment forms, namely the Footwear Assessment Form (Menz & Sherrington, 2000), Footwear Assessment Tool (Barton, Bonanno, & Menz, 2009), Clinical Footwear Assessment Tool (Wingwood et al., 2022) and Feet/Footwear- Related Fall Risk Screening Tool for Older Adults (Ellis, Branthwaite, & Chockalingam, 2022). Figure 2.1 illustrates various footwear styles that will be discussed in detail in this chapter.

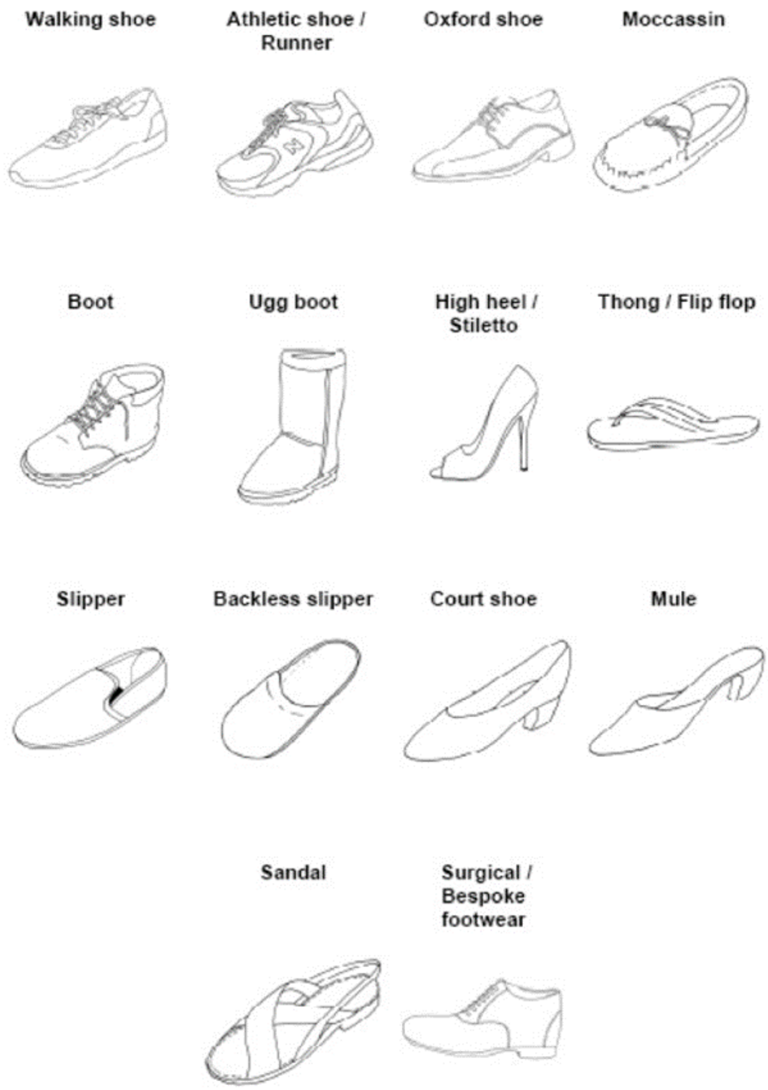

Figure 2.1 Different shoe types. From Barton, Bonanno, & Menz (2009)

- Bed Slippers

As stated earlier, bed slippers are a preferred choice of indoor footwear among older individuals (Chari et al., 2016), leading to their prevalence as the most commonly worn type of footwear during falls (Kelsey et al., 2010; Tsur et al., 2014). Studies have consistently associated slippers with fall incidents and injuries (Menz, Lord & Close, 2004; Kelsey et al., 2010; Tsur et al., 2014), with numerous researchers highlighting the risk associated with bed slippers (Najafi et al., 2013; Davis et al., 2016; Jellema et al., 2019). Koepsell et al. (2004) found a weak association between slippers and fall risk, however. Kerse et al. (2004) revealed that wearing slippers, as opposed to soft-soled shoes, increased the risk of falls-induced injures in older individuals. Additionally, Sherrington and Menz (2003) observed that bed slippers were predominantly worn by participants who had experienced tripping incidents.

It is worth noting that despite the numerous studies associating bed slippers with falls, few authors have explained the mechanism leading slippers to falls. Menz et al. (2001) explained that bed slippers have very thin soles and do not offer enough support during walking. Moreover, some people tend to stand on the back of them, causing instability. Munro & Steele (1999) have noted that although slippers are convenient to slip on and offer comfort, they often lose their shape and commonly feature slippery vinyl soles, which can result in an unstable base for walking. Davis et al. (2016) observed that bed slippers reduce minimum foot clearance during gait, thus increasing the risks for trips.

- High Heeled Shoes

Several studies have demonstrated that high-heeled shoes pose a fall risk factor, particularly in older women (Koepsell et al., 2004; Keegan et al., 2004; Guidozzi, 2017). High-heeled footwear was not a common footwear style observed to be worn by older women at the time of fall, since it is not the footwear of choice commonly worn by this demographic (Sherrington & Menz, 2003). However, this does not mean that wearing high-heeled shoes does not contribute to the risk of falling. Koepsell et al., (2004) revealed that when compared to other non-athletic footwear such as sandals, high-heeled shoes were strongly associated with falls. While this study (Koepsell et al., 2004) reported a strong trend between falls and high-heeled shoes, others have criticised it for having a low statistical power, thus indicating a Type 1 error, meaning a false positive result (Davis, Haines & Williams, 2019). However, this study wasn’t the only one to associate high-heeled shoes with falls. High-heeled shoes have been found to cause lateral instability and reduce stride length in laboratory studies, thus increasing the risks of falls (Hapsari, Xiong, & Yang, 2014). Chien, Lu & Liu (2014) noticed that when individuals were walking in high-heeled shoes they exhibited a shorter stride length and a more cautious walking pattern, than when walking in flat shoes, indicating reduced balance and stability.

- Flip-Flops

Flip-flops were not investigated in case report studies, possibly because they are not usually worn by older adults (Davis, Haines, & Williams, 2019). However, flip-flops were investigated in various laboratory-based studies. A lower foot clearance, especially by the hallux was observed when subjects were wearing flip-flops, which could increase the risk of tripping over uneven ground or climbing stairs (Sharpe et al., 2016). In fact, Sharpe et al., (2016) noted that during gait, there was an 8.8 cm separation at the heel during pre-swing and lower minimum clearance during mid-swing, thus increasing the risk of falls. Moreover, Shroyer & Weimar (2009) and Price et al. (2014) showed that walking in flip-flops resulted in increased dorsiflexion, a reduced stride length, a shorter stance time, and a smaller braking ground reaction force impulse. These changes in gait are all related to an increased risk of falling (Shimada, et al., 2012).

- Sandals

Studies on the relationship between sandals and falls have shown conflicting results, with some studies suggesting a potential association between wearing sandals and an increased risk of falls (Brenton- Rule, et al., 2014), while others have not found a significant correlation (Tencer et al., 2004). Keopsell et al. (2004) studied various footwear types and their relationship with falls, however, they failed to mention any effect sandals have on falls. Sherrington & Menz (2003) noticed that sandals were worn by 8% of older women at the time of fall, however, they failed to mention whether sandals increased the risk of falling. On the other hand, Keegan (2004) reported that sandals increased the risk of foot fracture from a falling.

Sandals may impair balance due to their footwear characteristics, including minimal heel counter stiffness and inadequate motion control (Brenton- Rule, et al., 2014). There are variations in sandal design which include backless, open-back and closed-back (Branthwaite & Chockalingam, 2019). Closed-back sandals are thought to be the safest sandals when it comes to falls since a rigid heel counter has been found to be vital in rear foot control and in providing mechanical support to the foot (Alcantara, Trudeau, & Rohr, 2018).

Apart from footwear styles, other footwear characteristics have been studied in relation to falls as described below.

2.6 Footwear characteristics associated with risk of falls in the older population.

2.6.1 Heel height and width

Research has shown that high heels elevate and shift the centre of mass forward, thus affecting balance and lead to postural and kinematic adaptations (Chien, Tung-Wu, & Liu, 2013). In fact, Tencer et al., (2004) have shown that heel elevation is associated with an increased risk of falls in older people, whilst Menant et al., (2008) noticed that shoes with heels higher than 2.5cm increased the risk of falls during walking by 1.9-fold when compared to athletic shoes.

Laboratory studies have noted changes in spatiotemporal parameters of gait, including a slower gait, shorter stride length, and increased walking cadence, when wearing high heeled shoes, compared to low, bevelled heeled shoes (Cronin, 2014; Yong Chew, Tan & Chan, 2017). Alsubaei (2020) has linked these changes in gait to a reduction in balance and stability in older people. Menant et al. (2008) observed how shoes with elevated heels were rated to be significantly less comfortable and less stable compared to standard shoes. Participants in this study adopted a conservative walking pattern and showed a reduction in postural stability and alteration of the centre of mass. Chien, Tung-Wu & Liu (2013) observed that high and narrow heels reduce the subjects' base of support during gait and also reduce the frontal and sagittal rate of change of inclination angles during double leg stance. Thus, this led to the subjects using a more conservative strategy for balance control, as also observed by Menant et al. (2008). Moreover, Tencer et al. (2004) observed how older individuals walking in high and narrow heels needed a smaller mediolateral perturbation in order to lose balance, and thus a smaller critical tipping angle of the high-heeled shoe is needed for a fall to occur. Also, Park, Park & Park (2019) have described how narrow and high heels increase the peak utilized coefficient of friction during gait, thus increasing the potential for slipping.

Various authors have described different heel heights that could be responsible for causing a lack of balance and stability in individuals of various ages (Menant et al., 2008; Lindemann et al., 2003; Xiong & Hapsari, 2014; Vass et al., 2015). However, there is a general consensus that in the prevention of falls in older people, heel heights should not exceed more than 2.5cm (Tencer et al., 2004; Keegan et al., 2004; Menant et al., 2008).

In summary, heels higher than 2.5cm are associated with instability and falling by shifting the body's centre of pressure, leading to injuries such as fractures and ankle sprains (Chien, Tung-Wu, & Liu, 2013; Sherrington & Menz, 2003).

2.6.2 Flexible heel counters

Studies have shown that heel counter stiffness is an essential footwear characteristic that is vital to improved stability during gait (Menz & Sherrington 2000; Barton, Bonanno & Menz 2009).

In a retrospective study carried out by Sherrington & Menz (2003), it was noticed that 43% of older individuals who sustained a fall-induced hip fracture, had shoes with excessively flexible heel counters. Similarly, Hourihan et al., (2000) reported that 68% of older adults who were admitted to hospital following a fall-induced hip fracture also had shoes providing minimal heel counters stability at the time of fracture. Contrastingly, Menz, Morris & Lord, (2006) found no significant associations between structural footwear characteristics, including heel counter stiffness, and falls in older people residing in a retirement village. This might be attributed to the study's methodology, which was retrospective, or to the specific balance assessment tests employed.

Laboratory studies were carried out to provide a more valuable insight into cause-and-effect relationships on this subject. Menz, Auhl & Munteanu (2017) carried out a series of tests of balance ability and gait patterns when the participants were wearing their own footwear, flexible footwear and experimental footwear (having a stiff heel counter as one of its main features) designed to improve dynamic balance. It was noted that when wearing the experimental footwear, the step width and sway reduced siginficantly when compared to the other footwear, indicating better balance control. However, there was no difference in limits of stability or gait patterns between the footwear conditions. This may be attributed to the fact that the flexible footwear used in the study lacked features known to promote balance, whereas the participants' own footwear, was generally considered adequate, with many wearing athletic or walking shoes (Mnez, Auhl & Munteanu, 2017), which are known to be associated with the lowest falls risk (Keopsell, et al., 2004).

2.6.3 Lack of footwear fixation

Various studies have showed that inadequate footwear fixation (fastening) due to the absence of dorsal fixation can significantly increase the risk of falls in older people (Sherrington & Menz, 2003; Davis, et al., 2016).

Sherrington & Menz (2003) reported that falls by tripping were the most common kind of fall induced by footwear with a lack of fixation. They have explained that shoes that lack fixation are more likely to separate from the feet during gait and thus, tend to promote a shuffling gait.

In fact, during their study, two of the participants who fell and were wearing shoes without fixation attributed their shoes for the fall. One participant said that her shoe slipped off, causing her to trip over it and the other said that her slipper 'got stuck' and caused her to lose balance. Fall-induced hip fractures were commonly observed in individuals wearing footwear with lack of fixation. This was observed in 63% of patients in a study by Sherrington & Menz (2003) and 22% of inpatients in a study by Keegan et al. (2004). Furthermore, Keegan et al. (2004) found that shoes without fixation were linked with a greater risk of a foot fracture from a fall (with an odds ratio of 2.3).

This is supported by a series of laboratory studies. Davis et al., (2016) described that footwear with poor fixation can lead to inadequate foot clearance during gait, which predisposes to trips. They observed that when compared to their well-fixated counterparts (footwear where the heel is secured with a strap and not slipping out of the shoe during gait), the less-fixated footwear caused greater heel slippage (by 19%), along with other spatiotemporal gait changes, such as a slower gait speed, which is a strong indicator of gait instability (Dyer, Lawlor, & Kennelly, 2020). This study though is not without limitations. This study did not specifically investigate how footwear fixation or foot clearance relate to falls among its participants. This is because the differences in footwear assessed were not limited only to dorsal fixation; rather, other features like material and midsole were also different. Moreover, this study did not directly examine the relationship between footwear fixation or foot clearance with falls, meaning that this study might not reflect the conditions in real life. It is possible that older individuals wearing securely fitting footwear may feel more confident and attempt activities that are perceived as riskier compared to when they wear less secure footwear. This phenomenon, known as risk compensation, has been described by Haines et al. (2015). It suggests that behaviors influenced by perceived safety could potentially undermine interventions designed to reduce the risk of falls in real-life situations.

Hida et al. (2021) suggest that poor fixation increased the variability in the knee and ankle joint angles during gait, which may subsequently impair balance and increase the risk of falls (Kobayashi et al. 2014). As opposed to Davis et al. (2016), Hida et al. (2021) did not find any difference in spatiotemporal parameters when participants were wearing different shoe conditions. This could be due to a number of reasons. The sample size (20 participants) was small, and they had no history of falls. Also, Hida et al. (2021) compared footwear which differed in some other characteristics such as heel counter rigidity and weight. These characteristics could have affected gait and joint angle results.

From the reviewed literature, the studies by Menz, Morris & Lord (2006) and Horgan et al. (2009) are the only ones who found no associaton between footwear fixation and falls. These studies, however, found no relationship between falls and all the other footwear characteristics studied (such as heel height and sole flexion point). The absence of differences noted in footwear characteristics could be attributed to the authors' decision to compare with the control group's most commonly worn footwear, assuming these shoes were also worn by participants at the time of their falls.

There seems to be a general consensus that good dorsal fixation is important in the prevention of falls in older people. However, information on what is thought to be a good footwear fixation modality is scarce. Menant et al. (2008) recommend lace-up shoes and Maden et al. (2021) consider straps, Velcro and laces as the best ways to provide good fixation, however, they do not explain the reasoning behind this. Other authors do not provide information on different types of footwear fixation. Thus, studies comparing different kinds of footwear fixation with balance and gait are recommended.

2.6.4 Tread Pattern

Slips and trips are the most common cause of falls in older adults, with slips making up 17% of falls in community-dwelling adults over the age of 70 (Kobayashi et al., 2014). Footwear tread pattern has been found to be directly related to slips, by affecting friction, especially in slippery or wet ground conditions (Liu et al., 2013).

Menant et al. (2009) observed that in certain situations, such as on visibly slippery surfaces, older individuals adapt their walking patterns, thereby reducing the required coefficient of friction. Shoes with a treaded sole perform well in these instances. However, when older adults are unaware that the floor is slippery, having greater friction between the sole and the floor becomes more essential. Worn-out or smooth treaded soles put an individual at greater risk of falls especially in wet or icy road conditions (Liu et al., 2013; Menant et al., 2008).

Contrarily, Menant et al., (2009) found that textured shoes did not enhance stability compared to smooth-soled shoes regardless of the participants age, when walking or stopping on a wet surface. This could be attributed to the participants' anticipatory adaptations to the wet, slippery surfaces, which obscured the anticipated effects of the textured sole shoe in comparison to the smooth-soled shoe.

While adequate slip resistance is necessary when walking on potentially slippery surfaces, excessive foot-floor grip may also increase the risk of falls among older adults. Indeed, Menz et al. (2006) prospective study in an older retirement village found that five fallers believed their falls were caused by their shoe getting 'stuck' to the ground. This suggests that excessive slip resistance might contribute to trips and falls. For older adults with a shuffling gait, such as those with Parkinson’s disease, too much friction between the shoe and walking surface can compromise stability. In these cases, a smoother surface may be more beneficial because a shuffling gait typically involves low toe clearance, increasing the risk of tripping on an uneven or highly slip-resistant surface. (Menant & Lord, 2013)

In summary, numerous studies have shown that when compared to smooth outer soles, textured soles provide the most friction and reduce the occurrence of slips in older people (Li & Chen, 2004). On the other hand, excessive slip resistance can cause trips, especially in people exhibiting a shuffling gait (Menant & Lord, 2013). Studies evaluating the effect of a partially and a fully worn tread pattern on friction and falls in older people (as mentioned in the Footwear Assessment Form and Footwear Assessment Tool) are still limited though.

2.6.5 Thick, soft soles

Numerous studies have investigated the effects of midsole hardness on stability in older individuals (Menant et al., 2009; Hatton et al., 2012).

Studies suggest that the use of thick, soft midsoles may compromise stability by reducing afferent feedback from the sole of the foot (Hatton et al., 2012). This is because footwear with a soft sole (less than shore A-30) can compromise balance control during ambulation and can interfere with propioception and contribute to instability (Losa Inglesias, Becerro de Bengoa Vallejo, & Palacios Pena, 2012).

Menant et al., (2008) studied footwear having the same design but different shoe features including sole hardness, during dynamic ambulation in both young and older participants, when walking on even and uneven surfaces. It was noted that mediolateral balance was compromised in shoes having a soft sole, for both the young and older participants. Furthermore, Perry, Radtke, & Goodwin (2007) investigated balance control in participants performing tests of rapid unplanned stopping when wearing midsoles of different hardness. When compared to the hard midsoles (A-50), the soft midsoles (A-15) significantly reduced the mediolateral range of the centre of mass (COM) displacement. This, along with a significantly greater vertical loading rate noted when using soft midsoles, shows how softer midsoles may compromise balance control in the sagittal plane during stopping. Therefore, Perry, Radtke & Goodwin (2007), concluded that footwear with soft soles may threaten an older individual's stability due to an increased demand for muscular activity, which is needed in order to maintain stability during stopping.

It is worth noting that the slip resistance of footwear is also influenced by the hardness of the sole. Initially, it was thought that harder-soled shoes had less friction and were riskier for slips (Redfern & Bibanda, 1994). However, McCaw, Heil, & Hamill (2000) found that harder soles increased stability by affecting vertical forces during walking. Similarly, a more recent study by Tsai & Powers (2009) suggested that hard-soled shoes reduce the need for friction during the initial phase of walking. This might be because people adjust their gait to reduce friction when they perceive their shoes as slippery. Thus, the relationship between sole hardness and slip resistance is more complex than originally thought.

In summary, laboratory studies have shown that balance during standing does not appear to be affected by sole or midsole hardness (Whitney & Wrisley, 2004). However, thick and soft soles have been shown to compromise stability during walking by reducing foot proprioception and mechanical stability (Perry, Radtke, & Goodwin, 2007). These can impose an even greater threat to stability during challenging tasks, such as walking on uneven surfaces (Menant, et al., 2009).

While there is a general consensus between authors that the above-mentioned footwear characteristics increase the risk of falling, other footwear characteristics have been scarcely studied and are occasionally inconsistent. These characteristics are discussed below:

2.6.6 Sole Flexion Point

One footwear characteristic that has been somewhat overlooked is the location of the shoe sole's flexion point in the sagittal plane. It is generally assumed that the sole flexion point should preferably be directly underneath the metatarsophalangeal joints (MTPJs), and that flexion points located more distally may increase the risk of falls (Barton, Bonanno, & Menz, 2009), however, no studies have evaluated this assumption. The location of the ideal sole flexion point as described by van der Zwaard et al. (2014) is shown in Figure 2.2.

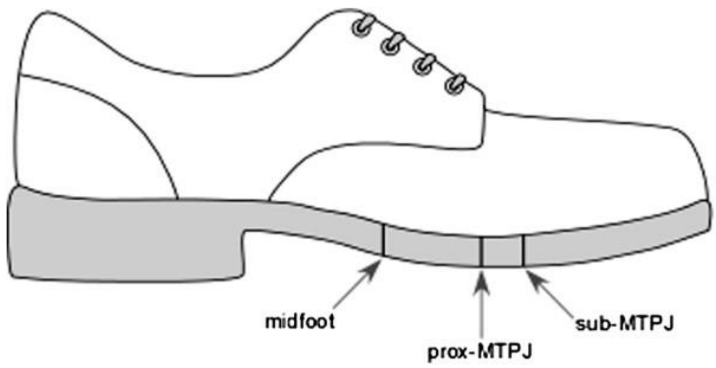

Figure 2.2 Ideal location of the sole flexion point; directly underneath the MTPJS (sub-MTPJs). From van der Zwaard, et al., 2014.

Menz & Sherrington (2000) and Barton, Bonanno & Menz (2009) included the assessment of the sole flexion point in the evaluation of footwear as they believe that a flexion point distal to the 1st metatarsophalangeal joint (MPJs) could compromise the shoe's stability, thus predisposing the wearer to falls.

Moreover, it is thought that a flexion point distal to the level of the 1st MPJ may compromise gait efficiency due to altered kinematics which results from inhibition of normal 1st MPJ function (Hall & Nester, 2004). Such altered kinematics include reduced ankle dorsiflexion during propulsion, a more flexed knee during midstance and a less extended hip during midstance (Hall & Nester, 2004). These altered kinematics have been found to be responsible for falls in older people (Goes et al., 2015; Kerrigan et a, 2011). Moreover, Hall & Nester (2004) and Van der Zwaard et al., (2014) hypothesized that a flexion point distal to the level of the 1st MPJ may disrupt a normal toe-off due to changes in the windlass mechanism during propulsion. Falls due to tripping have been associated with delayed foot clearance due to a disrupted toe-off (Begg et al., 2007).

Furthermore, a case study carried out by Menz, Morris & Lord (2006) and Horgan et al. (2009) found no significant associations between structural footwear characteristics, including sole flexion point, and falls in older adults living in a long-term institution. However, no other footwear characteristics showed any significant association in both studies, which could indicate a limitation in the study design, or tests used.

In summary, research pertaining to the association between the outer sole flexion point and falls in older individuals is scarce and occasionally inconsistent. While studies suggest that the ideal location of the flexion point should be directly under the metatarsophalangeal joints (MTPJs) (Barton, Bonanno, & Menz, 2009), this aspect has not been thoroughly examined through direct evaluation.

2.6.7 Longitudinal Sole Rigidity

Longitudinal sole rigidity is another footwear characteristic that has been relatively unexplored concerning its relationship with falls. Menz & Sherrington (2000) have included it in the Footwear Assessment Form, measuring it on an arbitrary 45° scale, as they believe that a flexible sole may pose a risk for falls in older adults. Barton, Bonanno, & Menz (2009) also believe that since the midfoot is required to form a rigid lever during propulsion, footwear stability in this area is an optimal motion control property.

However, other authors disagree with the above-mentioned studies. Reints et al. (2017) noted that footwear with a high longitudinal sole rigidity (footwear that flexes less than 10° relative to the horizontal plane), limits metatarsophalangeal joint movement and therefore, the hallux contribution to gait. This can increase the predisposition to falls as described in section 2.6.6. However, Willwacher et al., (2013) argue that a rigid sole, shifts the application of the ground reaction force more distally, causing an increased ankle plantarflexion moment, as illustrated in figure 2.3. A study by Bok, Lee & Lee (2013) showed that increased ankle plantar flexion moment was significantly correlated with improved balance stability in older people.

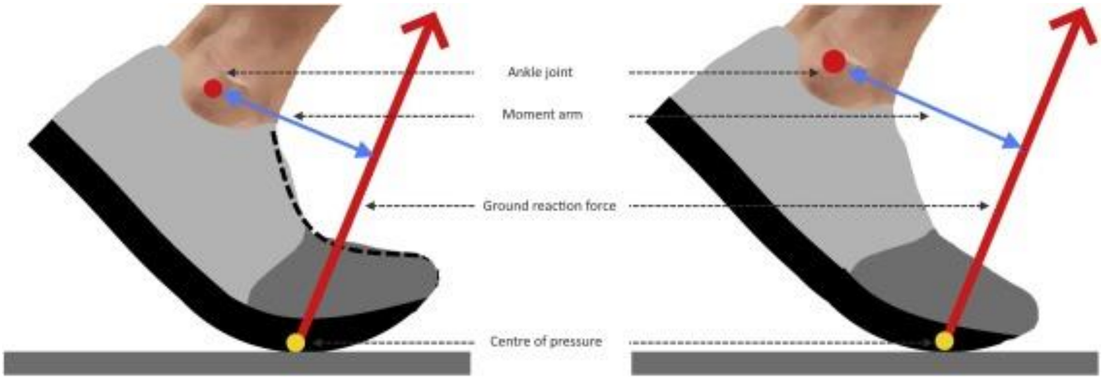

Figure 2.3 Schematic view comparing shoes with a low longitudinal sole rigidity (left) with shoes with a high longitudinal sole rigidity (right) during the push-off phase of gait. The ground reaction forces (red arrow) move more distally in the right shoes. From Willwacher et al., (2013)

These studies show that studies focusing on the relationship of the footwear outer sole rigidity with falls conflict with what Menz & Sherrington (2000) and Barton, Bonanno, & Menz (2009) hypothesized. More studies on this topic are needed, as the current studies are conflicting and limited.

2.7 Shoe fit and its effect on balance

Shoe fit and its effect on balance and falls is another aspect of footwear which has not been thoroughly investigated. Ill-fitting footwear, as described by Branthwaite & Chockalingam, (2019) can encompass shoes that are either too large with a sloppy fit in terms of length and width, or too small and cramped, resulting in a tight fit. However, ill-fitting footwear extends beyond just size to include shoes that hinder normal foot function and alter gait patterns (Buldt & Menz, 2018). However, ill-fitting footwear could be extended beyond length and width to include shoes that hinder the normal function of the foot and cause an altered gait pattern because of the shoe (Branthwaite & Chockalingam, 2019). For the scope of this study, ill-fitting footwear is defined as footwear being too small or too big in terms of length, depth, and width.

Evidence suggests that with age, feet get broader in the forefoot region and longer due to the flatting of the medial longitudinal arch (Echeita et al., 2016). Furthermore, older people are more prone to having foot deformities including hammer toes and hallux valgus (Menz, 2015). These differences in foot morphology may pose a problem for shoe fitting as most shoes are not designed to accommodate irregular bony deformities (Luximon, Goonetilleke & Tsui, 2003).

There is a general consensus that many older adults, regardless of their living situation, wear ill-fitting footwear. (Burns & Leese, 2002; Menz & Morris, 2005; Lopez Lopez & Becerro de Bengoa Vallejo, 2015), which may lead to foot problems, pain and loss of balance, thus increasing the risks of falls (Awale, et al., 2017). For instance, Burns et al. (2002) observed that 72% of older people admitted to a rehabilitation centre were wearing poorly-fitting shoes, with 90% of these shoes being identified as either too long or too wide. Similarly, Doi et al. (2010) observed that 86% of a sample of older adults living in the community wore shoes that were too loose, especially in the rearfoot region. Guidozzi (2017) suggested that older adults often choose wide or long footwear to accommodate painful feet. Menz & Morris (2005) also found that residents living in older term care wore poorly fitting indoor and outdoor shoes (81% and 78% respectively). They found a large degree of difference between shoe and foot dimensions, with participants wearing shoes 12mm shorter and 30mm narrower than their feet. Lopez Lopez & Becerro de Bengoa Vallejo (2015) measured foot and shoe size in a sample of 100 community-dwelling older adults. They revealed that only 17 participants used good-fitting shoes. Contrastingly, Vass et al., (2015) found that out of 291 inpatients over the age of 65, the majority of footwear had a good fit in terms of length (63%), width (68%), and depth (72%). However, this study fails to explain what methods were used in order to evaluate shoe fit. These findings are concerning since there is a general consensus that ill-fitting footwear can be responsible for falls in older adults (Branthwaite & Chockalingam, 2019; O'Rourke, et al., 2020).

Ensuring good- fitting footwear for older adults is often a complex task. Chantelau and Gede (2002) suggest that this difficulty arises because the footwear industry currently lacks the ability to design and manufacture shoes that effectively conform to the three-dimensional morphology of all feet. Foot morphology varies greatly between individuals, yet there is limited variety in the shapes of lasts used to construct footwear (Luximon & Luximon, 2009). Moreover, footwear selection is also influenced by qualitative factors such as comfort and convenience (Nicholls et al., 2018). This could explain why the majority of older adults, irrespective of their dwelling status were found to be wearing ill-fitting footwear in the mentioned studies.

Studies focusing on the relationship between ill-fitting footwear in older adults and falls are not as common as on the relationship between footwear characteristics and falls. However, there is a general consensus that ill-fitting footwear can be responsible for falls in older adults (Branthwaite & Chockalingam, 2019; O'Rourke, et al., 2020). Footwear fit is included in the assessment of footwear in various footwear tools (Barton, Bonanno, & Menz, 2009; Ellis, Branthwaite & Chockalingam, 2022; Wingwood et al., 2022), thus highlighting the importance footwear fit plays during gait and in the management of falls.

Menz & Lord (1999) have argued how improper shoe fit can lead to pain, functional limitations, and falls in the older population. Doi et al. (2010) explain that ill-fitting shoes that are too tight in a particular foot region are likely to alter the mechanical loading transmission between the foot and the shoe, which in turn increases the risk of falls (Blazer, Jamrog, & Schnack, 2018). Furthermore, if there is an area in the shoe that is too loose, the foot may be unstable at that point, potentially causing unfavourable slippage inside the shoe during the stance phase of walking. (Doi et al., 2010).

During case studies, Menant et al. (2008) and Blazer, Jamrog & Schnack (2018) have linked trip-related falls to wearing slippers or ill-fitting shoes (particularly shoes that are too long) in an older population. Also, Keegan et al. (2004) found that wearing ill-fitting shoes increased the risk of tripping and consequential fractures at five sites in the lower limb in middle and old-aged people. O'Rourke et al. (2020) carried out a retrospective study in an outpatient geriatric clinic, and it was noticed that a large percentage (56%) of individuals who wore ill-fitting footwear reported a recent fall, compared to those who wore good-fitting shoes (39%), thus highlighting the importance of wearing good-fitting shoes.

Laboratory studies have shown that shoes that are too loose produce a slower gait, shorter stride length, and a less regular gait pattern (Jellema et al., 2019). Doi et al., (2010) investigated the correlation of shoe fit with gait parameters in community-dwelling older people and concluded that shoe fit affects gait. Older people wearing ill-fitting shoes were also noted to walk more slowly and had a shorter stride length than those wearing well-fitting shoes. These changes in gait are all associated with a reduction in balance and stability in older people (Alsubaei, 2020). Doi et al. (2010) explained that loose footwear can lead to foot slippage inside the shoes during the stance phase of walking, along with an uneven contact between the foot and shoe. They concluded that loose-fitting shoes contribute to regional instability, which likely impacts gait (Doi et al., 2010).

Lopez Lopez & Becerro de Bengoa Vallejo (2015) explain that wearing shoes of the incorrect size corresponds with lack of foot sensitivity, a phenomenon which is a major contributor falls. Amiez et al., (2021) conducted a series of balance tests in older people when wearing their personal shoes and ‘balance shoes,’ which consisted of shoes having a good fit and a rigid heel counter. It was noted that wearing shoes of the correct fit, improved postural balance in some situations, particularly in the most difficult conditions such as when bipedal with eyes closed. However, apart from good fit, the balance shoes had other good characteristics which may not have been present in the participants' usual shoes, such as a rigid heel counter. Therefore, wearing good-fitting shoes alone, might not be directly associated with improving postural balance.

Ill-fitting footwear has also been strongly associated with foot pain and foot deformities (Buldt & Menz, 2018). Consequently, foot pain and deformities have been linked to high risks of falls in older people (Awale, et al., 2017). Therefore, ill-fitting footwear can be an indirect contributor to falls in older people by causing foot deformities which can be detrimental to balance and normal gait (Guidozzi, 2017). Studies seem to agree that ill-fitting footwear can be a precursor to falls, however, more studies specifically on the effect of inadequate shoe length and width on falls are beneficial.

2.8 The effect of adequate footwear on fall prevention

Oxford shoes and walking shoes are often recommended by authors as they are associated with the lowest risk of falls (Keopsell et al., 2004). Menz, Lord & McIntosh (2001) demostrated that when compared to ladies' slip-on shoes, Oxford shoes having a tread sole and a treaded, bevelled heel provide enough slip resistance for walking over dry and wet surfaces. Kelsey et al. (2010) observed that while Oxford shoes were the second most commonly worn footwear in older adults, they were not commonly worn in older adults at the time of fall, thus they were not found responsible for causing falls in older people. Furthermore, walking shoes have several shoe features such as a firm midsole, bevelled heel, firm heel counter, and an outer sole with a good tread pattern, which have been found to be detrimental in reducing falls in older adults (Jellema et al., 2019). Keopsell et al. (2004) discovered that walking shoes decrease the risk of falls by 8 to 11 times when compared to being barefooted.

Nonetheless, shoes with adequate fixations, having a low, wide heel provide the most balance and stability in older individuals (Jellema et al., 2019). Various authors recommend firm and high heel counters in shoes for older people as they are essential in falls prevention by promoting good stability of the rearfoot and reduced shoe slip whilst walking (Jellema, et al, 2019; Menant, et al., 2008).

Shoe soles of medium hardness (shore-A40) provide optimal balance in older adults when performing functional balance and stepping tests and when walking and stopping on different surfaces (Menant & Lord, 2013). On the other hand, Hatton et al. (2012) and Losa Iglesias, Becerro de Bengoa Vallejo & Palacios Pena (2012) have suggested footwear with a hard sole (shore-A50), as opposed to Menat & Lord (2013), who suggested medium density hardness. The suggested footwear characteristics are illustrated in figure 2.4 below.

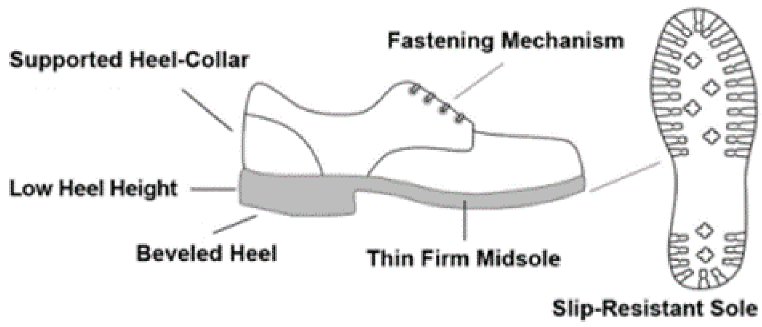

Figure 2.4 Recommended shoe features for older adults. From Menant et al., (2008).

In contrast, older adults should be discouraged from wearing heels higher than 2.5cm due to their detrimental effects on balance and gait patterns (Menant et al., 2008). Moreover, high heels have been reported to cause lack of comfort and stability (Jellema et al., 2019). Since shoes having a soft sole (less than shore A-33) can impact balance control during gait, older people should also be adviced to wear thin, hard- soles shoes for better propioception. Additionally, a treaded sole can help prevent slips on wet and slippery surfaces (Menant et al., 2008).

Given these footwear recommendations by various authors, it is expected to have thorough guidelines on footwear with the aim of providing more stability and balance to older people and thus reducing their risk of falls. Nevertheless, it is worth noting that some of these essential footwear attributes, as well as the importance of proper footwear fit, are occasionally overlooked or omitted in fall prevention guidelines. This will be further discussed in the section below.

2.9 Measures and Guidelines for Falls Prevention

Reducing fall risk among older adults has been a long-standing public health objective for years (Sattin, 1992). There are multiple guidelines focused on fall prevention in older people (CDC, 2017; Eckstrom et al.; 2012), but footwear as a risk factor for falls has been given little importance by some of these guidelines, as discussed below.

The Centre for Disease Control and Prevention (CDC) formed a coordinated care plan to lessen falls in older adults (CDC, 2017). This involved the introduction of the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) toolkit in the American and British Geriatric Societies with the aim to support healthcare providers in their efforts to meet the demand for effective fall prevention practice (CDC, Falls Risk Factors Checklist, 2017). The STEADI Toolkit contains an algorithm providing a detailed approach for screening and assessment procedures while guiding clinical interventions based on each individual's level of risk (Neville, Nguyen, & Wingwood, 2019). This algorithm includes the directive to 'assess feet/footwear' and general recommendations, which include assessing for 'footwear without good arch and heel support' and 'sturdy soles with good grip'. It also suggests assessing for foot conditions such as foot deformities that may alter balance and stability. If the individuals are classified as being at risk of falls it is then recommended to educate them on shoe fit, insoles and heel height (Eckstrom et al., 2021). Wingwood et al. (2022) created a screening tool based on this toolkit, after they criticised it for having limited guidance for screening and assessing feet and footwear- related risk factors. This screening tool aims to guide healthcare providers identify impairments or functional limitations related to feet or footwear that could increase the risk of falls in older adults. Although this tool mainly focuses on foot impairments and footwear characteristics, these are limited to avoiding walking barefoot or in socks, wearing heels higher than 2.5cm, wearing sandals, flip flops and slippers, and wearing of shoes that do not fit well. However, previous studies have demonstrated that several other footwear characteristics such as heel counter stiffness (Menz, Auhl, & Munteanu, 2017), sole hardness and footwear fixation (Davis et al., 2016) are detrimental to falls, which are not mentioned in this tool.

The World Falls Guidelines (WFG) were created in 2019, after the introduction of the STEADI toolkit, to provide other guidelines, which are independent to those proposed by the CDC, as mentioned above. These guidelines are the latest developed to date and are designed for healthcare professionals and others working with older adults in community and long-term care settings. They offer guidance on identifying and evaluating fall risk factors, as well as determining necessary interventions for a patient-centred approach (Montero-Odasso, et al., 2022). The proposed guidelines contain more limited information than the STEADI toolkit, on footwear assessment as they only recommend screening for foot problems and 'potential inappropriate footwear including barefoot walking and referral to a podiatrist' (Montero-

Odasso, et al., 2022). However, these guidelines do not explain what inappropriate footwear consists of and when referral to a podiatrist is necessary.

Guidelines on fall management for long-term care facilities are more thorough than for community-dwelling older adults. The National Guideline Clearinghouse (2009) published several proposals necessary to the successful implementation of a fall prevention program in elderly homes. They recommend assessing fall risk on admission and after a fall. However, the WFG guidelines (same as mentioned above) strongly recommends not to perform fall risk screening to identify residents at risk for falls since all residents should be considered at high risk of falls. However, a comprehensive multifactorial assessment at admission should be conducted to identify all fall risk factors and to implement the necessary interventions to reduce falls and fall- related injuries (Montero-Odasso, et al., 2022). Conversely, guidelines for older people living in the community advice on yearly screen or screening after an acute fall (CDC, 2017).

Footwear assessment is almost never mentioned in guidelines for nursing homes (McCarthy, Adedokun, & Fairchild, 2023; Montero-Odasso, et al., 2022). The National Guideline Clearinghouse (2009) recommends that nurses include strength training exercises in fall intervention program. Other recommendations include medication reviews and environmental modification such as examination for wet areas, clutter and poor lightning. Footwear was not included as an environmental fall hazard in these guidelines (McCarthy, Adedokun, & Fairchild, 2023). The World Falls Guidelines (WFG) recommend assessment and interventions that are mostly focused on vitamin D deficiency, medications, and supervised exercises. At no point is footwear assessment recommendation mentioned in these guidelines. Schoberer et al., (2022) developed clinical practice guidelines to avoid falls and their consequences in long-term facilities following 79 controlled trials on fall prevention. These guidelines strongly recommended multifactorial interventions, body exercises interventions, education and counselling interventions. Wearing bed slippers was considered as an extrinsic risk factor, however, no other reference to footwear was mentioned in these guidelines.

Although Malta does not follow any of the published guidelines, informal and unstructured guidelines have been published in a couple of papers to raise awareness on fall prevention (Calleja, 2009; Zammit, 2013; Sant, 2018). These papers highlight various risk factors related to falls, and inadequate footwear, namely, high-heeled shoes, flip-flops and shoes with thick, heavy soles (Zammit, 2013; Sant, 2018), which are similar to international guidelines as discussed above. A Falls Prevention Task Force was set up by the government in 2009 to raise awareness about the dangers of falls in the elderly and the serious effects it has on their lives (Malta Independent, 2010). The task force was composed of health professionals, including nurses, geriatric consultants, physiotherapists and occupational therapists. An information leaflet was produced and distributed to the elderly in various day centres for older people who regularly organized education sessions and gave presentations regarding the prevention of falls for older people within their home and community. The leaflet and presentations focused on environmental fall risk factors present at home such as curtains, slippery surfaces, and loose carpets. Footwear, particularly bed slippers was also considered as a fall risk factor, and supportive footwear with a non-slip sole was recommended (Aquilina, 2023). Unfortunately, the task force became obsolete a few years later (Powell, 2023).

2.10 Tools commonly used to assess footwear

While addressing footwear guidelines for fall prevention is crucial, it is equally important to consider the tools used for assessing footwear. These assessment tools play a vital role in ensuring that the recommended guidelines are effectively implemented and that the footwear choices are optimized for older individuals to enhance their stability and balance while reducing the risk of falls.

Health professionals and researchers require a valid and reliable assessment tool to conduct accurate and comprehensive assessments of an individual’s footwear. Footwear assessment involves evaluating the suitability of a patient's footwear (Tsekoura & Sakellari, 2021), and the most common footwear assessment tools are mentioned in table 2.1 and discussed in more detail below.

Table 2.1 Different footwear assessment tools.

Tool	Targeted Population
Footwear Checklist (Williams , 2006)	General Population
Footwear Suitability Scale (Nancarrow, 1999)	Patients with diabetes mellitus
Footwear Assessment Score (Byrne & Curran, 1998)	Children
Footwear Assessment Form (Menz & Sherrington, 2000)	Older adults with postural instability
Footwear Assessment Tool (Barton, Bonanno, & Menz, 2009)	General population
The Screening Tool for Feet/Footwear-Related Influences on Fall Risk (Wingwood et al., 2022)	Community dwelling older adults at risk for falling
Clinical Footwear Assessment Tool (Ellis, Branthwaite, & Chockalingam, 2022)	General population

These tools offer a range of options for healthcare professionals and researchers to assess footwear, with varying levels of subjectivity, reliability, and applicability to different populations. For example, some tools like the Footwear checklist and the Footwear suitability score have been criticised for using assessment methods that are subjective in nature (Nancarrow, 1999; Williams, 2006). The Footwear Suitability Score was created to screen for footwear for people with Diabetes (Nancarrow, 1999), while the Footwear Assessment Score is mostly intended for use in children (Byrne & Curran, 1998). Other screening tools are targeted at the general population. The Clinical Footwear Assessment Tool was developed to clinically screen for important footwear variables required for good foot health by the general population (Ellis, Branthwaite, & Chockalingam, 2022), while the Footwear Assesment Tool was developed following other previously published tools (such as the Footwear Assessment Form), in order to enable professionals to assess an individual’s footwear with accuracy and efficiency. Therefore, careful consideration of the specific context and objectives is essential when selecting the most suitable tool for a given assessment.

The Footwear Assessment Form and the Screening Tool for Feet/Footwear-Related Influences on Fall Risk are intended for the assessment of older people at risk of falls:

- Footwear Assessment Form

Menz & Sherrington (2000) created the Footwear Assessment Form (FAF) which contains information on shoe variables (all discussed in section 2.6) which are important for postural stability. These variables were derived from a comprehensive literature review by Menz & Lord (1999).

The FAF (Footwear Assessment Form) has been demonstrated as a reliable clinical tool for assessing shoe type, heel height, heel counter stiffness, longitudinal sole rigidity, and tread pattern (Menz & Sherrington, 2000; Barton, Bonanno & Menz, 2009) . However, a more objective procedure to enhance the reliability of sole hardness assessment is suggested. The authors found that overall, the examiners' assessments of footwear were highly reliable (κ = 0.47–1.00 for inter-tester comparisons, κ = 0.40–1.00 for intra-tester comparisons), except for the inter-tester assessment of sole hardness (κ = 0.03–0.48). For this reason, Menz & Sherrington (2000) suggested using a more objective method such as the Shore A standard test for durometer hardness to measure material density. Barton, Bonanno & Menz (2009) has tested the reliability of using the Shore A durometer and proved excellent intra-rater and inter-rater reliability for midsole and heel sole hardness.

The FAF is used in multiple studies to evaluate the influence of footwear characteristics to instability and falls in older adults (Sherrington & Menz, 2003; Horgan, et al., 2009; O'Rourke, et al., 2020; Tsekoura & Sakellari, 2021).

- The Screening Tool for Feet/Footwear-Related Influences on Fall Risk

While the FAF only assesses footwear variables, the Screening Tool for Feet/Footwear-Related Influences on Fall Risk screens for both feet and footwear-related influences on fall risk in community-dwelling older adults (Wingwood et al., 2022). The items assessed in this fall risk screening tool reflect the 8 types of feet and footwear factors identified in a study by Neville, Nguyen & Wingwood (2019) that negatively impact falls risk in older adults. This newly developed screening tool has high face and content validity and can be used by interprofessional health care provides involved in mulitfactorial fall risk screening, however, some professionals, such as nurses might require some training in using this tool (Wingwood et al., 2022). Moreover, thorough studies are needed to investiage the tool's validity and reliability (Wingwood et al., 2022).

2.11 Measuring of shoe fit

Ensuring the right fit of footwear is another critical element in reducing the risk of falls among the older population (O'Rourke, et al., 2020) and as such, the implementation of proper footwear measurement is imperative.

There is no consensus on the definition of shoe fit due to several factors, including lack of standardisation in commercial footwear sizing, various measurement procedures, and significant variation in acceptable foot-to-shoe gap ranges (Jones et al., 2019). Additionally, there are no guidelines specifying the most appropriate methodology for measuring foot dimensions or internal footwear length/width. Different approaches are taken in comparing foot and shoe dimensions when assessing footwear fitting, with some studies following a rational approach based on shoe sizing (Harrison et al., 2007; Schwarzkopf et al. 2011). For example, Schwarzkopf et al. (2011) considered a correct shoe fit, if the shoe was at least half a British shoe size larger or smaller than the foot.

Conversely, in other studies, shoe fit was considered to be incorrect if measurements such as overall area, length, or width varied between the footwear and the foot. (McHenry et al., 2015). Several authors have quoted various ranges for shoe-to-toe length, raging from from 6-20mm (Burns, 2002; Chaiwanichsiri, Tantisiriwat & Jachai, 2008; Tovaruela- Carrion et al., 2017). Figure 2.5 illustrates these ranges. However, the most commonly used values identified as the ideal gap between the distal point of the foot and the shoe ranges between 10 to 15mm (Chantelau & Gede, 2002; McInnes, et al., 2012; Bergin, et al., 2013; Blazer, Jamrog, & Schnack, 2018).

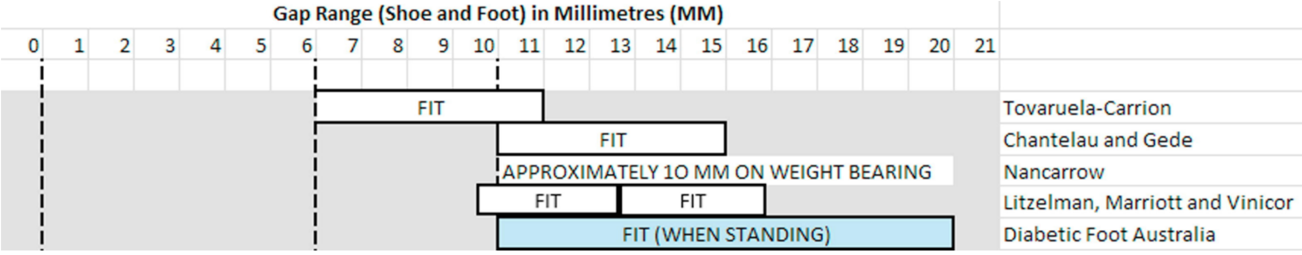

Figure 2.5 Visualisation of various Foot-to-Shoe Length Gaps. From Jones et al., (2019).

Foot-to-shoe width is also involved in the measurement of shoe fit, however, this is less assessed than foot-to-shoe length and there is less consensus on the ideal values. The most common values identified ranged up to a gap of 7mm between the shoe and the foot at the widest part (Burns et al., 2002; Harrison et al., 2007; Bakker et al., 2012; Bergin et al., 2013). Some studies take into consideration the depth needed to accommodate the foot, a consideration that is closely related to width, however the ideal values are not commonly discussed (McInnes, et al., 2012).

2.11.1 Tools used for the measurment of foot length and width

In the realm of measuring foot length and width for the purpose of achieving proper shoe fit, a variety of tools and techniques have been employed, each with its own set of advantages and considerations. These tools and methods include:

- *Brannock Device*

The Brannock Device is a widely recognized and dependable tool for assessing foot dimensions. It takes into account three essential measurements—heel-to-toe, heel-to-ball/arch length, and foot width (Buldt & Menz, 2018). Due to the lack of standarization in footwear sizing, some authors used the Brannock to measure the length and width of the foot in millimeters by using a marker pen to mark the position of the longest toe/width of the foot on the brannock and then measuring the distance from the heel of the device to the mark using a calibrated ruler (McInnes, et al., 2012; Lopez-Lopez, et al., 2016). Several studies have adopted this device (McInnes, et al., 2012; Menz, et al., 2014; Isip et al.; 2016; Novo- Trillo, et al., 2021), and its validity and reliability are well-established, with intraclass interrelation coefficients ranging from 0.96 to 0.99 (Harrison et al., 2007). Researchers have utilized the Brannock Device in studies focused on calculating shoe fit and reported favorable inter-rater and intra-rater reliability (Barton, Bonanno, & Menz, 2009).

- *Callipers and Shoe Sticks*

An alternative to the Brannock Device involves using manual and digital calipers and calibrated shoe sticks to measure foot dimensions. However, the precision of digital calipers may be susceptible to human error, although some studies have reported high intra-class correlation for digital caliper measurements (Lee, Lin & Wang, 2014). Manual calipers are also used in measuring foot dimensions, as demonstrated in Figure 2.6.

Figure 2.6 Using manual calipers to measure foot dimensions (Chaiwanichsiri, Tantisiriwat, & Jachai, 2008)

- *Measuring Tape and Foot Tracing*

Another approach involves using a measuring tape or tracing the outline of the foot on graph paper. While these techniques have been employed in previous research, they are not immune to human errors (Zhao et al., 2008). Menz & Morris (2005) and Ramachandra et al. (2016) used a different technique by tracing the outline of the foot on a graph paper and then measuring the distance from the tip of the longest toe to the posterior aspect of the heel, and from the widest point of the 1st and 5th metatarsophangeal joints. When this methodology was tested, it produced high test-retest reliability (Menz & Morris , 2005).

- *2D and 3D Scanning*

Recent advances have seen the integration of 2D and 3D scanning technologies for measuring foot dimensions. Studies have compared the precision and accuracy of these scanning methods with traditional measurement techniques (Muller et al., 2023; Menz et al., 2014). Lee, Lin & Wang (2014) found that 3D foot scanning demonstrated higher precision and accuracy compared to conventional methods like digital calipers and footprints. Similarly, Mueller et al. (2023) compared 3D scanning with established measurement methods, highlighting the advantages of 3D scanning for foot width and the preference for 2D scanning for foot length. Although 3D scanning offers superior assessment of foot morphology, it is associated with high initial setup costs and longer data processing times (Menz et al., 2014).

In light of the diverse range of measurement tools and techniques available, the choice of the most suitable method depends on factors such as precision, accuracy, and practical considerations. Researchers and clinicians must carefully select the approach that aligns best with their specific objectives and available resources. These tools are essential in achieving the proper measurement of footwear, which, in turn, plays a crucial role in reducing the risk of falls in older individuals and enhancing overall foot health (Jones et al., 2019).

2.11.2 Tools used for Footwear Measurment

Studies on measuring footwear dimensions are not as common as tools for foot dimensions. In fact, most tools have not been tested for validity and reability, thus studies have used various approaches to meaure footwear dimensions (Barton, Bonanno & Menz, 2009; Jones et al., 2019). Some studies have checked the appropriateness of footwear width by grasping the upper of footwear over the metatarsal heads and categorising footwear as beeing too wide, good or too narrow according the the bunching of the upper (Barton, Bonanno, & Menz, 2009; Ellis, Branthwaite & Chockalingam, 2022). Footwear can also be assessed for its length by the 'rule of thumb', where a thumb's width should fit between the longest toe to the front of the shoe (Jones et al., 2020). However, both of these methods are subjective and have showed poor reliabilty measures (Ellis, Branthwaite, & Chockalingam, 2022). Other more objective measurments methods include:

- Callipers

Most studies have used tape measurments and callipers to calculate footwear width (Burns, Leese, & McMurdo, 2002; Chaiwanichsiri, Tantisiriwat & Jachai, 2008; Harrison et al., 2007), as shown in figure 2.7. However, the reliabilty of these methods in assessing fit has not been reported.

Figure 2.7. Using tape measure (1st picture on left) and shoe callipers to measure footwear internal length and width (Chaiwanichsiri, Tantisiriwat, & Jachai, 2008).

- Straw Method

Barton, Bonanno & Menz (2009) suggested measuring the inside of a shoe with a flexible straw, and then placing it against a calibrated ruler to read the measurements. However, this produced moderate intra-rater and inter-rater reliability in measuring footwear length. Moreover, during the development of a new footwear assessment tool by Ellis, Branthwaite & Chockalingam (2022), a group of experts of foot health professions, rejected this method, as they thought this method of being subjective. Ellis, Branthwaite & Chockalingam (2022) have attempted at measuring shoe length in terms of fit by removing the insole or shoe liner from footwear and comparing it against the foot whilst weightbearing, however this also produced poor reability results.

- Plus 12 Tool

The Plus 12 Tool is a portable device tool, which measures both foot and footwear length. When measuring footwear length it adds up an extra 12mm in order to allow for some extra space for the foot, following the principle that for a proper fit, shoes need to be at least 12 mm longer than the length of the feet (Kinz, 2023). Ellis, Branthwaite & Chockalingam (2022) suggested using the Plus 12 Tool to measure shoe size when shoe liner cannot be removed, however this also showed poor reability and validity measures. This could be due to more training need to use the tool, especially since it is not commonly used in practice.

- Internal Shoe Gauge

Most studies measure footwear using a manual device such as an internal shoe gauge. The SATRA 225 internal shoe gauge is an example of this. It is a metal device which was built to measure standard lasts or insoles lengths. It fits inside the shoe and extends outwards until it reaches the internal front end of the footwear, and is designed to measure the internal length of a shoe in millimeters (Jones, et al., 2019). The SATRA internal shoe gauge was used in various studies to measure the inside length of the footwear (O'Rourke et al., 2020; McInnes et al 2013), however no specific studies have tested its reliability.

It appears that utilising various methods to gather foot and footwear dimensions can result in inconsistent findings (Lee, Lin & Wang, 2014; Zhao et al., 2008). Additionally, there is no consensus on the ideal shoe-to-length and shoe-to-width distances for footwear to be considered appropriately fitting. Additional research is necessary to establish valid criteria for well-fitting footwear, standardize approaches to measure foot and shoe parameters (such as length, depth, and width), and define the optimal gap between the foot and shoe dimensions to determine ideal shoe fitting (McInnes, et al., 2012). Achieving these standards can enhance the role of footwear in fall prevention efforts.

2.12 Conclusion

The above-mentioned studies have provided ample information on the ideal footwear for enhanced balance and stability for the older adults. However, more research is needed on the effect of ill-fitting footwear (in terms of length and width) on balance and stability and on the criteria and methodologies used to determine which footwear is considered as being 'ill-fitting'. More research is also required on certain footwear characteristics such as longitudinal sole rigidity and sole flexion point to have a more definitive answer on the safest footwear for older people. The effects of certain footwear styles such as sandals on falls is still conflicting and thus more research is required.

Moreover, studies and guidelines on the effect of footwear on balance on the frailest individuals, living in a long-term care are scarce. In Malta, there are no known studies on footwear and falls in older people, and also, there are no guidelines for fall prevention for both community-dwelling older individuals and older adults living in long term care facilities.

This chapter, focusing on the effect of footwear characterisics and fit on balance and stability in older people, along with studies on different footwear assessments have shaped the current study's methodology in order to answer the research question: Does footwear design affect the risk of falling in a geriatric population at a long-term care facility?

Chapter 3:

Research Design and Methodology

3.1 Introduction

This chapter explains and justifies the research design and methods used in the study. The research participants, ethical considerations, and underlying philosophical tenets of the research method are also explained. In research, methodology pertains to the precise procedures used to identify, select, process, and analyze information relevant to a particular topic.. Methodology aims at providing information on how data was collected, generated, and analysed, thus allowing the reader to critically evaluate the study's overall validity and reliability (Wilkinson & Birmingham, 2013).

In order to answer the research question, which is: 'Does footwear design affect the risk of falling in a geriatric population at a long-term care facility?' the study was conducted in 3 phases as described below:

Phase 1: Evaluation of footwear characteristics and fit worn by a sample of residents living in a Maltese long-term elderly residence.

Phase 2: Evaluation of footwear characteristics and fit worn at the time of fall.

Phase 3: Testing the functional stability and balance of participants wearing the footwear worn at the time of fall versus adequate footwear

3.2 Inclusion and Exclusion Criteria

The inclusion and exclusion criteria for this study were defined prior to the recruitment of participants for all three phases in order to eliminate participant selection bias. Participants had to meet the following criteria to be eligible for this study, for all of the three phases:

Inclusion criteria:

- Residents over the age of 65 years, of either gender.
- Residents able to ambulate, either aided (e.g. walking frame) or unaided.

Exclusion criteria:

- Residents with dementia or other form of cognitive impairment.
- Residents with a history of amputations, both minor and major.
- Residents with active ulcerations.
- Residents with foot drop.
- Residents making use of any form of insoles or other orthotics.

Furthermore, for Phase 3 of the study another exclusion criterion was set:

- Participants who sustained a fracture or any other form of severe injury during the fall.

Justifications for Exclusion Criteria

- Participants under the age of 65 were excluded in the study as they are not considered to be older adults (Orimo et al., 2006), and thus they do not fall within the scope of the study.
- Residents making use of a walking aid were still included in the study as they are representative of a population residing inside an elderly residence (Deandrea, et al., 2013) and it has been argued that individuals making use of walking aids are at more risk of falls (Tuvemo Johnson et al., 2022).
- Residents with dementia were excluded as they are unable to provide consent to participate in the study and might also find it difficult to follow simple instructions during data collection, which can put their safety at risk.
- Individuals with amputations often have custom footwear or other orthoses and prosthesis, requiring different shoe fit than those individuals without foot amputations, due to the presence of shoe fillers (Yoo, 2014). For this reason, residents with foot amputations were excluded from this study. Additionally, giving these individuals generic footwear during Phase 3 of the study would have posed challenges in ensuring proper fit and could have also raised safety concerns.
- Individuals with footdrop usually make use of Ankle Foot Orthoses which alter the stability of footwear (Silver- Thorn et al., 2011) and can also affect shoe fit. For this reason, individuals with footdrop were excluded from this study.
- Insoles also alter foot stability and have been found to reduce falls in older people (Qu, 2015), thus they were excluded from the study since the presence of insoles might influence the results. This is because balance and stability might be affected by the presence of insoles and not by footwear.
- Residents with active ulcerations were also excluded from this study, for the reason that they also might require different footwear, and the presence of foot dressings and offloading might compromise stability and shoe fit. Also, individuals with active ulcerations are often advised to rest, so it would be inappropriate to ask them to participate in Phase 3 of this study.

- For Phase 3, participants who sustained a fracture during a fall were not invited to participate, due to safety reasons.

3.3 Ethical and Regulatory Considerations

Ethical and regulatory considerations were maintained throughout the whole study.

This study took into account various ethical considerations. Research ethics encompass the principles guiding scientific researchers to uphold standards that protect the dignity, rights, and welfare of research participants (WHO, 2022). To ensure adherence to ethical guidelines, this study protocol was submitted for review to both the University Research and Ethics Committee and the Faculty Research and Ethics Committee (Appendix 1) at the University of Malta, following the principles outlined in the Declaration of Helsinki. To conduct the study at the residence premises, several permissions were obtained including:

- Consent from the CEO and Medical Superintendent of the elderly residence (see Appendix 11 and 12).
- Approval from the Data Protection Officer of the elderly residence to access data on consenting residents (see Appendix 13).
- Permission from the consultants of the respective wards to recruit residents for the study (see Appendix 14).
- Authorization from the Chief Nursing Managers and Senior Nursing Managers of the residence, who acted as intermediaries for data collection (see Appendix 15 and 16).
- Consent from the Podiatry Department Manager to utilize their premises for data collection (see Appendix 17).
- Approval from an experienced podiatrist who assisted the researcher during data collection (see Appendix 18).
- Permission from the Podiatry Lead to conduct the research (see Appendix 19).

3.4 Informed Consent and confidentiality

Informed consent and confidentiality were maintained throughout the duration of all 3 phases of the study.

Before each phase, all potential participants were provided with a comprehensive explanation of the study aims and procedures by the intermediaries. Both verbal and written explanations were given to ensure clarity and understanding. The researcher and researcher's supervisor contact numbers were also provided in case of any queries raised by potential participants. It was clearly stated in both the information letter (Appendices 2, 3 & 4) and consent form (Appendices 5, 6 & 7) that if the participants decided to withdraw from taking part in the study, they were free to do so without providing an explanation. This would have no effect on their treatment or care provided by the residence in any way. Residents with dementia or any other form of cognitive difficulties which prevent them from understanding their role in the study and give consent were not invited to participate in the study.

Due to the vulnerability of the recruited population, ethical issues such as data protection were considered a priority. Confidentiality was maintained throughout the study and the participants' identity and personal information were not made identifiable in the public domain. To maintain confidentiality, the names of the participants' wards and the institution from where they were recruited were not recorded during data collection. Additionally, they were not mentioned in the study to ensure their anonymity. All data collected was pseudonymised meaning that the data was assigned codes, and that this data was stored securely and separately from any codes and personal data. The data files were stored on the researcher`s personal computer which was password protected and in an encrypted format. Any material in hard-copy form was placed in a locked cupboard accessible only to the researcher and research supervisor.

3.5 Philosophical Paradigms adopted in the study

A paradigm is a framework that defines a worldview shaped by philosophical assumptions about the nature of social reality (ontology), methods of acquiring knowledge (epistemology), ethical principles, and value systems (axiology). It guides researchers to ask specific questions and employ appropriate systematic inquiry approaches, known as methodology, which detail how a study is conducted (Patton, 2002). There are 5 main philosophical paradigms: positivism, post-positivism, critical theory/transformative, constructivism and pragmatism.

This study followed the post-positivism approach because it viewed reality as being objective and knowable. It is also based on precise observation and verifiable measurement (Chilisa & Kawulich, 2013). Postpositivists contend that a researcher's ideas and personal identity can influence their observations, thus shaping their conclusions. Post-positivism aims for objective outcomes by acknowledging and addressing such biases within the theories and knowledge developed by theorists (Chilisa & Kawulich, 2013). Post-positivism research designs include quantitative approaches, and observational experiments in more natural contexts (Patton, 2002), as held in this study.

This dissertation followed the post-positivism approach by making use of previously validated and reliable tools in the form of a footwear assessment form and clinical balance and stability tests (described in more detail in section 3.7), to evaluate the relationship between footwear and falls in older people.

3.6 Research Design

This study adopted a quantitative design since the researcher was trying to quantify a problem or address the 'what' or 'how many' aspects of the research question (Dewitt Wallace Library, 2021).

Study Setting

All phases were conducted in Malta's largest residence for elderly care. This residence is governmental run and provides care for the most vulnerable older adults of the island which amount to 1,300 residents.

3.6.1 Phase 1: Evaluation of footwear characteristics and fit worn by residents living in a Maltese long-term elderly residence (Scoping Study)

The aim of this phase was to provide an overview of the footwear attributes (such as heel height and heel counter stiffness) and fitting preferences within a geriatric population residing in a long-term care facility. Moreover, this scoping study provided some information on the population that was later studied in more detail for Phase 2 and 3 of the study. Phase 1 was conducted during the month of June, 2022.

- Study Location

Phase 1 took place within the participants' ward, offering enhanced convenience for all involved.

- Study Design

Phase 1 adopted a non-experimental design because it did not manipulate the control or independent variable (Salkind, 2010). There are 3 main forms of non-experimental research, specifically, cross-sectional research, correlation research, and observational research (Salkind, 2010). This phase adopted an observational approach since it observed the behaviour of the research subjects (elderly residents) in a natural setting (in residential wards) without manipulating the variables (footwear).

- Sampling Method

All research requires some form of sampling, which is a selection of who or what to study. A sample is usually selected to be representative of a population being studied. This saves the researcher time and money since it reduces the number of individuals being studied. There are five main types of research sampling: Random, Systematic, Convenience, Cluster, and Stratified (Holborn, 2008). This phase used a simple random sampling method. Senior Nursing Officers, who acted as intermediaries, randomly invited residents from their respective wards who met the inclusion criteria outlined in section 3.2 to participate in the study. This approach minimized researcher bias and ensured an equal opportunity for all eligible individuals to be selected for the study. An advantage of random sampling is that it ensures each sample unit has an equal opportunity to be selected for the study (Holborn, 2008). However, a disadvantage is that it relies on statistical probability to achieve sample representativeness. (Sharma, 2017).

- Sample size

This phase had a sample size of 135 participants. A number of factors were considered when the sample size was calculated for Phase 1 of the study. These included:

Population size (N): It is estimated that 1,300 individuals live in the elderly residence from which participants were chosen for this study.

Margin of error /confidence interval (e): This is expressed in terms of mean numbers and shows the difference that is allowed between the mean number of the sample and the mean number of the population. For this study, a 95% confidence interval was used, meaning that that the researcher is 95% confident that results can vary by +/- 5% (Smith, 2013).

Confidence interval: This refers to how confident the actual mean falls within the margin of error. A 95% confidence level has a Z- score of 1.96 (Smith, 2013).

Standard deviation (σ): This estimates how much individual values vary from the mean value. A low standard deviation indicates that values are closely clustered around the mean, while a high standard deviation suggests values are spread across a wider range. A standard deviation of 0.5 is considered a safe choice, indicating that the sample size is sufficient for reliable results (Smith, 2013).

To determine the sample size, the formula below was utilized, incorporating the aforementioned factors (Smith, 2013) to enhance the accuracy of the calculation.

$$n = \frac{Z^2\sigma^2 N}{e^2(N-1) + Z^2\sigma^2}$$

$$135 = \frac{1.96^2 0.5^2 1300}{0.08^2(1300-1) + 1.96^2 0.5^2}$$

A sample size of 135 residents, guarantees a maximum margin of error of 8% assuming a 95% confidence level.

- Data Collection

The intermediaries invited residents from various wards who met the inclusion criteria outlined in section 3.2 to participate in the study. Potential participants were provided with an information sheet and consent form in either Maltese or English language (see Appendix 2 and 5) to ensure comprehension and facilitate informed consent. Upon consent, participants were contacted by the researcher to discuss data collection details.

On the day of the appointment, demographic data including age and gender, medical history including medical conditions and medications, history of falls in the last year and any use of mobility assistive aid, and a recent (up till 6 months) Barthel Index Score (an Activity of Daily Living measurement scale) were retrieved from their medical record files and inserted in the record sheet (Appendix 8). Then, participants were asked to present their mostly worn pair of footwear, which was assessed and both fit and characteristics were recorded.

  - *Evaluation of Footwear Characteristics*

The footwear characteristics were assessed using to the Footwear Assessment Form (FAF), (discussed in section 3.7), which allowed the researcher to evaluate aspects of shoe stability. All details were recorded in the record form (Appendix 8). This included the general shoe type, heel height, type of fixation, heel counter stiffness, longitudinal sole rigidity, sole flexion point, sole hardness and tread patterns (Menz & Sherrington, 2000).

- A calibrated ruler was used to measure the heel height from the base of the heel to the centre of the heel sole interface. Measurements were categorised as being 0 to 2.5 cm, 2.6 to 5.0 cm, or >5.0 cm, with measurements recorded using a ruler, from the base of the heel to the centre of the heel sole interface.

- Types of footwear fixation were categorized as none, laces, straps/buckles and Velcro.

- Heel counter stiffness was characterised as none, minimal (>45°), moderate (<45°), or rigid (<10°). This was measured by firmly pressing halfway through the posterior aspect of the heel counter and the angular displacement was estimated.
- Longitudinal sole rigidity was categorized as minimal (>45°), moderate (<45°), or rigid (<10°), depending on the degree of sole flexion relative to the horizontal plane. This was done exerting firm pressure to the front of the shoe while stabilizing the rear part of the shoe and documenting the estimated displacement.
- The sole flexion point is defined as the point at which the sole flexes first when pressure is applied while performing the previous test (Menz & Sherrington, 2000). It was documented whether flexion was occurring at the level of the metatarsophalangeal joints or proximal to the metatarsophalangeal joints.
- Tread pattern was divided into four items consisting of smooth (no texture), partially worn, fully worn, or textured (Menz & Sherrington, 2000).
- Sole hardness was characterized as soft, firm or hard, by using a shore A durometer (discussed in section 3.7). The footwear was placed on a flat, hard, horizontal surface. The durometer was held between both hands over the inner region of the heel of the shoe and it was pushed down perpendicularly until the intender made firm contact with the sole of the shoe, as shown in figure 3.1 below. Measurement was recorded as the average of 3 separate readings, as recommended by Barton, Bonanno & Menz (2009). The sole was characterized as soft, firm or hard as explained in section 3.7.

Figure 3.1 Using the shore A durometer to measure sole hardness.

- *Evaluation of Footwear Fit*

Footwear fit was assessed by measuring (in millimetres) the shoe length and width using an internal shoe gauge and calliper and comparing it to the foot length and width (in millimetres) using a Brannock device. These tools are discussed in section 3.7 of this chapter.

<u>Foot measurement</u>

The width bar of the Brannock device was set to its widest position and the arch length indicator was slid back, so that the foot could have been positioned easily on the device. The participants were asked to remove their shoes and stand on the Brannock device, placing their right heel into the right heel cup. The participants were instructed to stand with equal weight on both feet to ensure the foot being measured was elongated and spread to its maximum size. Care was taken to ensure the participants' heels were properly positioned against the back of the heel cup for accurate measurements. In order to measure the length of the foot, the participants' toes were pressed flatly against the base of the device and the reading of the longest toe was measured. Next, a fine, non-permanent marker pen and straight-edge were used to mark this position on the device (as shown in Figure 3.2). The distance from the heel of the device to this marked point was then measured in millimetres using a calibrated ruler.

Figure 3.2 Measuring footwear length using the Brannock Device

The width of the foot was then measured by sliding down the width bar firmly to the edge of the foot. The position from the width bar to the widest part of the foot was marked on the device using a marker and the distance was measured in millimetres using a calibrated ruler. The Brannock device was reversed, and the same procedure was done for the left foot. The device was cleaned with an alcohol wipe after each participant.

<u>Footwear Measurement</u>

The participants' footwear was then measured for its internal length. The footwear was placed on a firm, level surface, and then the SATRA 225 internal shoe size gauge was inserted into the shoe. The flat bar of the device was pushed into the shoe until it made clear contact with the anterior end of the shoe internally, while the posterior arm made contact with the inside of the heel counter (refer to figure 3.8) as per instruction manual. The internal length of the shoe was recorded in millimetres. The footwear width was measured using a spring calliper with outward pointed ends. The shoe was placed on a flat surface and the callipers were inserted into the shoe. The callipers where then opened, and measurement was taken at the maximal width in millimetres as observed in figure 3.7. The same procedure was repeated for the other shoe.

All measurements including the difference between footwear and foot measurements were then calculated and recorded in the record sheet (Appendix 8).

Several authors have suggested ideal shoe-to-toe length ranges (Burns, 2002; Chaiwanichsiri, Tantisiriwat, & Jachai, 2008; Tovaruela- Carrion, et al., 2017), with a gap between the foot's longest toe and the tip of the shoe ranging from 10 to 15mm (Chantelau & Gede, 2002; McInnes, et al., 2012; Bergin, et al., 2013; Blazer, Jamrog, & Schnack, 2018). As discussed in chapter 2, there is less consensus on the ideal shoe-to-foot width but most common values identified ranged up to a gap of 7mm between the shoe and the foot at the widest part (Burns et al., 2002; Harrison et al., 2007; Bakker et al., 2012; Bergin et al., 2013). Therefore, based on previous studies, a good fit was considered as having footwear with a gap of 10 to 15mm between the longest toe and the anterior aspect of the shoe. Additionally, for width to be adequate, the measurement of shoe width had to be either equal to the foot width, or up to 7mm wider than the foot (Harrison, et al., 2007). A participant was considered to be wearing ill-fitting shoes if one or more of the measurements taken from either foot was outside the pre-determined ranges.

- <u>Statistical Analysis</u>

Descriptive statistics were used using SPSS version 28.0 in order to represent data collected during this phase. The Chi squared tests was then used to investigate the association between two categorical variables such as gender and shoe fit. Chapter 4, section, 4.2 and 4.3 illustrate the results for Phase 1 of this study.

3.6.2 Phase 2: Evaluation of footwear worn at the time of fall.

The aim of Phase 2 was to investigate the footwear attributes and fit of residents who experienced a fall within a 9-month duration.

- <u>Study Setting</u>

Phase 2 of the study was held at the Podiatry Clinic located within the long-term residential home. This provided a calmer environment (than conducting the study in the participants' wards) and gave the participants more privacy.

- Study Design

Similar to Phase 1, Phase 2 of the study employed a non-experimental approach since variables were measured as they naturally occur without any manipulation.

Phase 2 adopted a prospective approach since it observed outcomes during the study period of 9 months. Common characteristic features of prospective studies include the initial selection of study subjects who are at risk for a specific condition but do not have the disease at the start of the study. Researchers then monitor whether the condition occurs or not over a defined period following the subjects' recruitment (Holborn, 2008). Contrastingly, a retrospective study gathers information about a sample population regarding the occurrence of specific outcomes that have already taken place in the past (Salkind, 2010).

For the purpose of this study, a population of older individuals residing at a long-term facility was closely monitored for any falls experienced over a period of 9 months (during the study period). Since this type of study was held over an extended period of time, it had the advantage of being tailored to collect specific data on falls such as time and date of fall.

In this study, a prospective approach was preferred since assessing previous falls could have hindered the accuracy of results by recall bias or possible lack of data.

- Study population and size

All residents who met the inclusion criteria outlined in section 3.2 and experienced a fall during the study period of 9 months (July 2022 till March 2023) were invited to participate in order to assess the footwear worn at the time of their fall. Therefore, Phase 2 did not have a sample population but included all residents who experienced a fall and were eligible for the study. This excluded the disadvantages of having a sample in a study, such as researcher bias and selection error (Holborn, 2008). For this phase, a total of 76 participants were recruited.

- Data Collection

Phase 2 of the study began once Phase 1 was completed. Participants were provided with an information sheet and a consent form in both Maltese or English language (Appendix 3 and 6). Residents hospitalised after sustaining a fall, were asked to participate in the study immediately after returning to their respective residence wards. For the purpose of this study, a fall was defined as **an unintentional fall to the ground that occurred whilst walking, not preceded by loss of consciousness (such as hypotension) and without an external force (ex. someone**

being pushed) as a causative factor. Upon consent, the residents were contacted by the researcher in order to set an appointment for data collection, ideally within a week of the fall.

On the day of the appointment, demographic data such as age and gender, medical history namely the participants' medical conditions and medications, history of falls in the last year and any use of mobility assistive aid, and a recent (completed in the last 6 months) Barthel Index Score (discussed in section 3.7) were retrieved from the participants' medical record files and inserted into a record sheet (Appendix 9). Details on the fall, such as date, time and location of fall, type of fall, and any injuries sustained were also retrieved from the patient's file and also by asking the participants.

Participants were then asked to present the footwear worn at time of fall, for assessment of fit and other characteristics as described in Phase 1. All data was recorded in the record sheet (Appendix 9).

- Statistical analysis

Descriptive statistics were used using SPSS version 28.0 in order to represent data collected during this phase. The Chi squared tests where then used to investigate the association between two categorical variables such as footwear characteristics and type of fall. Chapter 4, section 4.6 and 4.7 demonstrate the results for these tests.

3.6.3 Phase 3: Testing the functional stability and balance of participants wearing the footwear used at the time of fall.

Phase 3 aimed to evaluate the balance and stability of participants (by doing 2 clinical tests: Functional Reach Test and Time Up and Go) while wearing the same footwear they had on at the time of the fall and compared it to footwear having ideal features as mentioned in the literature.

Study Setting

Phase 3 of the study was held between from July 2022 till March 2023 and was conducted at the long-term residence's Podiatry Clinic for safety reasons as described below.

- Study Design

Phase 3 adopted an experimental approach since the study occurred in an unnatural setting (Podiatry Clinic), and the variables (footwear) were manipulated in order to measure the effect of footwear on balance and stability.

Experimental research uses a scientific approach by manipulating one or more control variables and study the effect of this manipulation caused. This type of research is mostly used when assessing the cause-and-effect relationships between variables (Holborn, 2008). However, having control over extraneous variables may lead to human error and to the personal bias of the researcher (Samek, 2019). There are 3 types of experimental research, specifically; pre-experimental, quasi-experimental, and true experimental research (Salkind, 2010). This study adopted a quasi-experimental research design to provide a cause-and-effect relationship between an independent (footwear) and dependent (time/distance) variable. In this research, a comparison is made, as in an experiment, but no random assignment of participants to groups occurred (Salkind, 2010).

- <u>Study population and size</u>

Similar to Phase 2, Phase 3 did not have a sample population, but all eligible participants from Phase 2 were invited to participate in the study to evaluate their balance and stability while wearing two different types of footwear. Forty-one participants were recruited for Phase 3.

- <u>Data Collection</u>

The information sheet and consent forms (Appendix 4 and 7) were given to all eligible participants and upon consent an appointment for data collection was given. Functional balance and stability were assessed using the Functional Reach Test (FRT) and Touch Up and Go Test (TUG), with participants wearing the shoes worn at time of fall. The same tests were conducted when wearing 'appropriate' footwear, which was provided by the researcher. These tests are discussed later on in this chapter, in section 3.8. In order to eliminate the 'learning effect' and thus having a better response on the second assessment due to more familiarity of the test (Meeusen, 2020), a random testing order was used so as to avoid obtaining a better response when wearing a particular footwear.

The provided footwear (Figure 3.3) had appropriate features as described in the literature (Menant et al., 2008; Jellema et al., 2019). These include:

- A good fit in length (10-15mm gap between shoe-to-toe) and width (0-7mm gap between shoe-to-foot).
- Surgical/bespoke footwear, in this case Diabetic Shoes were used.
- Velcro fixation
- Rigid heel counter

- Heel height of 2.5cm
- Rigid sole
- Sole which flexes at MTPJs
- Textured tread pattern
- A hard sole (Shore A50)

Before the tests commenced, the participants were asked to walk around the room with the provided footwear for about two minutes, or longer if needed, in order to get acclimatized to it. If required, enough rest was given before the tests commenced.

Figure 3.3. The Researcher's footwear provided to the participants to complete the FRT and TUG test.

The Podiatry clinic, located in the residence premises was set up for the Functional Reach Test (FRT) by attaching a yardstick on a wall, so that it was at shoulder level of the participants. Participants were instructed to stand next to, but not touching, the wall and position the arm that is closer to the wall at 90° of shoulder flexion with a closed fist, as illustrated in Figure 3.4. The starting position at the 3rd metacarpal head on the yardstick was recorded. The participants were instructed to reach as far as they could go forward without taking a step. The location of the 3rd metacarpal was recorded (CDC Govt., 2020).

Figure 3.4 Performing the Functional Reach Test (FRT) from Duncan et al. (1990)

The difference between the start and end position (the reach distance) was recorded (Appendix 10). This test was performed with the provided footwear and the footwear worn at the time of fall. In each case, 3 trials were conducted and the average of the last 2 was recorded. As recommended by Weiner et al. (1992), the first trail was discarded as it was used for acclimatizing the participants to the test. In order to ensure the participants' safety, the data collection session was terminated if any of the participants were noted to exhibit any loss of balance or if their feet were noted to be lifted up from the floor during the test. During this test, the researcher was accompanied by a podiatrist with more than 10 years working with geriatric patients. The podiatrist guided the participants from the front to assist them if needed.

The Time Up and Go test (TUG) was then performed by asking the participants to sit on a chair with armrests. The participants were instructed to stand up from their seated position, walk 3 meters, turn around a cone, and walk back to the chair and sit down, as shown in figure 3.5.

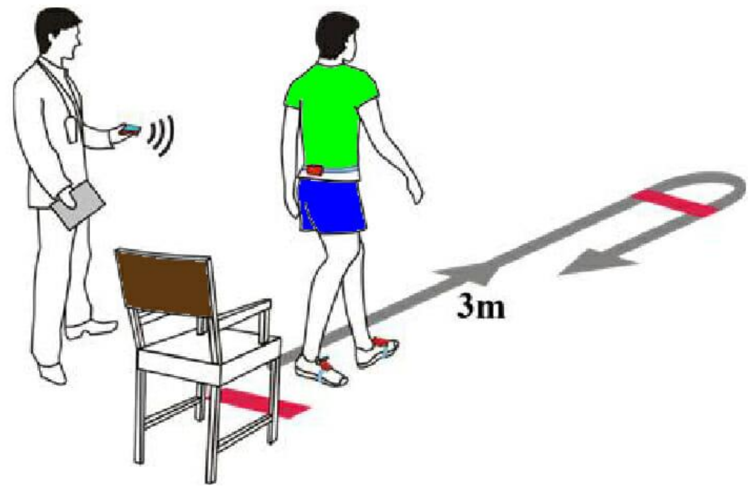

Figure 3.5. Performing the Time Up and Go test (TUG). From Ewing (2019)

A stopwatch was used to record the time taken from when the participants were instructed to stand up, till they sat down (CDC Govt, 2020). Residents making use of a walking aid were instructed to use it. In this case, the assistance device was recorded in the record sheet (Appendix 10). This test was performed twice, once with the provided footwear and once with the footwear worn at the time of the fall. The time taken to complete each test (in seconds) was recorded in the record sheet (Appendix 10). During the test, the participants were provided with a Gait Belt, and the experienced podiatrist walked slightly behind and to the side of the participants whilst holding the belt, in the centre of the back, so as to assist in case of loss of stability. The test was terminated if it was noted that the participant was losing balance or was feeling uncomfortable.

- <u>Statistical Analysis</u>

The paired sample T-Test was used to determine whether there is a significant difference between the time and distance achieved in the TUG and FRT with the researcher's footwear and participants' footwear. The Analysis of Variance (ANOVA) was used to determine if any of the footwear characteristics can significantly impact the difference in time during the TUG test and difference in distance during the FRT test. Results of this phase are presented in chapter 4, section 4.9.

3.7 Tools Used for the Study

Since the aim of the study was to evaluate shoe fit worn by residents at long-term elderly facility care, a number of tools were used.

For Phase 1 and 2 various tools were used, namely:

- The Footwear Assessment Form was used to record footwear characteristics that are thought to be important in the prevention of falls in older people.
- Durometer shore A was used to measure the hardness of the footwear's sole.
- The Brannock Device, used to measure foot length and width.
- The SATRA STD 225 internal shoe size gauge and an Internal Spring Calliper, both used to measure the length and width of the inside of the shoe, respectively.
- The Barthel Index (modified 10-point version) was used to record the extend of the participants' functional independence.

Phase 3 required the following tools in order to measure balance and functional stability of participants when wearing different footwear:

- Timed Up and Go Test (TUG), used to measure balance performance.
- Functional Reach Test (FRT), used to measure functional stability.

Justifications for choosing these tools are discussed below:

- The Footwear Assessment Form (FAF)

As discussed in section 2.10 there are various screening tools used to assess footwear intended for different populations. The Footwear Assessment Form (FAF) was used for this study as it is the only assessment form intended to assess footwear characteristics related to postural stability and falls risk in older adults (Menz & Sherrington, 2000), that was available upon the start of data collection. Other footwear forms intended to the general population were not used as they are not aimed at assessing footwear characteristics which can influence fall risk. The Screening Tool for Feet/Footwear-Related Influences on Fall Risk was not used in the study as it became available in 2022, during data collection of this study and validity tests for this tool had not yet been developed. Moreover, this tool screens for fall risk, according to foot and footwear variables, which is not the aim of the study.

The FAF has been used in numerous studies (Sherrington & Menz, 2003; Horgan, et al., 2009; O'Rourke, et al., 2020; Tsekoura & Sakellari, 2021) to evaluate footwear characteristics and their association with falls in older people. Similarly, the FAF was used in this study to analyse the footwear characteristics worn by a sample of older people residing in a long-term facility. It was also utilised to analyse footwear characteristics worn by residents who sustained a fall.

Menz & Sherrington (2000) have reported the FAF to be highly reliable and valid for all shoe variables, with the exception of inter-tester assessment of sole hardness (= 0.03–0.48). This could be because their suggested method of examining sole hardness (by simply pressing on the sole with a thumb and determining if the sole is soft, firm or hard) is highly subjective. Therefore, they recommended using a more objective measure such as the Shore A durometer to measure material density (Menz & Sherrington, 2009).

- Shore A Durometer

To minimize researcher subjectivity and bias in evaluating sole hardness, a shore A durometer was used for this study, in order to determine sole density. This decision was made in response to criticisms of the reliability of the FAF in this area (Menz & Sherrington, 2000), and in accordance with recommendations by Barton, Bonanno & Menz (2009).

A durometer is an international, standardized tool used to measure the hardness of materials like rubber and plastics (Su et al., 2017). Barton, Bonanno & Menz (2009) found strong reliability findings when using Shore A durometer measurements of footwear material density and stated that using a durometer produces valid results.

The following Durometer scores were classified as soft, firm, and hard (as mentioned in the Footwear Assessment Form) according to common values used in the literature (Robbins, Gouw, & McClaran, 1992; Perry, Radtke, & Goodwin, 2007; Menant, et al., 2008; Su, et al., 2017).

Table 3.1. Classification of sole hardness according to Durometer scores

Soft	Firm	Hard
A0-30	A31-49	A50-100

- The Brannock Device

For the purpose of this study, the Brannock device (shown in figure 3.6) was used to measure both the length and width of the foot (in millimetres) by using a non-permanent marker pen to mark the position of the longest toe/width of the foot on the device and then measuring the distance from the heel of the device to the mark using a calibrated ruler.

As discussed in section 2.11.1 the Brannock Device has been used in numerous studies in order to calculate shoe fit (McInnes, et al., 2012; Menz, et al., 2014; Isip et al.; 2016; Novo- Trillo, et al., 2021). The Brannock device has been found to be valid and reliable (Barton, Bonanno & Menz 2009; Harrison et al.; 2007), with an intraclass interrelation coefficient of 0.96-0.99 (Harrison, et al., 2007). Other manual measurements, such as callipers and measuring tape produced mixed reliability results in measuring foot length (Kouchi et al., 1999; Kouchi & Mochimaru, 2011; Lee, Lin & Wang, 2014). For this reason, the Brannock Device was used in this study in order to read foot length and width.

Figure 3.6 The Brannock device used in the study from (Brannock, 2021).

- The Spring Calliper and the SATRA 225 internal shoe gauge

The spring calliper (refer to Figure 3.7) was used to measure the internal width at the widest part of the shoe while the SATRA 225 internal shoe size gauge was used to measure the internal length of the shoe (refer to Figure 3.8).

Studies about measurement of the internal width of footwear are limited. Some methods, such as grasping the upper of footwear over the metatarsal heads and categorising footwear width are subjective and produce poor reliabilty results (Barton, Bonanno & Menz, 2009; Ellis, Branthwaite & Chockalingam, 2022). Most studies have used callipers to calculate footwear width (Burns, Leese, & McMurdo, 2002; Chaiwanichsiri, Tantisiriwat & Jachai, 2008; Harrison et al., 2007). Although, the reliabilty of these methods in assessing fit has not been reported, spring callipers were used in this study, in order to obtain a numerical value for foot width.

The SATRA 225 internal shoe gauge was used to measure footwear length in this study. It is a metal device which fits inside the shoe and extends outwards until it reaches the internal front end of the footwear, and is designed to measure the internal length of a shoe in millimeters (Jones, et al., 2019). As discussed in section 2.11.2 the SATRA internal shoe gauge was used in numerous studies (O'Rourke et al., 2020; McInnes et al 2013). Other footwear measuring methods such as thumb palpation, using a flexible straw, the Plus 12 Tool or removing the shoe liner from footwear and comparing it againt the foot, were discarded in this study as they are subjective and have showed moderate to poor reability and validity measures (Ellis, Branthwaite, & Chockalingam, 2022; Barton, Bonanno, & Menz, 2009).

Figure 3.7 Using the spring calliper to measure the internal width of the shoe.

Figure 3.8 Using the SATRA 225 internal shoe size gauge to measure the internal length of the shoe

- Barthel Index (modified 10-point version)

The Barthel Index (BI) evaluates the degree to which an individual can function independently and manage their activities of daily living (ADLs). It also helps assess the level of assistance required for older adults in residential care. The ADLs assessed by the BI include feeding, bathing, grooming, dressing, bowel and bladder control, toileting, chair transfers, ambulation, and stair climbing. Additionally, the BI identifies the need for assistance in providing care

(Marvin & Zeltzer, 2015). The Barthel Index generates a total score out of 100, with higher scores indicating a greater degree of functional independence. (McDowell & Newell, 1996).

The Barthel Index score (modified 10-point version) was used for this study since it is routinely carried out by Occupational Therapists or the Nursing Officers at least every 6 months for each patient in the study residence. Therefore, to gather additional information about the participants' level of dependency and mobility, the Barthel Index (BI) was retrieved from their files. This allowed for a more comprehensive understanding of their functional status. The residence uses a modified 10-point version of the BI, where functional categories may be scored from 0 to 1, 0 to 2, or 0 to 3, depending on the item. Total scores range from 0 to 20 (Collin, et al., 1988), as opposed to 0-100 in the standard BI. The modified 10-point BI has been shown to have high reliability and validity in hospitalized older patients (Aminalroaya, et al., 2020). In a study by Yang et al., (2022), the modified BI showed excellent test–retest reliability and a relatively lower random measurement error than the standard BI, hence the authors argue that the modified BI is a better ADL measure. Another test of ADL measures is the Katz AD, however, this test only measures the basic activities of daily living and does not provide detailed assessment for level of assist (Wallace & Shelkey, 2007).

3.8. Tests used for Phase 3 of the Study

- Timed Up and Go (TUG)

The Timed Up and Go Test (TUG) is a clinical tool used regularly to assess the ability to control movement of the centre of gravity over a moving base of support (Hatton & Rome, 2013). This test was used for this study since it studies most activities of daily living, and it been found to be a valid and reliable test for evaluation of balance and functional performance (Bischoff, et al., 2003). Moreover, Shumway-Cook, Brauer, & Woollacott (2000) showed that the TUG has high inter-rater reliability and high intra-rater reliability in a sample of older individuals, with the two of them having an intraclass correlation coefficient of 0.99.

The TUG test has also been used in various published research and has been shown to be sensitive in detecting changes in balance performance when wearing different types of footwear in older people (Arnadottir & Mercer, 2000; Bhatia & Kalra, 2011; Cudejko, et al., 2020).

This study used the TUG test in combination to the Functional Reach Test, because studies have shown that the TUG test alone, or when used in combination with the Functional Reach Test is the best measurement of balance when compared to other tests, such as the Berg Balance Test (Bennie et al., 2003). The Functional Reach Test was used in this study in order to evaluate balance and stability over a fixed base of support, while the TUG was used to evaluate balance and stability over a dynamic base of support.

- Functional Reach Test (FRT)

The functional reach test (FRT) captures the ability to control movement of the centre of gravity over a fixed base of support (as opposed to a moving base of support as in the TUG test), in the standing position (Duncan, et al., 1990). The FRT has also been used in numerous studies and demonstrated the effect of different footwear on balance performance (Arnadottir & Mercer, 2000; Bhatia & Kalra, 2011; Mohammed, et al., 2020).

The FRT has been shown to have excellent test- retest reliability (Duncan, et al., 1990; Lin, et al., 2004; Russell, et al., 2013) and high validity (Robichaud, Pfann, & Cindy, 2006; Teixeira, et al., 2016) in predicing falls in individuals.

The Berg Balance Test is another balance test that has been used in studies to assess the ability of participants to maintain their balance when performing functional activities (Pavana et al., 2020). However, such activities include tasks performed when sitting down (Berg et al., 1989). Footwear doesn’t play a major role in these mentioned tasks (Dhruvkumar & Vashi, 2010); thus, this test was not used in this study as the results might not completely reflect the effect of footwear on the participants’ balance and stability. This was observed in a study by Horgan, et al. (2009) who did not observe any difference in Berg Balance Test scores when using footwear with different characteristics.

Moreover, the Berg Balance test is not indicated for participants using walking assistive devices (Bennie, et al., 2003), and as discussed in section 3.2, residents making use of assistive devices were included in the study as they are representative of the geriatric population residing in an old term facility. Fatigue has been observed to alter results in participants when performing the Berg Balance Test twice (in order to assess the difference between barefooted and shod) in a sample of older women (Horgan, et al., 2009) and also in a sample of Multiple Sclerosis participants (Karpatkin & Cohen, 2013). During this study, the tests were also repeated twice, using different shoe conditions, therefore, the Berg Balance Test was not used in this study, and the TUG and FRT were opted for.

3.9 Conclusion

The information gathered through data collection was analysed and presented in tables and graphs in the next chapter. This included descriptive statistics about the participants and their choice of footwear for Phase 1 and 2 of the study. Statistical analysis, particularly for Phase 3 of this study are also presented in detail in the next chapter.

Chapter 4:

Results and Statistical Analysis

Phase 1: Evaluation of footwear characteristics and fit worn by residents living in a Maltese long-term elderly residence.

4.1 Introduction

The aim of this phase was to provide an overview of footwear typically worn by Maltese older adults living in long-term elderly residence. The data used for statistical analysis was collected from a sample of 135 residents, satisfying the inclusion criteria (refer to section 3.2). All data was recorded in a data collection sheet (refer to appendix 8), which was later analysed using the SPSS version 28. Demographic data about the participants such as age and mobility status is presented in this chapter. This also applies to data on footwear characteristics and fit.

4.2 Descriptive Statistics

4.2.1 Age and Gender Distribution

The age of the participants ranged between 65 and 95 years, as shown in figure 4.1. The most common age range was that of 86-90 years (n=34), followed by 76-80 years (n=32).

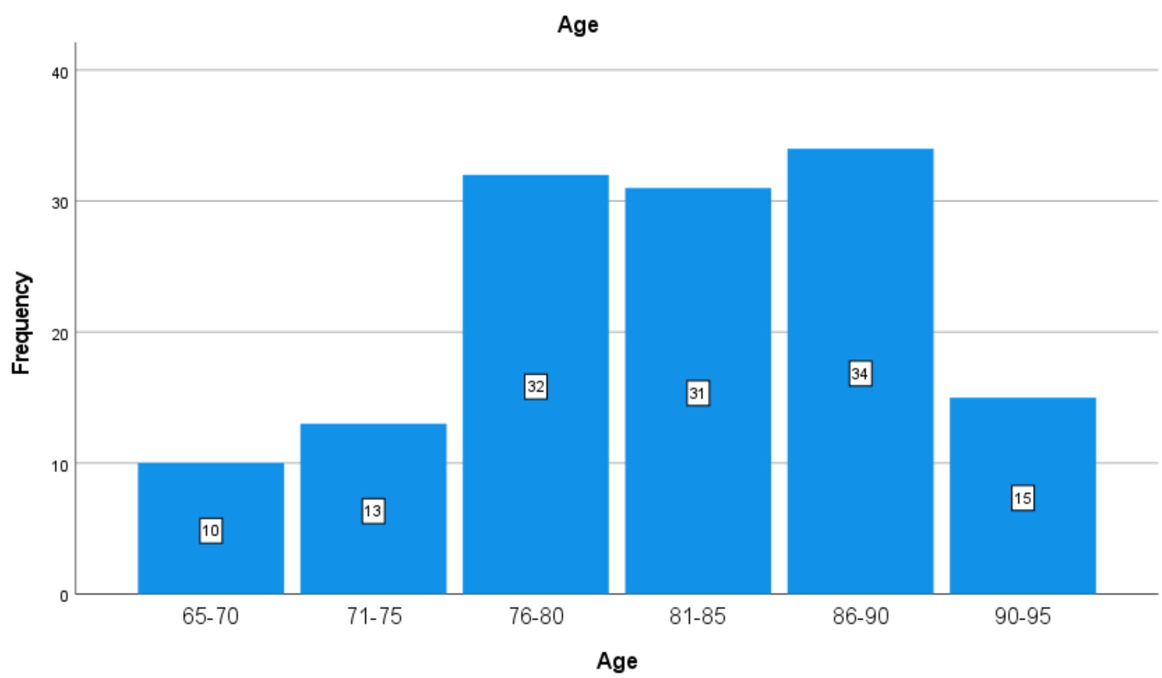

Figure 4.1 Participants age (years) distribution

Figure 4.2 illustrates that the majority of participants (63.7%) were females, with the remaining 36.3% being males.

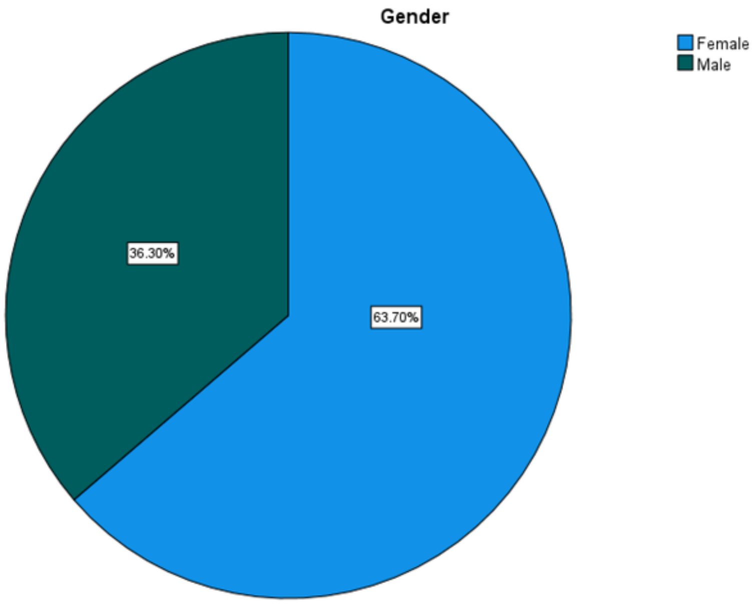

Figure 4.2 Participants gender distribution

<u>4.2.2 Participant's mobility and functional status</u>

Table 4.1 demonstrates that nearly 61% of the study population utilized an assistive device such as walking frames and waking sticks for ambulation, whereas 39% walked unaided.

Table 4.1 Participants' mobility status

Variable	Frequency	%
Uses Assistive Device	82	60.7
Walks Unaided	53	39.3
Total	135	100

The Barthel Index (BI) assesses functional dependence when performing activities of daily living. A score of 0 indicates full dependency while a score of 20 indicates independence. As shown in table 4.2 below, the participants' Barthel Index Score ranged from 6 to 20, with 16 being the most common (n=22), amounting to 16.3% of all scores, followed by a Barthel Index Score of 17 (14.8%). This indicates that a significant proportion of participants in this phase were independent in most activities of daily living.

Table 4.2 Participants' Barthel Index Score

BI Score	**Frequency**	**%**
6	1	0.7
7	1	0.7
8	4	3.0
9	3	2.2
10	4	3.0
11	4	3.0
12	3	2.2
13	7	5.2
14	5	3.7
15	12	8.9
16	22	16.3
17	20	14.8
18	17	12.6
19	18	13.3
20	14	10.4
Total	135	100

4.2.3 Participants health conditions that increase risk of falling.

A list of the most common health conditions that increase risk of falling (falls risk factors) in older people was compiled from the literature (Tsai et al., 2020; Woolcott et al., 2009) and recorded in the data collection sheet. The participants' health conditions that are commonly associated with increased fall risk were subsequently extracted from their records, documented in the data collection sheet, and are presented in table 4.3 below.

Table 4.3 Participants' health conditions related with increased fall risk

Falls Risk Factors	Frequency	%
Visual impairment	29	21.8%
Parkinson's disease	6	4.5%
History of stroke	16	12.0%
Lower limb arthritis	39	29.3%
Polypharmacy	97	72.9%
Hypotension	12	9.0%
Urinary incontinence	6	4.5%
Depression	50	37.6%
Peripheral neuropathy	8	6.0%
Paget's disease	4	3.0%
Anxiety	9	6.8%
Hearing impairment	12	9.0%
Osteoporosis	7	5.3%
Back pain	2	1.5%
Huntington's disease	1	0.8%
Recurrent syncope	1	0.8%

Polypharmacy (taking more than 4 medications) was the most common risk factor associated with falls identified. In fact, it was noted that 72.9% of participants had polypharmacy. This was followed by participants with depression (37.6%) and lower limb arthritis (29.3%).

History of falls in an extrinsic factor which is associated with increased fall risk (Hopewell, et al., 2019). In the study cohort (n=135), 53.3% reported experiencing a fall within the past year, as depicted in Figure 4.3.

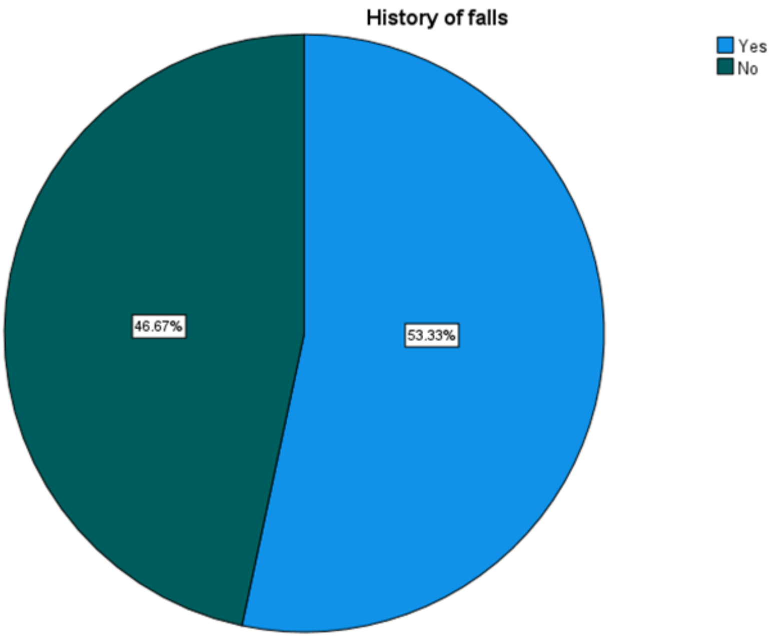

Figure 4.3 Participants history of falls in the past year

4.2.4 Participants' Shoe Fit

Participants' shoe-to-foot measurements were categorized based on specific criteria outlined in section 3.7. Those with a shoe-to-foot length between 10 to 15mm were deemed to have a good fit. Measurements under 10mm indicated shoes that were too short, while over 15mm indicated shoes that were too long. Similarly, shoe width was assessed to ascertain an adequate shoe fit. An adequate shoe fit was recorded when the measurement of shoe width was either equal to the foot width, or up to 7mm wider than the foot. An ill-fitting shoe fit was recorded when measurements for one or both feet were not within the pre-determined ranges of 0-7mm shoe-to-foot width. Moreover, participants needed to have both feet falling within the identified criterion to be considered to have poorly fitting shoes.

Table 4.4 illustrates that only 38.5% of the participants were wearing shoes with appropriate length. However, significant proportion of the study population had issues with shoe length: 37% wore shoes that were 'too short', while 24.4% wore shoes that were 'too long'. Regarding shoe width, the majority (65.9%) of participants were wearing shoes having a good fit. However, 26.7 % of the study population wore shoes which are too narrow and 7.4 % wore shoes which are too wide.

Table 4.4 Participants' footwear fit

Variable	**n (%)**
Length	
Good	52 (38.5)
Too long	33 (24.4)
Too short	50 (37.0)
Width	
Good	89 (65.9)
Too wide	10 (7.4)
Too narrow	36 (26.7)

When combining results from both data sets together, i.e. shoe-to-foot length and width, it was found that only 23.7% of participants were wearing shoes having a good fit, as illustrated in figure 4.4.

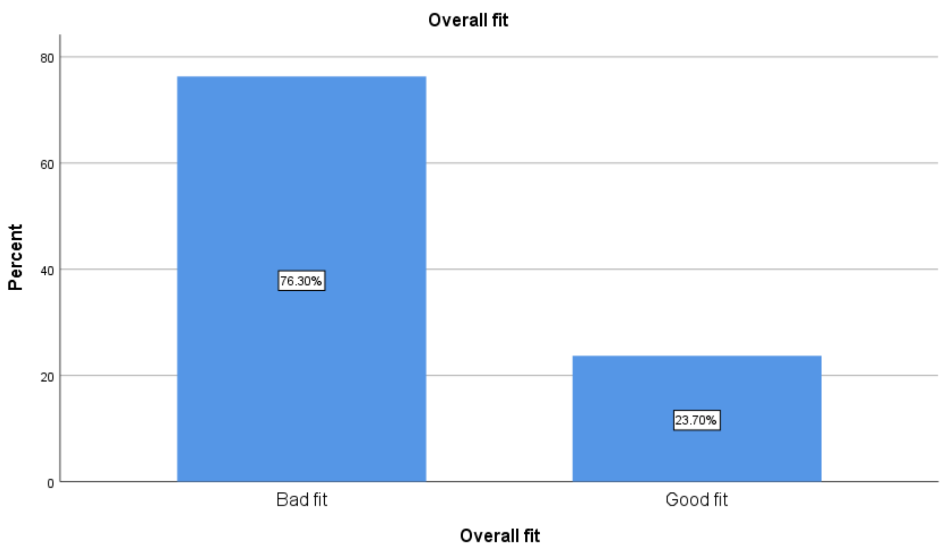

Figure 4.4 Participants' Overall Shoe Fit

Those participants having a bad fit, mostly had shoes which were too short (30.1%), and shoes which were too long (25.22%). This is illustrated better in table 4.5.

Table 4.5 Breakdown of reasons for ill-fitting footwear

Overall fit	**n (%)**
Too short	31(30.07)
Too long	26 (25.22)
Too short, too narrow	16 (15.52)
Too narrow	14 (13.58)
Too long, too narrow	6 (5.82)
Too wide	6 (5.82)
Too short, too wide	3 (2.91)
Too long, too wide	1 (0.97)

4.2.5 Footwear characteristics

- Footwear style

Table 4.6 shows that bed slippers were the most common shoe style worn by the participants (29.6%), followed closely by sandals (26.7%) amongst others.

Table 4.6 Footwear styles worn by the study population.

Footwear style	**n (%)**
Bed Slippers	40 (29.6)
Sandals	36 (26.7)
Backless Slippers	25 (18.5)
Walking Shoes	15 (11.1)
Athletic Shoes	12 (8.89)
Flip-flops	4 (2.96)
Oxford Shoes	2 (1.48)
Courtshoes	1 (0.74)

- Other Footwear characteristics

The footwear assessment form was used to assess the participants' footwear. The data was documented and analysed and presented in Table 4.7 below.

Table 4.7 Footwear characteristics worn by study population.

Variable	**N (%)**
Heel Height	
0.0-2.5cm	48 (35.6)
2.6-5.0cm	86 (63.7)
>5cm	1 (0.74)
Fixation	
None	47(34.8)
Velcro	70 (51.9)
Laces	6 (4.4)
Straps or buckles	9 (6.67)
Zips	3 (2.22)
Heel Counter Stiffness	
None	49 (36.3)
Minimal (<45^{o})	29 (21.5)
Moderate (>45^{o})	40 (29.6)
Rigid (0-10^{o})	17 (12.6)
Longitudinal Sole Rigidity	
Minimal (<45^{o})	40 (29.6)
Moderate (>45^{o})	63 (46.7)
Rigid (0-10^{o})	40 (29.6)
Sole Flexion Point	
At MTPJs	82 (60.7)
Before MTPJs	53 (39.3)
Tread Pattern	
Textured	40 (29.6)
Smooth	51 (37.8)
Partly Worn	34 (25.2)
Fully Worn	10 (7.4)
Sole Hardness	
Soft	41 (30.4)
Firm	65 (48.2)
Hard	29 (21.5)

- The most common **heel height** ranged between 2.6 to 5.0 cm. This exceeds the ideal 2.5cm heel height described in the literature (Jellema et al., 2019).
- Most (62.5%) participants used some sort of **shoe fixation** as opposed to 34.8% who had none. Out of the 62.5% of the study population who used a shoe fixation system, more than half (51.2%) used Velcro, followed by straps or buckles (6.67%) and laces (4.44%).
- **Heel counter stiffness** was assessed by applying firm pressure approximately 20mm from base of the heel counter, and the resulting angular displacement was measured. 36.3% of participants had shoes lacking a heel counter. Among those with a heel counter, the majority exhibited stiffness exceeding 45°, thus providing limited foot stability.
- **Longitudinal sole rigidity** was measured by gripping both the rearfoot and forefoot components of the shoe and attempting to flex the shoe at the midfoot in the sagittal plane. The degree of shoe flexion was categorised as being >45°, < 45°, < 10°. Almost half of the participants (46.67%) had their shoes with an outer sole rigidity of more than 45°. This was followed by participants having a rigid sole (29.6%), meaning a sole showing minimal longitudinal flexion.
- **Sole flexion point** was measured by applying a sagittal bending force to the sole of the shoe's sole and the point at which the bend occurred was noted (at the MTPJs or before the MTPJs). Out of 135 participants, 82 (60.7% of the study population) had their shoe sole which flexed at the MTPJs, thus providing adequate footwear stability.
- The participants' outer sole **tread pattern** was examined and documented as either textured, smooth, partly worn or fully worn. As shown in Table 4.7, 37.8% of participants wore shoes with a smooth tread pattern. This was followed by participants wearing shoes with a textured tread pattern, deemed crucial for fall prevention. Additionally, 7.41% of the study population had fully worn outer soles, placing them at the highest risk of falls.
- A durometer shore A was used to measure the footwear's **sole hardness**. Readings of A0-30 categorised the sole as being soft, A31-49 as being firm and A50-100 as being hard. Almost half of the participants (48.2%) wore shoes with a firm sole. A smaller proportion of participants, 21.5%, wore shoes with a hard sole, while 30.37% wore shoes with a soft sole.

4.3 Statistical analysis

4.3.1 The association between gender and shoe fit.

Foot anthropometrics are often influenced by gender (Mickle et al., 2010), thus affecting shoe fit. In order to determine this, the Chi squared test was used to investigate the association between gender and shoe fit, in terms of both length and width. The following hypothesis was set:

Null hypothesis, H0: There is no significant difference between gender and shoe fit.

Alternative Hypothesis, H1: There is a significant difference between gender and shoe fit.

When analysing shoe fit in terms of length, the p-value (0.301) was greater than 0.05, and thus the null hypothesis is accepted, and no significance difference was observed between gender and shoe fit, in terms of shoe length.

With regards to shoe fit in terms of width, the p-value (0.049) was less than 0.05, and thus the alternate hypothesis was accepted. Therefore, this study found a significant difference between gender and shoe fit, in terms of width.

A table further explaining these results can be found in appendix 20.

4.3.2 The association between gender and shoe style

Studies have shown that that women have difference preferences in footwear preferences than males (Cheng & Lee, 2021). In order to evaluate the association between gender and shoe style the following hypothesis was set:

Null hypothesis, H0: There is no significant difference between gender and shoe style.

Alternative Hypothesis, H1: There is a significant difference between gender and shoe style.

The p-value was equal to 0.05, thus the alternate hypothesis was accepted, and thus it can be said that this study found a significant difference between gender and shoe style.

A table further explaining the results can be found in appendix 21.

4.4 Conclusion

Phase 1 of this study found that:

- The study population mostly consisted of females, aged between 86 to 90 years, making use of an assistive device for ambulation and with a history of falls in the past year.
- The study population was found to be wearing footwear with sub-optimal features such as heel height of more than 2.5cm and footwear with no heel counters.
- Bed slippers was the most common shoe style worn by this study population, followed by sandals.
- The majority (76.3%) of the population was found to be wearing footwear having a bad fit, in terms of length and width.

Phase 2: Evaluation of footwear worn at the time of fall

4.5 Introduction

The aim of this phase was to analyse the data collected from residents who experienced a fall during a 9-month period (July to March), capturing all seasons of the year. This consisted of 76 residents, satisfying the inclusion criteria (refer to section 3.2). Various footwear factors associated with falls (fit and characteristics) were recorded in a data collection sheet (refer to appendix 9), which was then analysed using the SPSS version 28.

4.6 Descriptive Statistics

4.6.1 Participants' age and gender distribution

The age of the participants who sustained a fall during the 9-month period ranged between 65 and 99 years, with the most common age range was that of 81-85 years (n=23), followed by 76-80 years (n=19) as illustrated in figure 4.5.

The majority of participants were females (69.7%), with the remaining 30.3% being males.

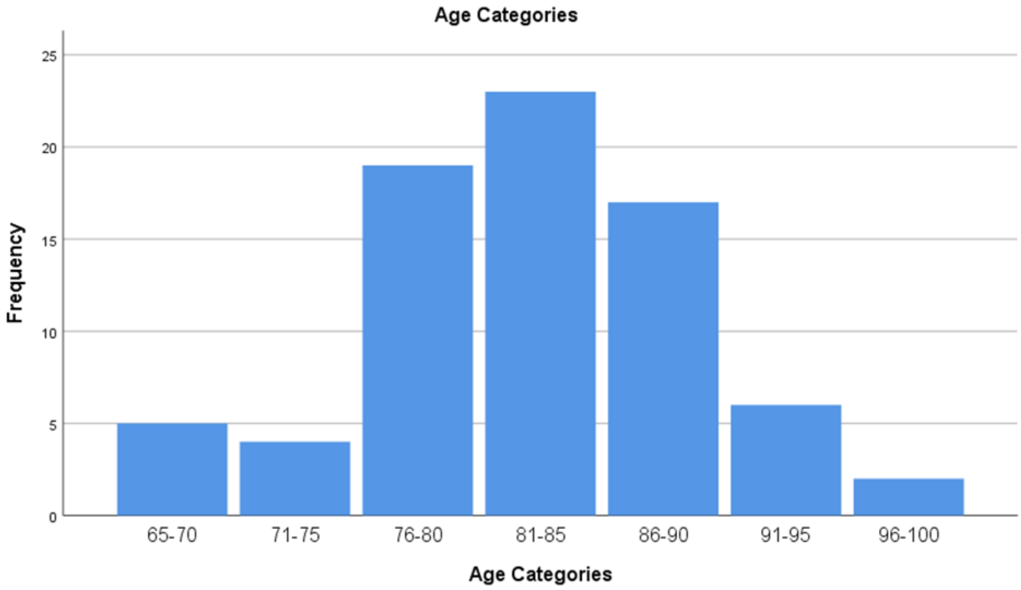

Figure 4.5 Participants age distribution

4.6.2 Participants' mobility and functional status

Mobility and functional limitations have been associated with increased fall risk in older adults (Lee et al., 2021). It is worth noting that just over half of the participants who experienced a fall (51.3%) made use of an assistive device to ambulate while the other 48.7% walk unaided as demonstrated in table 4.8.

Table 4.8 Participants' mobility status

	Frequency	**%**
Uses Assistive Device	39	51.3
Walks Unaided	37	48.7
Total	76	100

Figure 4.6 illustrates how the majority of participants exhibited a relatively high level of functional independence in performing activities of daily living, with the most common Barthel Index score being 18 (19.7%), followed by a score of 15 and 16 (both amounting to 13.2%).

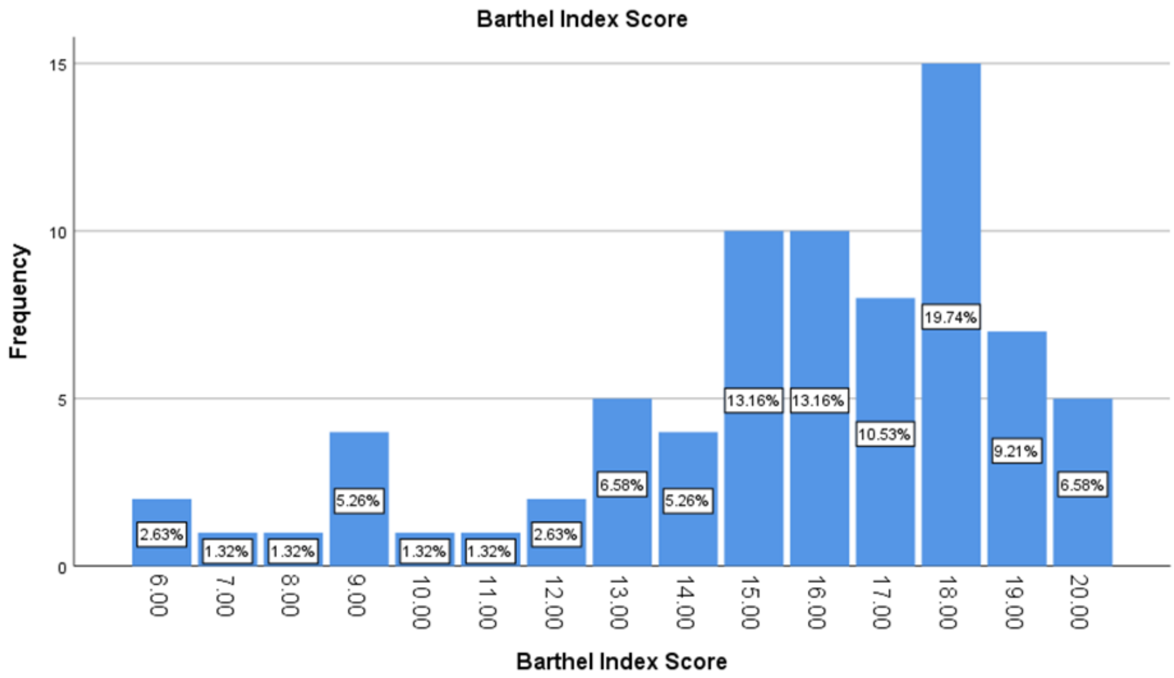

Figure 4.6 Participants' Barthel Index Score distribution

4.6.3 Participants health conditions that increase risk of falling.

The participants' health conditions that are commonly associated with increased fall risk were subsequently extracted from their records, documented in the data collection sheet, and are presented in figure 4.7 below.

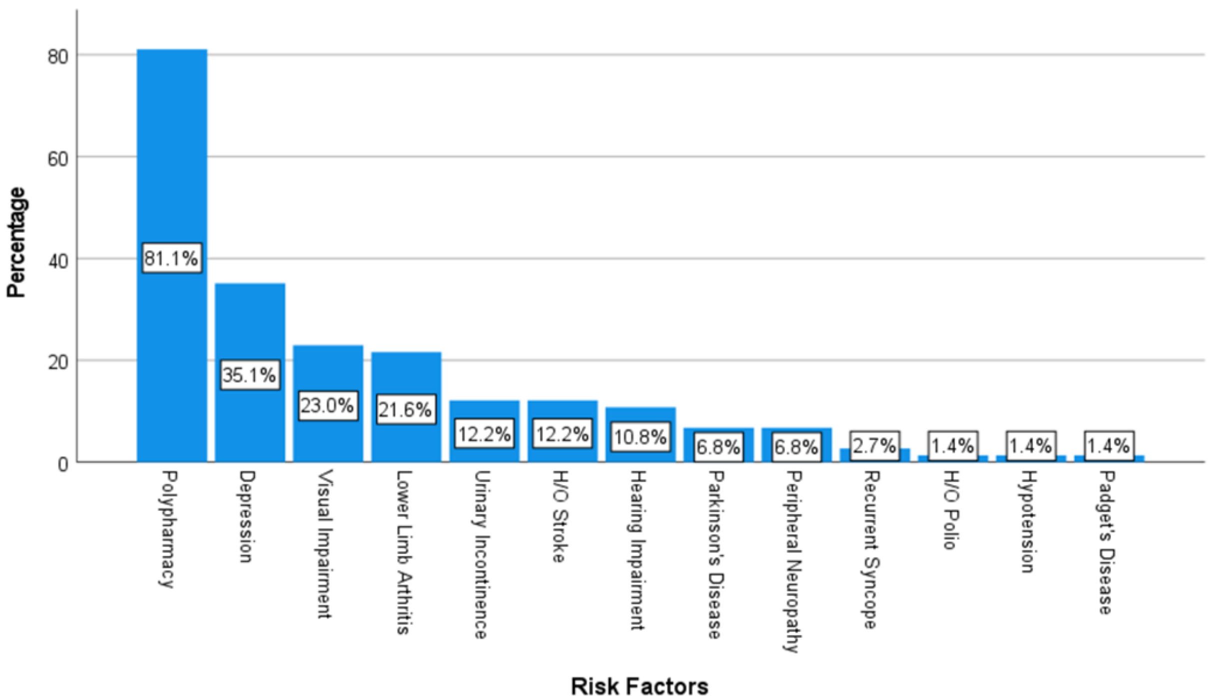

Figure 4.7 Participants' health conditions related with increased fall risk

It can be observed that polypharmacy (taking more than 4 medications) was the most common health risk factor for falls identified in this population. In fact, this was present in 81.1% of the total population. This was followed by participants suffering from depression (35.1%), visual impairment (23.0%) and lower limb arthritis (21.6%).

History of falls is another fall risk factor often documented in the literature (Lee et al., 2021). It is well noting that from all the participants reported to suffer a fall during the 9-month study period, 72.4% of the participants sustained at least one fall in the past year as demonstared in figure 4.8 below.

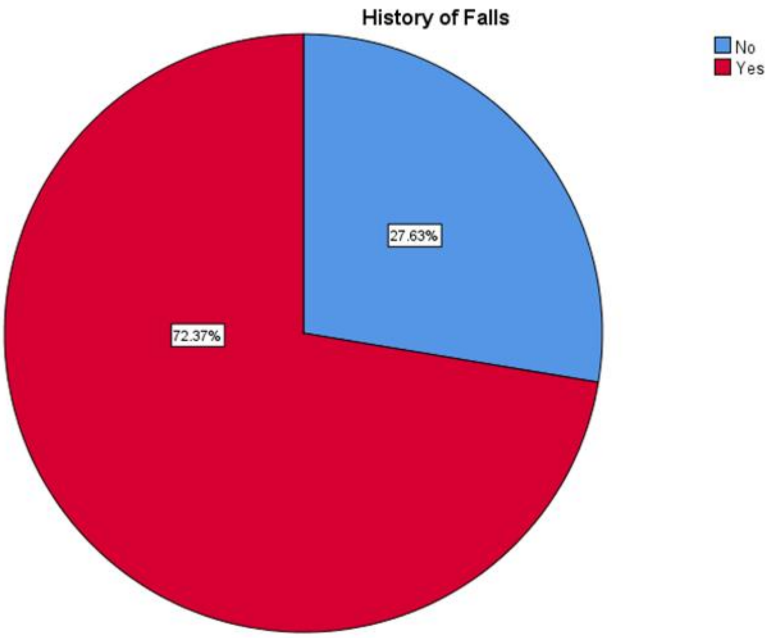

Figure 4.8 Participants history of falls in the past year

4.6.4 Date, time and location of falls

As illustrated in Figure 4.9, most of the falls occurred during the summer period. In fact, August had the most falls (21.05%), followed by July (14.5%) and September (11.8%). January and March had the least falls, each having 5.3% of falls.

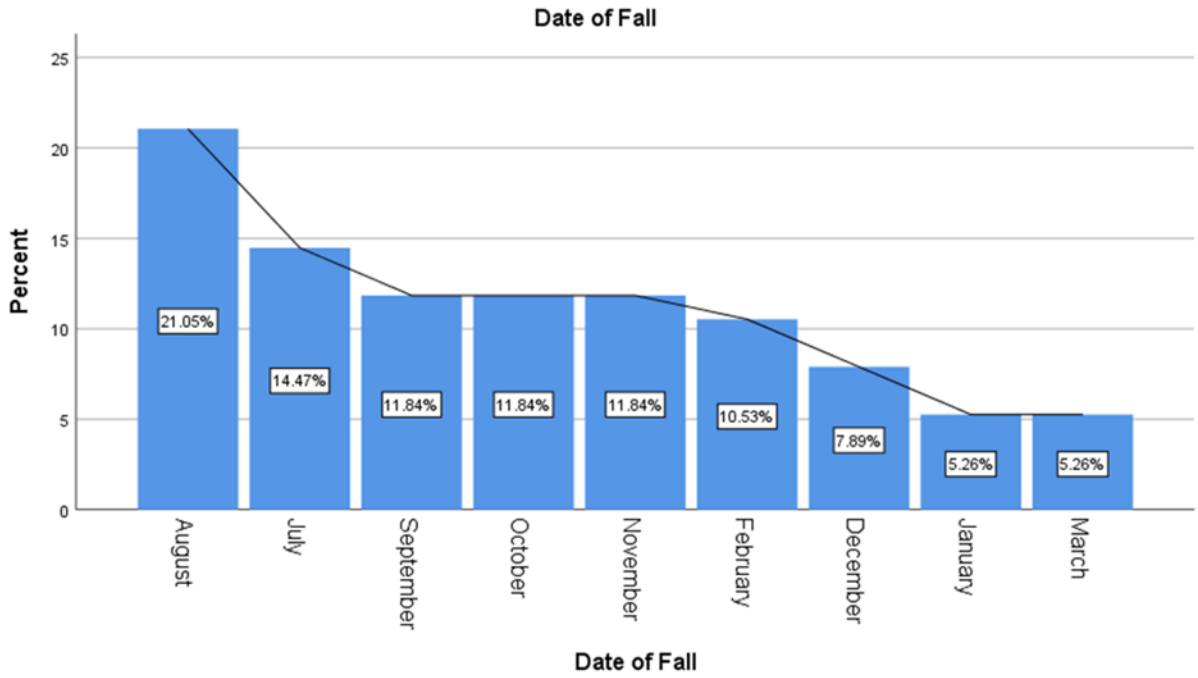

Figure 4.9 Distribution of falls occurrence by month

Table 4.9 shows that 57.9% of falls (n=44), occurred in the morning, followed by the afternoon amounting to 28.9% of falls (n=22).

Table 4.9 Time of sustained falls

	Frequency	**%**
Morning	44	57.9
Afternoon	22	28.9
Evening	10	13.2

Most falls occurred in the bathroom (28.95%) followed closely by the bedroom (27.63%). Corridors and dining rooms saw the same number of falls, each making up to 18.42% of falls. This is represented in figure 4.10 below.

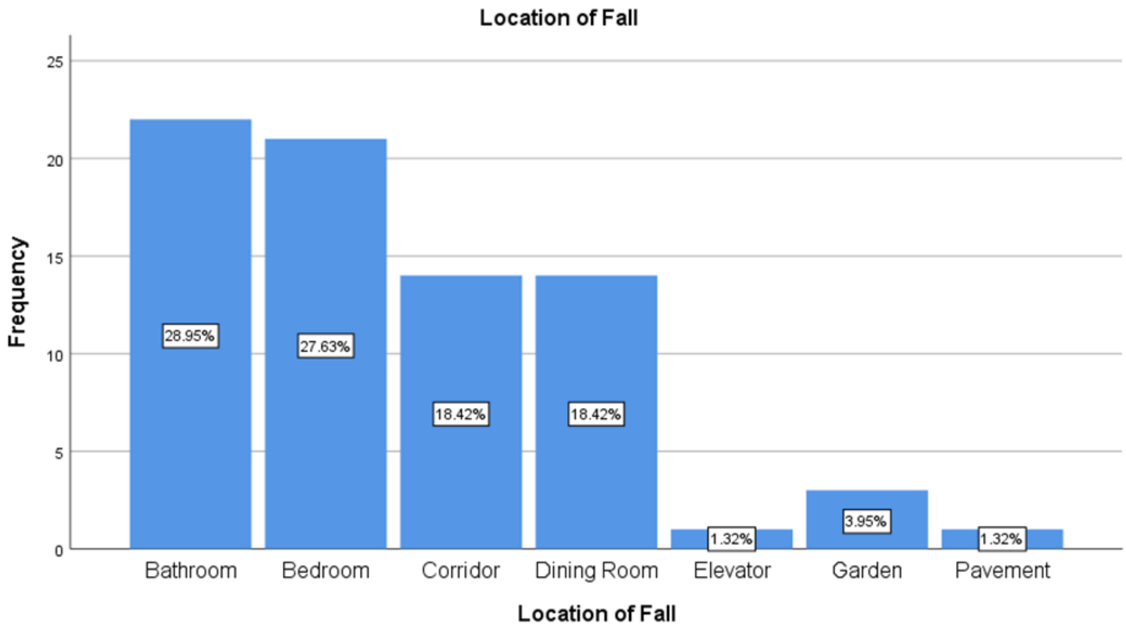

Figure 4.10 Distribution of location of falls sustained in the study population.

4.6.5 Types of falls and injuries sustained from the fall

The type of fall (tripping, slipping, loss of balance, legs gave way, unknown) was documented after asking the participants and retrieving information from their medical files. Falling due to tripping and loss of balance were the most common reported mechanisms of falls, each amounting to 34.2% of falls, as shown in figure 4.11 below.

Figure 4.11 Presentation of the type of falls that occurred in the study population.

Injuries were common following a fall. In most cases, a participant had more than one injury per fall. Table 4.10 shows that bruises were the most common injury present in this population (63%), followed by skin cuts/lacerations (38.2%) and fractures (23.7%).

Table 4.10 Injuries sustained following a fall in the study population.

Injury	**%**
Bruises	63
Skin Cuts/ Lacerations	38.2
Fractures	23.7
No Injuries	17.5
Sprains	10
Head Injuries	8.1

4.6.6 Ground conditions during the falls

The majority of falls (93.4%) occurred on dry ground conditions. Only 5 falls (6.6%) occurred on wet terrain, as presented in Figure 4.12 below.

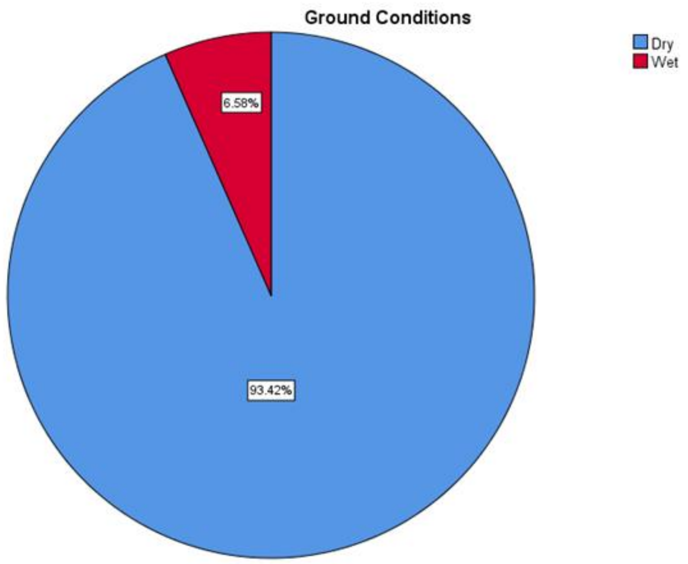

Figure 4.12 Ground conditions during time of fall

It is worth noting that the majority of participants (96.1%) reported wearing their usual footwear at the time of the fall. Only 3 participants indicated they were not wearing their usual footwear.

4.6.7 Participants footwear characteristics at time of fall

Similarly to Phase 1 of the study, participants who sustained a fall during the 9-month study period had their shoes assessed. For this reason, shoe characteristcs were noted, measured and recored. This data is vital in order to try and determine the appropriatness of footwear and possible causes of falls related to footwear sustained during this period.

- Shoe style

Sandals were the most common shoe style worn by the participants who experienced a fall (35.5%), followed closely by bed slippers (32.9%). This is shown in Table 4.11.

Table 4.11 Participants' shoe style distribution

Footwear style	**n (%)**
Sandals	27 (35.5)
Slippers	25 (32.9)
Walking Shoes	13 (17.1)
Backless Slippers	4 (5.3)
Courtshoes	3 (4.0)
Athletic Shoes	2 (2.6)
Ugg Boots	1 (1.3)
Oxford Shoes	1 (1.3)

- Other footwear characteristics

The Footwear Assessment Form was used to assess the participants' footwear. The data was documented and analysed and presented in Table 4.12 below.

Table 4.12 Footwear Characteristics of participants who sustained a fall

Variable	N (%)
Heel Height	
0.0-2.5cm	28 (36.8)
2.6-5.0cm	48 (63.2)
>5cm	0 (0)
Fixation	
None	34(44.7)
Velcro	34 (44.7)
Laces	1 (1.3)
Straps or buckles	4 (5.3)
Zips	3 (3.6)
Heel Counter Stiffness	
None	23 (30.3)
Minimal (<45°)	11 (14.5)
Moderate (>45°)	35 (46.1)
Rigid (0-10°)	7 (9.2)
Longitudinal Sole Rigidity	
Minimal (<45°)	34 (44.7)
Moderate (>45°)	29 (38.2)
Rigid (0-10°)	13 (17.1)
Sole Flexion Point	
At MTPJs	37 (48.7)
Before MTPJs	39 (51.3)
Tread Pattern	
Textured	25 (32.9)
Smooth	22 (28.9)
Partly Worn	24 (31.6)
Fully Worn	5 (6.6)
Sole Hardness	
Soft	14 (18.4)
Firm	35 (46.1)
Hard	27 (35.5)

- The most common **heel height** ranged from 2.6 to 5.0cm (63.2%), which is more than the ideal 2.5cm heel height as described in the literature (Jellema et al., 2019).
- 44.7% of patricipants had either no form of **shoe fixation**, or velcro. Another 44.7% of participants used Velcro as a method of shoe fixation.
- Almost a third (30.3%) of participants had footwear with no heel counter. The majority of those having a heel counter, had a **heel counter with stiffness** of more than 45°, meaning that they provided little foot stability.
- Only 17.1% of the participants had a rigid sole. Almost half of the participants (44.7%) had shoes with an outer **sole longitudinal rigidity** of less than 45°, while 38.2% had an outer sole rigidity of more than 45°. A rigid sole is thought to be ideal in providing the most stability during gait (Barton, Bonanno & Menz, 2009), however others believe that a rigid sole may predispose the wearer to falls (Sherrington & Menz; 2003; Jessup, 2007).
- The number of participants having their sole bending at the level of the MTPJs and proximal to the MTPJs was almost equal. Thirty seven participants had a **sole flexion point** at the MTPJs, while 39 participants had a sole flexion point proximal to the MTPJs, thus decreasing shoe stability .
- Almost one third (32.9%) of the participants wore shoes with a textured **tread pattern**, which is thought to be ideal in reducing falls by slipping. This was followed closely (31.6%) by participants who wore a partially worn tread pattern.
- The **inner sole hardness** was mesured with a shore A durometer and recorded. The minority of participants (18.4%) had a soft inner sole which is thought to contribute to loss of balance in older adults. Almost half (46.1%) of the participants had a firm inner sole.

4.6.8 Participants' Shoe fit

Same as Phase 1, shoe fit was measured in terms of length and width. The difference in shoe-to-foot length and width were measured as described in section 2.9 and recorded.

Participants having their shoe-to-foot length between 10 to 15mm were considered as having a good fit. Participants with measurements less than 10mm were considered as having their shoes too short, and participants having their shoe longer 15mm than their foot were considered as having their shoes too long.

In this population, 26.3% of participants had their shoe-to-foot length between the ideal 10 to 15mm range, as shown in figure 4.13. This is lower than participants in the 15.5 to 20.5mm gap (32.9%), but higher than the other shoe-to-foot length ranges.

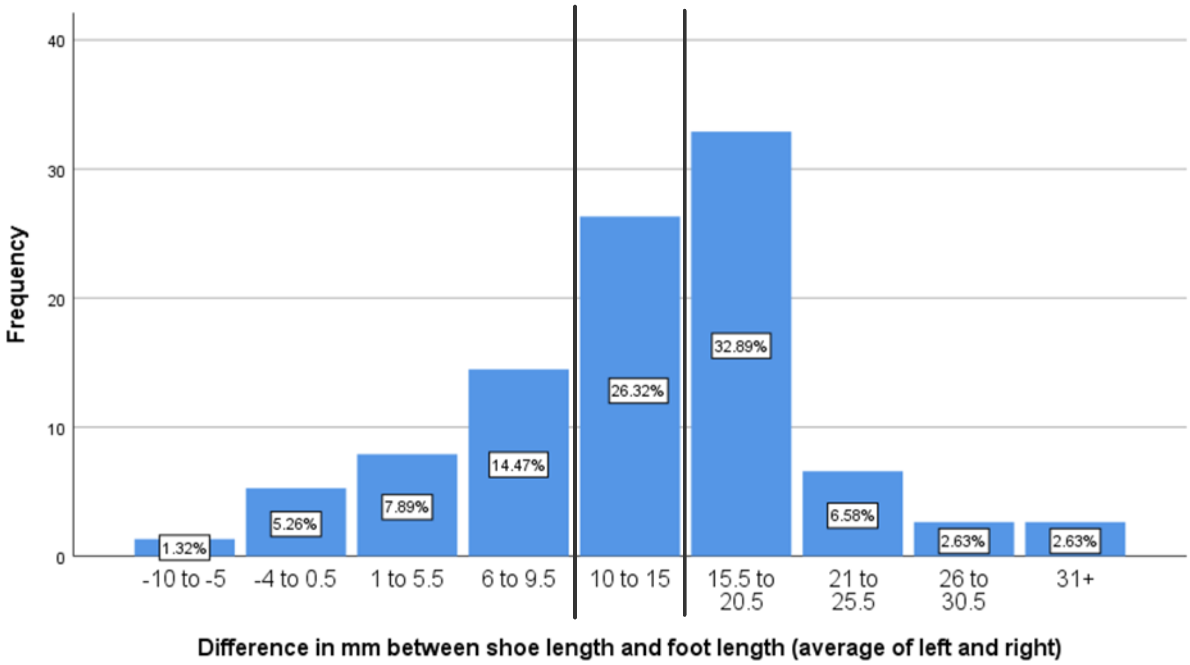

Figure 4.13 Representation of the participants' shoe-to-foot length values

Furthermore, an adequate shoe fit was recorded when the measurement of shoe width was either equal to the shoe width, or up to 7mm wider than the foot. An ill-fitting shoe fit was recorded when measurements for one or both feet were not within the pre-determined ranges of 0-7mm shoe-to-foot width.

In this study population almost half (44.7%) of the participants had their shoe-to-foot width within the ideal 0 to 7mm range, as shown in figure 4.14. This was followed by 23.7% who had their shoe-to-foot width within the 7.5 to 12mm range.

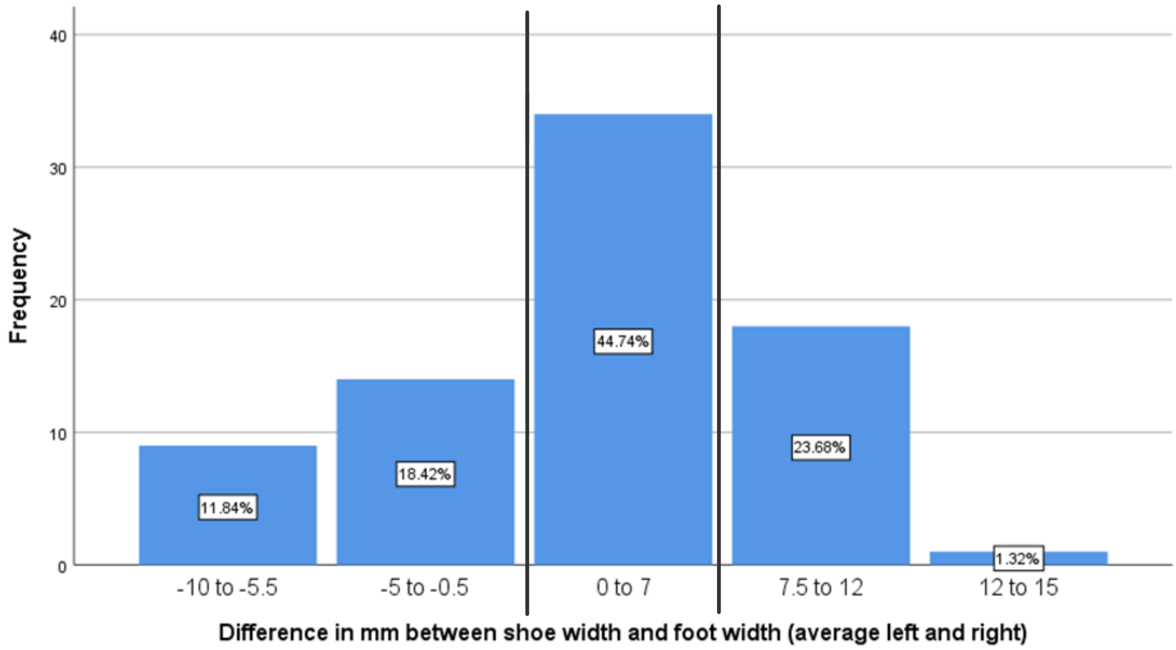

Figure 4.14 Presentation of the participants' shoe-to-foot width values

Table 4.13 shows that almost half (44.7%) of participants had their shoes too long in terms of fit, while 28.6% had their shoes too short in terms of fit. This was followed closely (26.3%) by those having a good fit, which is the lowest category. Regarding shoe width, almost half (44.7%) of participants were wearing shoes having a good fit, while 30.3% had their shoes too narrow. Participants having their shoes too wide were in the lowest category making up 25% of the population.

Table 4.13 Participants' footwear fit

Variable	n (%)
Length	
Good	20 (26.3)
Too long	34 (44.7)
Too short	22 (28.9)
Width	
Good	34 (44.7)
Too wide	19 (25)
Too narrow	23 (30.2)

When combining results from both data sets together, i.e. shoe-to-foot length and width, it was found that only 9.2% of participants were wearing shoes having a good fit, as illustrated it figure 4.15.

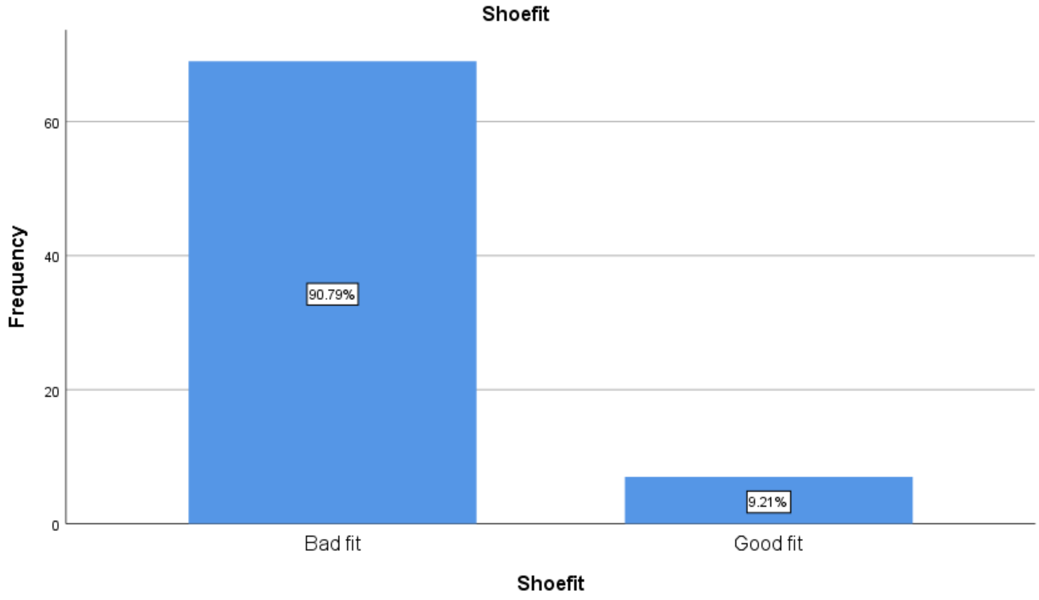

Figure 4.15 Participants' Overall Shoe Fit

From the 90.8% (n=68) participants wearing footwear with a bad fit, it was found that 25.3% (n=19) had shoes that were too long but had good width, followed by 14.7% having shoes that were too short and too narrow (n=11). This is illustrated in figure 4.16.

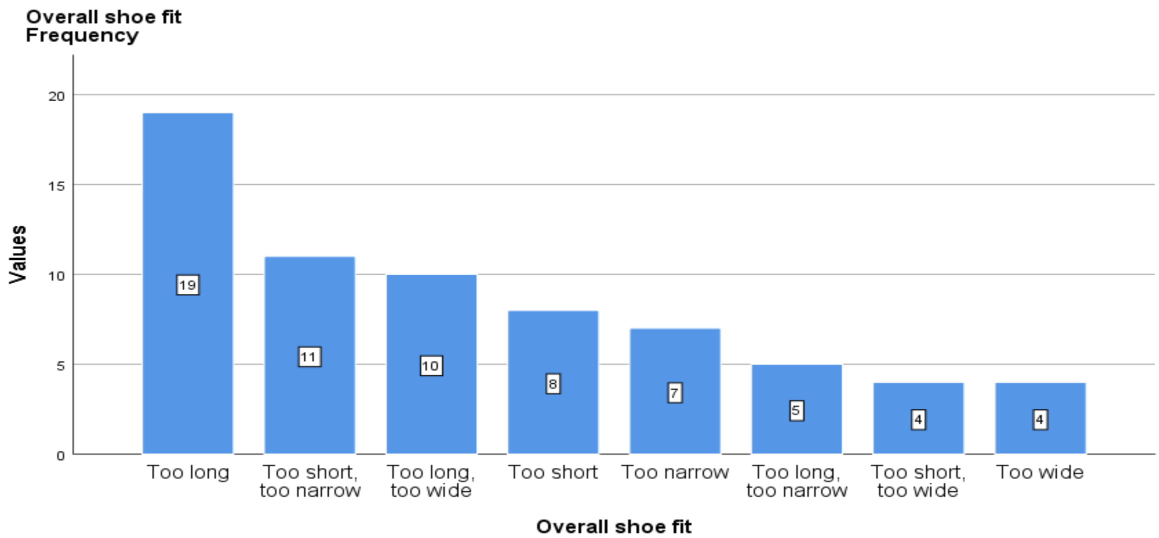

Figure 4.16 Breakdown of bad fitting footwear worn by the study population.

4.7 Statistical analysis

4.7.1 Association between footwear characteristics and type of fall

The Chi square test was used to investigate the association between the two categorical variables i.e. footwear characteristics and type of fall. The null hypothesis specifies that there is no association between the categorical variables and is accepted if the *p*-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that there is a significant association between the two categorical variables and is accepted if the p-value is less than the 0.05 criterion.

Therefore, the following hypothesis was set:

Null hypothesis, H0: There is no significant difference between footwear characteristics and type of fall.

Alternative Hypothesis, H1: There is a significant difference between footwear characteristics and type of fall.

Since the *p*-values for all footwear characteristics and fit exceeded the 0.05 level of significance, the null hypothesis is accepted, therefore, there was no significant difference between none of the footwear characteristics and type of fall. Table 4.14 explains this further.

However, even though the results were not significant, some trends between footwear characteristics and type of fall were noted:

- Most of the participants who tripped were wearing sandals (14.5%) and slippers (13.2%).
- Falls by tripping and loss of balance were common in participants who wore shoes with flexible heel counters. This is because out of the 26 participants who fell by tripping, 10 were wearing shoes with a heel counter stiffness of more than 45° and out of the 26 participants who fell due to loss of balance, 15 were wearing shoes with a heel counter stiffness of more than 45°.
- A very flexible sole was related to loss of balance, while tripping was mostly common in participants wearing a fairly flexible sole. Out of the 26 participants who fell by tripping, 15 were wearing footwear with a longitudinal sole rigidity of less than 45º, while out of the 26 participants who fell due to loss of balance, 15 were wearing footwear with a longitudinal sole rigidity of more than 45º.

- Loss of balance was common in participants wearing footwear with a sole flexion point before the MTPJs, while falls due to tripping were common in shoes with a sole flexion point at the level of the MTPJs. Indeed, out of the 26 participants who fell due to loss of balance, 18 had a sole flexion point before the MTPJs, while 16 out of the 26 participants who tripped had their sole flexion point at the level of the MTPJs.
- A firm sole was common amongst participants who fell due to loss of balance, and a hard sole was common in participants who tripped. This is because out of the 26 participants who fell due to loss of balance, 13 had a firm sole, while 12 out of 26 participants who fell due to tripping had a hard sole.
- The majority of participants who tripped had a textured tread pattern (16 out of 26), and most of the participants who lost balance had a partly worn tread (10 out of 26).
- Long shoes were common in falls by tripping, while short shoes were common in short shoes. In fact, out of the 26 participants who tripped, 17 were wearing shoes that were too long, and out of the 26 participants who fell due to loss of balance, 11 were wearing shoes that were short.

Table 4.14 Association between footwear characteristics and fit and type of falls

Variable	df	Pearson Chi-Square	*p*-value
Shoe Style	28	22.516	0.757
Heel Height	4	3.859	0.425
Heel Counter Stiffness	12	11.25	0.508
Shoe Fixation	16	11.70	0.767
Longitudinal Sole Rigidity	8	13.47	0.097
Sole Flexion Point	4	8.64	0.070
Sole Hardness	8	9.02	0.340
Tread Pattern	12	19.57	0.076
Shoe fit (length)	8	8.84	0.356
Shoe fit (width)	8	9.46	0.305

4.7.2 Association between injuries sustained and type of fall

The chi square test was used to find if there is any association between type of fall and any injuries sustained from the fall. Bruises were the most common in most participants who tripped (13%) or lost balance (12%). However, since the *p*-value (0.969) is more than the 0.05 level of significance, this study found no significant association between injuries sustained and type of fall in this population.

A table further explaining these results can be found in appendix 22.

4.8 Conclusion

After analysing all data from Phase 2 of this study the following can be concluded:

- The study population mostly consisted of females between the age of 81-85, making use of an assistive device with a history of falls.
- Most falls occurred during the summer period. The bathroom and bedroom were the most common locations for falls. Most falls occurred in the morning.
- Most falls occurred due to tripping or loss of balance. Bruises were the most common injuries sustained following a fall.
- The study population (participants who sustained a fall) was found more likely to wear footwear with sub-optimal features such as heel height of more than 2.5cm and footwear with no fixation.
- Sandals were the most common shoe type worn by this population.
- Only 9.2% were found to wear footwear having a good fit, in terms of length and width. Most of the participants were wearing footwear which was too long for their feet.
- No significant difference was found between footwear characteristics and fit and type of falls.

The next part of the results chapter will analyse data of Phase 3 of the study, that is, the data results of participants from Phase 2 after completing two tests (FRT and TUG).

Phase 3: Testing the functional stability and balance of participants wearing the footwear used at the time of fall

4.9 Introduction

During Phase 3, the participants were asked to complete 2 tests (FRT and TUG) in order to assess stability and balance. This was done by doing the tests wearing 2 sets of footwear; the participants' footwear worn at time of fall, and another footwear provided by the researcher, having ideal characteristics, which, for the purpose of this study will be referred to as the researcher's footwear. The aim was to determine if adequate footwear provided better balance and stability for the participants than the footwear worn at the time of fall.

4.9.1 Descriptive statistics

Out of 76 participants recruited during Phase 2, only 41 completed Phase 3, as shown in table 4.15. Most of the participants who did not participate in Phase 3 was because they had sustained a fracture during their fall (n=18), which was an exclusion criterion for Phase 3. Eight of the participants became wheelchair-bound after the fall, so they were excluded from Phase 3. Out of the 7 participants who refused to participate in Phase 3, four said that it was because they were afraid of falling during the tests. The other 3 who refused, did not provide a reason for doing so. One of the participants was stopped from completing the tests because he could not carry out the tests as per the researcher's instructions. Another participant discarded the footwear he had fallen with because he blamed it for this the previous fall, before completing Phase 3, where this shoe was necessary for data comparison, therefore he was excluded from Phase 3.

Table 4.15 Participants reason for not participating in Phase 3

	Frequency	**%**
Could not understand tests	1	1.3
Sustained Fracture	18	23.7
Participant discarded his footwear	1	1.3
Became wheelchair dependent	8	10.5
Refused, no reason	3	3.9
Refused, fear of falling	4	5.3
Participated in Phase 3	**41**	**53.9**

Out of the 41 participants who completed Phase 3, 27 were females, and 14 were males. The participants were encouraged to use their mobility assistive device if they usually make use of it or if they feel safer with it. Table 4.16 shows that more than half (56.1%) used an assistive mobility device during Phase 3 of the study.

Table 4.16 Use of Assistive device during Phase 3 of the study

	Frequency	**%**
Use of assistive device	23	56.1
Walked unaided	18	43.9

The distance covered for the FRT test was recorded for all participants with both sets of footwear and analysed as shown in table 4.17. Results show that the participants completed the FRT in an average of 142mm with their footwear and 143.8mm with the researcher's footwear. The average time taken to complete the TUG was 25s with the participants' footwear and 24.1s with the researcher's footwear. Mean results indicate that the participants performed better with the researcher's footwear, for both tests, however further analysis is needed to determine if the change is significant. This will be presented in section 4.9.2 below.

Table 4.17 Summary of FRT distances and TUG times covered with researcher's footwear and footwear worn at time of fall.

		FRT Distance (mm) Footwear worn at time of fall	FRT Distance (mm) Researcher's Footwear	TUG Time (s) Footwear worn at time of fall	TUG Time (s) Researcher's footwear
N	Valid	41	41	41	41
	Missing	0	0	0	0
Mean		142.00	143.80	25.01	24.13
Median		125.00	125.50	23.40	23.06
Std. Deviation		163.69	160.78	6.59	6.55
Range		116.50	126.50	25.99	26.41
Minimum		58.5	52.5	15.01	14.09
Maximum		175.00	179.00	41.00	40.50

4.9.2 Comparing the results of the FRT and TUG between two sets of footwear.

FRT is a test which records a distance reached over a fixed base of support, and TUG is a test which records the time taken to walk a certain distance. The distance and time for both tests were recorded utilizing both sets of footwear. The time taken to do the TUG with the participants' footwear was subtracted from the time taken with the researcher's footwear. Similarly, the distance covered during the FRT with the researcher's footwear was subtracted from the distance covered with the participants' footwear. This difference in distance (for FRT) and time (for TUG) was recorded.

Then the full set of data was then checked for outliers. This was done for both the FRT and TUG results. Outliers are extreme data values that greatly stand out from the overall pattern of values in a dataset or graph (Vinutha, Poonima, & Sagar, 2018). Statisticians argue how even a small number of outliers can greatly impact even simple analyses (Osborne & Overbay, 2004). Removing outliers significantly improves accuracy and reduces inference errors. Regardless of the sample size, even one or a few outliers can disproportionately affect statistical analyses, potentially creating false significance or masking real relationships (Sullivan, Warkentin, & Wallace, 2021).

- FRT Test

Data was checked for outliers by plotting a boxplot (Figure 4.17) and analysing any points which do not fall between the two ends of the boxplot whiskers. In this case, 4 data points were classified as outliers, therefore participant number 10, 14, 39 and 41 data for the FRT was removed to ensure that the analysis reflects the typical patterns in the dataset without being skewed by unusual values (Vinutha, Poonima, & Sagar, 2018) .

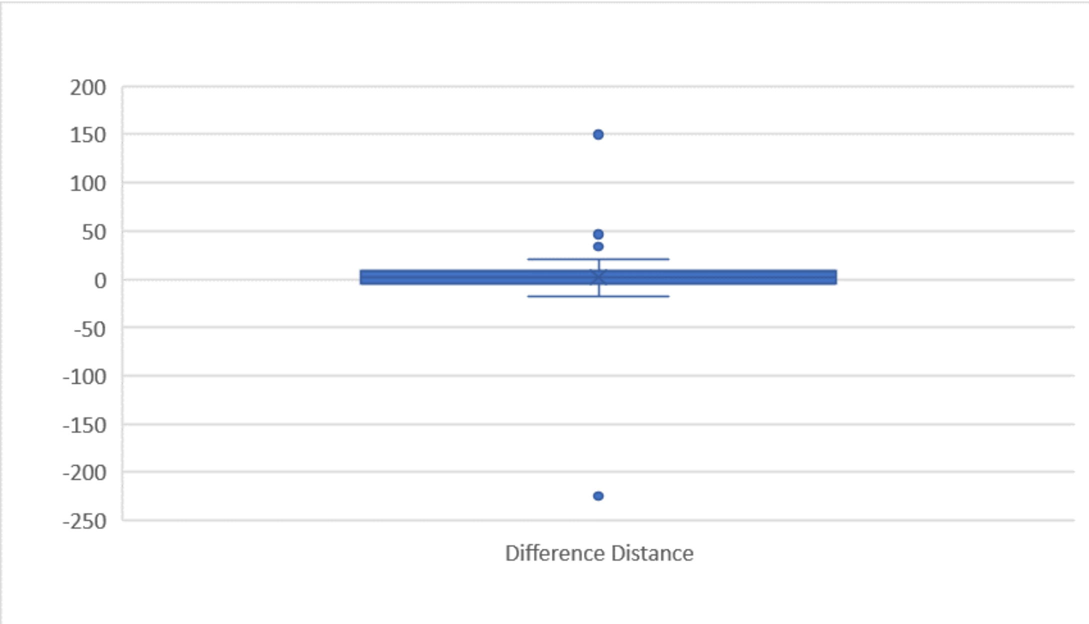

Figure 4.17 Boxplot with full data on FRT

After excluding these outliers, the boxplot was re-plotted. A scatter plot was also produced before and after eliminating the additional outliers, as demonstrated in Figure 4.18.

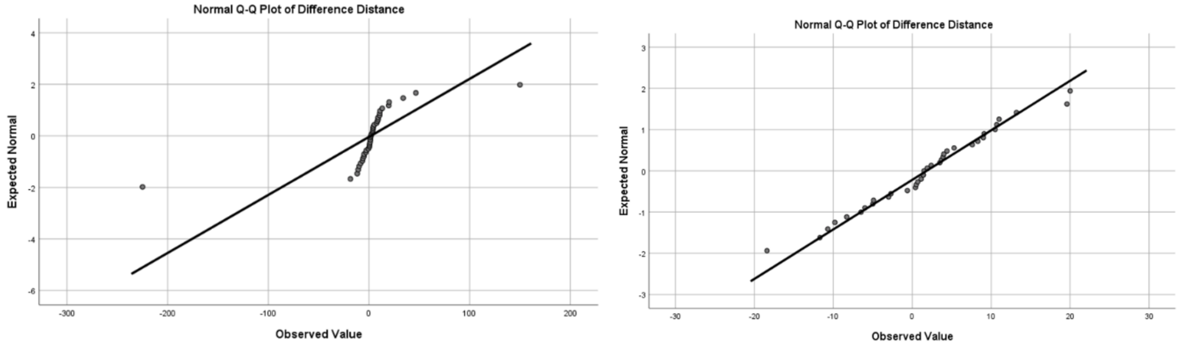

Figure 4.18 Scatter plot before (left) and after removing outliers (right) for TUG

- TUG Test

The full set of data for the TUG test was also checked for outliers. A box plot (Figure 4.19) was plotted and any points that did not fall between the two ends of the boxplot whiskers were removed. In this case, 3 data points were classified as outliers (TUG results for participant number 4, 8 and 18) and thus were removed to obtain more accurate results.

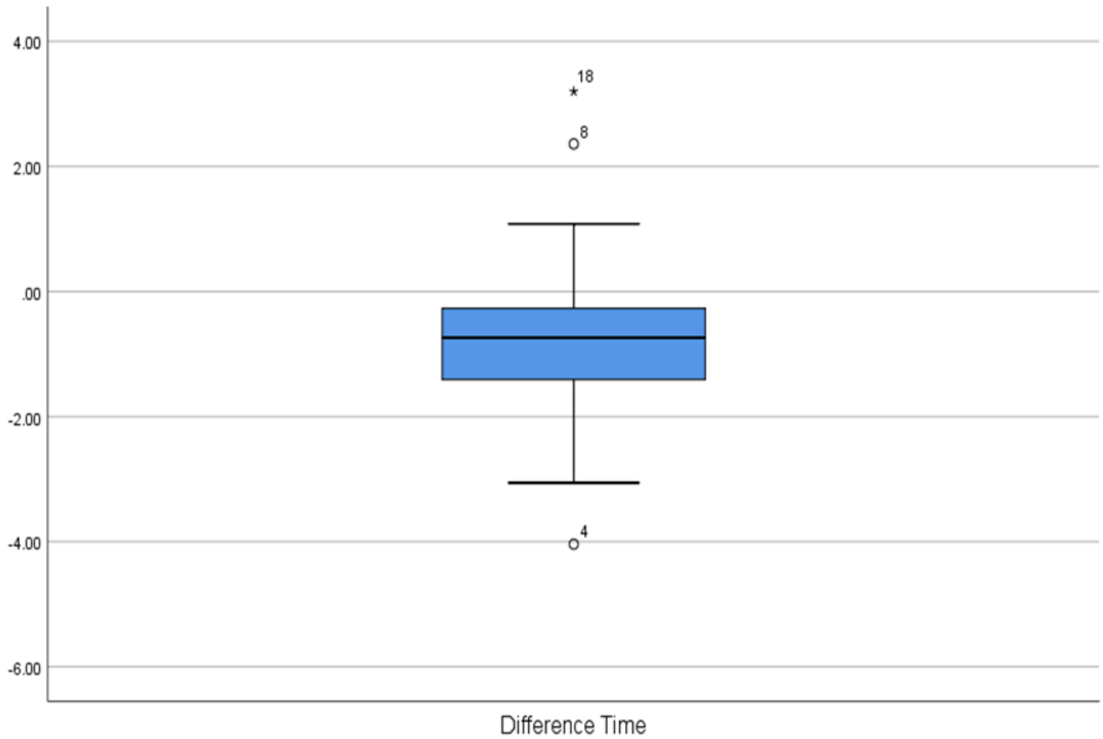

Figure 4.19 Box plot with full data on TUG

After excluding these outliners, a boxplot was re-plotted. A scatter plot was also produced before and after eliminating the additional outliers, as demonstrated in Figure 4.20.

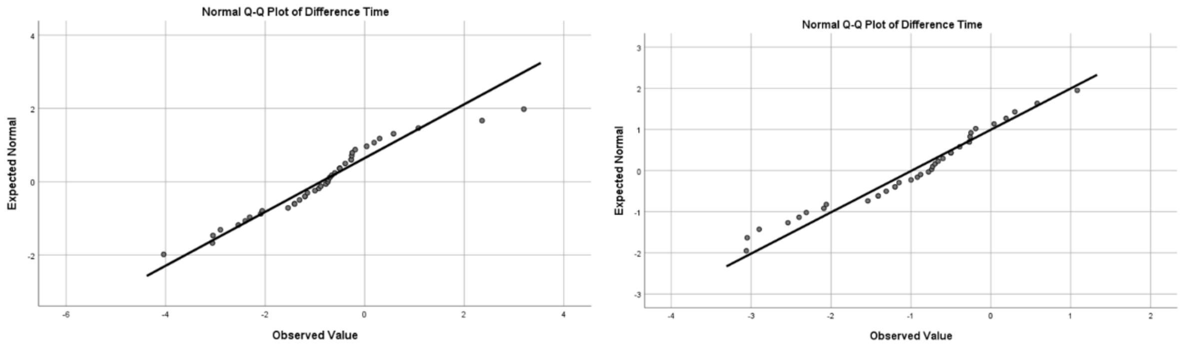

Figure 4.20 Scatter plot before (left) and after removing outliers (right) for FRT

Based on a sample size of 37 and 38 for the FRT and TUG respectively, the data was then tested for normality to determine which tests are to be used for analysis. The Shapiro-Wilk test was used to determine whether a score distribution is normal or skewed (non-normal). The null hypothesis specifies that the score distribution is normal and is accepted if the *p*-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that the score distribution is skewed and is accepted if the p-value is less than the 0.05 criterion. In this case, both data for the FRT (difference in distance) and TUG (difference in time) exceed the 0.05 level of significance, thus the data can be considered to be normal, and thus parametric tests were utilised for analysis. This can be shown in table 4.18 below.

Table 4.18 Tests of Normality

	Df	**Test Used**	**P-value**	**Normality?**
Difference (Distance)	37	*Shapiro-Wilk*	0.871	Yes
Difference (Time)	38	*Shapiro-Wilk*	0.179	Yes

The paired samples T-Test was used to determine whether there is a significant difference between the time and distance achieved with the researcher's footwear and participants' footwear. The paired samples t-test is appropriate when the data is collected in pairs or when the same subjects are used for different tests. In this case, since the same participants were tested with both types of footwear, the data is paired. The following points explain why this test is best for analysing the data:

- Dependency: The observations in one group are related or paired with the observations in the other group (researcher's footwear vs participants' footwear).
- Reduction of individual differences: By using the same participants for both footwear conditions, one can control the individual variability, making the test more sensitive to detecting true differences.
- Increased statistical power: The paired samples t-test has generally higher statistical power compared to the independent samples t-test when dealing with paired data. Therefore, it's better at detecting a true effect, if it exists (Smith, 2019).

Null Hypothesis (HO): The true mean difference between the two sets of data is equal to zero.

Alternate Hypothesis (H1): The true mean difference between the two sets of data is not equal to zero.

Table 4.18 shows that since the *p*-value for the FRT test is greater than the 0.05 level of significance (0.191), the null hypothesis is accepted. Therefore, the difference in distance for the FRT test, for both sets of footwear is not statistically significant.

On the other hand, table 4.19 shows that since the *p*-value for the difference in time for the TUG test is 0.00 which is lower than the 0.05 criterion, the null hypothesis is rejected. Therefore, the difference in time for the TUG, between the two sets of data is statically significant.

Table 4.19 FRT and TUG results between two sets of footwear

	Paired Differences							
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	**Sig. (2-tailed)**
				Lower	Upper			
FRT- Distance with Participant's footwear vs Distance with Researchers Footwear	-1.825	8.321	1.368	-4.599	0.950	-1.334	36.000	**0.191**
TUG- Time with Participants' footwear vs Time with Researcher's footwear	0.989	0.997	0.162	0.661	1.317	6.115	37.000	**0.000**

In summary, the participants performed significantly better when using the researcher's footwear for the TUG test. However, there was no significant difference in performance between the two sets of footwear for the FRT test. Figure 4.21 demonstrates the comparison of both sets of data utilizing boxplots, for both the FRT and TUG test.

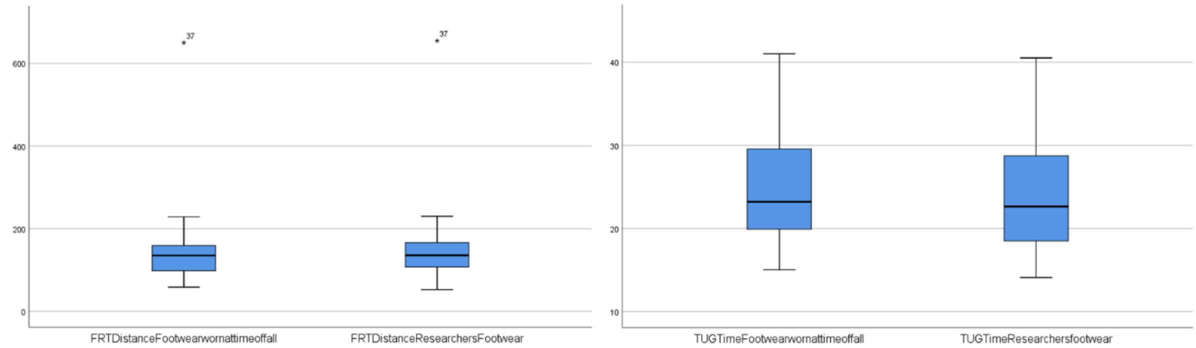

Figure 4.21 Comparing the box plots for participants' footwear vs researchers' footwear for the FRT test (left) and TUG test (right).

<u>4.9.3 Analysing specific footwear characteristics which might alter the FRT and TUG results.</u>

Footwear characteristics which were assessed in the methodology were then analysed to determine if any specific characteristic was responsible for any change in distance for the FRT or change in time for the TUG, thus responsible for improving balance and stability during these tests. These characteristics are:

- Shoe fit in terms of length
- Shoe fit in terms of width
- Shoe type/style
- Heel Height
- Fixation
- Heel Counter Stiffness
- Longitudinal Sole Rigidity
- Sole Flexion Point
- Tread Pattern
- Sole Hardness

The Analysis of Variance (ANOVA) test was used to determine if there is a significant difference in the means of distance difference (FRT test) and means of time difference (TUG test) among the footwear characteristics. In this case, the FRT and TUG results are dependent variables, and the footwear characteristics are independent. The ANOVA test is appropriate for this scenario since the independent variables are categorical (Vinutha, Poonima, & Sagar, 2018). This test can also handle scenarios where an independent variable has more than two groups (e.g. Sole hardness can be categorised in 3 groups – soft, firm and hard).

Table 4.20 shows that none of the independent variables (footwear characteristics) showed statistically significant effects on the TUG results since all exceeded the 0.05 level of significance. This suggests that, at the given significance level, none of these variables significantly impact the mean of the dependent (TUG results) variable.

Table 4.20 ANOVA Test results for footwear characteristics for TUG test

	Type III Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**
Shoe Fit-Length	3.013	2	1.506	1.346	**0.297**
Shoe Fit-Width	3.412	2	1.706	1.524	**0.257**
Shoe Style	4.086	5	0.817	0.730	**0.615**
Heel Height	0.019	1	0.019	0.017	**0.898**
Fixation	2.635	4	0.659	0.588	**0.677**
Heel Counter Stiffness	2.837	3	0.946	0.845	**0.495**
Long. Sole Rigidity	0.259	2	0.129	0.116	**0.892**
Sole Flexion Point	0.038	1	0.038	0.033	**0.858**
Tread Pattern	0.474	3	0.158	0.141	**0.933**
Sole Hardness	1.511	2	0.756	0.675	**0.528**
Error	13.435	12	1.120		
Total	73.942	38			
Corrected Total	36.777	37			

a. R Squared = .635 (Adjusted R Squared = -.126)

Table 4.21 shows that none of the independent variables (footwear characteristics) showed statistically significant effects on FRT results. This suggests that, at the given significance level, none of these variables significantly impact the mean of the dependent (FRT results) levels.

Table 4.21 ANOVA Test results for footwear characteristics for FRT test

	Type III Sum of Squares	**df**	**Mean Square**	**F**	**Sig.**
Shoe Style	569.606	5	113.921	1.310	**0.328**
Heel Height	72.535	1	72.535	0.834	**0.381**
Fixation	193.462	4	48.366	0.556	**0.699**
Heel Counter Stiffness	242.973	3	80.991	0.931	**0.458**
Long. Sole Rigidity	192.285	2	96.142	1.106	**0.365**
Sole Flexion Point	1.544	1	1.544	0.018	**0.896**
Tread Pattern	268.292	3	89.431	1.029	**0.418**
Sole Hardness	7.450	2	3.725	0.043	**0.958**
Shoe Fit-Length	95.966	2	47.983	0.552	**0.591**
Shoe Fit-Width	31.172	2	15.586	0.179	**0.838**
Error	956.420	11	86.947		
Total	2615.721	37			
Corrected Total	2492.543	36			

a. R Squared = .616 (Adjusted R Squared = -.256)

4.10 Conclusion

- Participants performed significantly better in the TUG test when wearing the researcher's footwear.
- There was no significant difference in the FRT test between the footwear worn at the time of fall and the researcher's footwear.
- None of the footwear characteristics were found to significantly impact the difference in time during the TUG test and the difference in distance during the FRT test. This could be due to the relatively small sample size of 37 and 38 participants (after removing the outliers) and various independent variables which may limit the accuracy of the test and therefore reduce the statistical power of the analysis. The following chapter will discuss these study results into more detail.

Chapter 5:

Discussion

5.1 Introduction

Falls are multifactorial, and the risk of falling appears to increase with increased number of risk factors. Old age and residency in a long-term care facility are significant risk factors, in addition to various medical conditions commonly associated with aging (Baixinho & Dixe, 2015). This was demonstrated in both Phase 1 and Phase 2 of this study, where most participants had multiple risk factors for falls, such as polypharmacy, visual impairments and history of falls. Moreover, more than half of the population made use of a walking aid for ambulation and had a reduced Barthel Index score, indicating mobility and functional limitations, which further increased their risk of falls. Multifactorial interventions are essential in fall prevention programmes (Hopewell, et al., 2019); however, footwear, an extrinsic risk fall factor, is sometimes overlooked in fall prevention guidelines (Montero-Odasso et al., 2022). Therefore, this study aimed to highlight the importance of footwear in fall prevention by answering the research question: Does footwear design affect the risk of falling in a geriatric population at a long-term care facility?

This study has demonstrated that inadequate footwear does affect the risk of falling in a geriatric population living in a long-term care facility. The footwear worn at the time of the fall negatively impacted participants' balance during walking, as evidenced by their improved performance on the TUG (Time Up and Go) test when wearing well-fitting footwear having adequate characteristics as mentioned in the literature. However, participants' stability over a fixed base of support was not affected when wearing 'adequate' footwear when assessed by the FRT (Functional Reach Test) since there was no significant difference in this context. This suggests that adequate footwear plays a major role during walking but plays a less significant role when standing stationary. Nevertheless, none of the footwear characteristics were found to significantly impact any changes in stability and balance observed during the FRT and TUG tests. Therefore, while there was no direct association between footwear characteristics and the risk of falling in older adults, individuals demonstrated significantly improved performance on ambulatory tests when wearing footwear having ideal characteristics. This will be discussed in more detail below.

In light of the mentioned gaps in existing research, this study addressed critical aspects related to footwear and falls in older adults. While previous research has primarily focused on certain footwear types such as bed slippers, and footwear characteristics specifically heel height, heel counter stiffness, and footwear fixation (Lopez-Lopez et al., 2018), this study evaluated other footwear characteristics that were sparsely investigated in previous studies (Jellema et al., 2019), specifically the sole flexion point, and longitudinal sole rigidity. By comprehensively examining these characteristics, this study aimed to provide a more complex and complete understanding of their impact on falls in the aging population.

Another aspect that was taken into consideration during this study was the impact of shoe fit on balance and stability in older adults. Unlike prior studies that predominantly concentrate on shoe fit in terms of shoe length (Burns & Leese, 2002), this study considered the often-overlooked dimension of width in footwear worn by the ageing population, thus offering a more holistic perspective on the influence of footwear fit on balance and stability in older people. Furthermore, whilst previous investigations have mainly focused on the diabetic population in the context of ill-fitting footwear, (Jones et al., 2019), this study evaluated the older demographic, since some studies have shown how ill-fitting footwear can contribute to falls in older adults (Doi et al., 2010). Published research examining both footwear characteristics and fit jointly are scarce. Both of these footwear variables are important to consider collectively since various studies (Davis, Haines & Williams, 2019; Burns & Leese, 2002) have attributed them independently to each other to falls in older adults, but none have examined these variables together. This was only observed in a study by O'Rourke et al., (2020) which like the current study, assessed both shoe characteristics and fit (in terms of length) and their relationship to falls in a geriatric population. However, the population in the O'Rourke et al. (2020) study, did not experience falls during the study period, thus a direct correlation between 'inappropriate' footwear and falls could not be established.

Moreover, most studies conducted on footwear and falls in older adults are retrospective questionnaires/interviews relying on recollection of footwear worn at the time of a previous fall, which could hinder the accuracy of the results (Davis Haines, & Williams, 2019). This research adopted a prospective approach, by closely monitoring a population for falls for a period of time, thus possibly obtaining a more accurate overview of the problem.

5.2 Review of findings

5.2.1 Effects of adequate footwear on balance and stability

The participants were provided with footwear having the ideal characteristics as mentioned in the literature (Jellema et al., 2019; Menant et al. 2008), and described in section 3.6.3 of the Methodology chapter. The results of the FRT and TUG were compared to the footwear worn at the time of the fall.

In this study, participants showed significant better results (*p*-value = 0.00) in the TUG when wearing footwear with the ideal characteristics. Cut-off times for classifying individuals at high risk of falls vary based on the study and participants (Shumway-Cook, Brauer, & Woollacott, 2000). Generally, an older adult who takes more than 13.5seconds to complete the TUG is at a higher risk of falls (Barry et al., 2014). In this study, participants took an average of 24.1s with the provided footwear and 25s with the footwear worn at the time of fall, underscoring the elevated risk of falls within this population. Therefore, although gait speed improved with the provided footwear, participants remained at high risk of falls. However, the increase in gait speed with the provided footwear indicates that fall risk decreases with appropriate footwear.

Conversely, there was no significant difference (*p*-value = 0.191) in the FRT when participants wore the provided adequate footwear and the footwear worn at the time of fall. This indicates that adequate footwear did not play a role in providing balance and stability over a fixed base of support. A forward reach in the FRT, of less than or equal to 15 cm was found to be predictive of a fall in older adults (Duncan et al., 1990). In this study, the average distance covered by the participants with both sets of footwear was less than 15cm, further highlighting the participants' increase falls risk. This aligns with other studies indicating that institutionalised older adults are the most risk of falls (Baixinho & Dixe, 2015).

A number of studies have investigated the impact of footwear characteristics such as sole hardness (Losa Inglesias, Becerro de Bengoa Vallejo, & Palacios Pena, 2012), heel height (Kim et al., 2012), and fit (Lopez-Lopez, et al., 2016) on postural stability and gait in older adults. However, these studies did not assess all footwear characteristics, but focused on specific aspects. It is often documented that adequate footwear is dependent on many factors including proper fit, good fixation, heel counter stiffness and sole hardness and width (Jellema et al., 2019). Moreover, participants in these studies typically used different footwear rather than their habitual footwear. There are only a few studies that examined all properties of adequate footwear (Horgan et al., 2009; Guchan et al.,2014; Maden, et. 2021), which are described below.

- Dynamic Balance in older adults

This study has shown that adequate footwear significantly improves dynamic balance in older adults, since participants gait speed increased during the TUG test which indicates improved balance and mobility. Other studies have demonstrated different results which could be explained by the different methodologies employed or different study populations used. Maden et al. (2021) carried out a study similar to this current study, where appropriate footwear was compared to ill-fitting footwear to study their effect on functional performance and balance, when compared to barefoot. Participants in the study by Maden et al., performed significantly better with the appropriate-fitting footwear in the Berg Balance Scale (BBS) which is a clinical test that measures balance, but no significant difference was noted for the TUG test. However, the methodology employed in the current study differed from that of Maden et al. (2021), which may explain the discrepancy in results. Contrary to the current study where the same group of participants was assessed with both set of footwear, the study by Maden et al., (2021), used two separate groups of participants based on their habitual footwear fit: one wearing ill-fitting footwear and one wearing appropriately fitting footwear. These groups were then instructed to perform the BBS and TUG tests twice—once with their footwear and once barefoot—to compare their habitual footwear performance with being barefoot. Consequently, the study's findings may not adequately reflect the differences between adequate and inadequate footwear within individual participants, since results may reflect difference between participant populations rather than solely the impact of footwear conditions.

Similarly to Maden et al., Horgan et al. (2009), assessed participants with and without shoes when doing the BBS. The participants performed significantly better when wearing their own footwear; however, this does not necessarily indicate the impact of adequate footwear on balance, since the participants' own footwear may not have been adequate. Another potential issue affecting the results of the last two mentioned studies is the phenomenon called the 'learning effect' associated with repeated assessments of the BBS. This effect can lead to improved performance on subsequent BBS tests due to increased familiarity with the tasks (Jbadbi, Boissy, & Hamel, 2008). To mitigate this limitation in this current study, participants were asked to complete the Functional Reach Test (FRT) and Timed Up and Go (TUG) test, with the provided footwear or the footwear worn at time of fall, in a randomized order. Additionally, repeated BBS assessments can induce fatigue, resulting in decreased performance on subsequent tests due to muscle fatigue. Notably, Horgan et al. (2009) observed that BBS scores were, on average, 1.4 points lower during the second test. For this reason, the BBS was not included in this current study, particularly given the frailty of the institutionalized population and instead assessed participants using less demanding tests: the FRT and TUG.

A study which conflicts with this study findings, is by O'Rourke et al. (2020) who compared the TUG scores of participants wearing appropriately fitting and ill-fitting shoes. Contrary to the findings of the current study, O'Rourke et al. found no significant difference in TUG scores between participants wearing ill-fitting shoes and those wearing well-fitting shoes. It's worth noting that, unlike the current study where the same group of participants was assessed with both ill-fitting and adequate shoes, O'Rourke et al. used two separate groups of participants: one wearing ill-fitting shoes and the other wearing adequate shoes. This methodological difference suggests that the observed TUG score variations in O'Rourke et al.'s study may reflect differences between participant populations rather than solely the impact of footwear conditions.

Other studies have used the same clinical balance and stability tests but to assess the differences between different shoe styles. Arnadottir & Mercer (2000) observed that older women completed the TUG test significantly faster when wearing walking shoes, compared to dress shoes. Similarly, the TUG showed worse performances with high-heeled shoes compared to being barefoot and walking shoes in a study by Bhatia & Kalra (2011). However, Bhatia & Kalra (2011) found no significant difference between being barefoot and wearing walking shoes, which contradicts a study by Arnadottir & Mercer (2000) which states that participants wearing walking shoes have a slower TUG speed when barefooted. This could be due to increased foot proprioception when walking barefoot, compared to being shod (Bhatia & Kalra, 2011).

Studies show different results on TUG performance particularly with different shoe styles (Arnadottir & Mercer, 2000), however, there is a general consensus between this study and other studies (Maden et al., 2021) that footwear having appropriate characteristics and fit, improve balance during gait.

- Balance and Stability over a fixed base of support

In contrast to other studies, this study did not find any difference in FRT results when using the two types of footwear. Arnadottir & Mercer (2000) used the FRT to investigate the effect of wearing walking shoes, dress shoes and being barefoot, on balance performance in healthy, older women. They found that participants performed significantly better in the FRT when barefoot or wearing walking shoes, compared with dress shoes, likely due to better proprioception and a greater base of support (Arnadottir & Mercer, 2000). Similarly, Bhatia & Kalra (2011) concluded that high heeled shoes negatively affected FRT scores in older women. These findings highlight that the FRT scores improve with walking shoes or when barefoot, compared to high heeled shoes. Conversely, the current study, found no significant FRT differences between adequate and non-adequate footwear, possible due to the FRT's limited sensitivity in detecting subtle changes related to footwear, as opposed to more pronounced differences identified in previous studies (Arnadottir & Mercer, 2000; and Bhatia & Kalra 2011).

The absence of significant differences in the FRT but notable results in the TUG test in the present study suggest that footwear may not significantly affect stability when maintaining a fixed base of support but does play a beneficial role in balance control during walking or ambulation. This aligns with findings presented by Guchan et al. (2014) who reported that appropriate-fitting footwear improved dynamic balance, but not static balance in a sample of 70 young, healthy individuals. Similarly, Hausselle et al., (2021) observed that, except for high heeled shoes (not included in this current study as no participants were wearing high heels at the time of falls), footwear conditions did not alter postural stability during standing in young healthy subjects. The results might differ in older adults, who typically experience decreased balance due aging. Therefore, further studies involving older adults are recommended to better understand potential age-related differences in footwear effects on balance.

5.2.2 The Impact of Footwear Characteristics on the Risk of Falling.

When individually assessing each footwear characteristic and fit variables, none significantly impacted the FRT and TUG times, as all *p*-values exceeded the 0.05 level of significance. This indicates that in this study population, neither footwear characteristics nor fit played a significant role in improving balance and stability.

These findings are similar to those reported by Horgan et al. (2009), Menz, Morris & Lord (2006) and Tencer et al., (2004). Similar to the current study, Horgan et al. (2009) found that balance scores (BBS) where signifcantly higher when wearing footwear, yet, footwear characteristics were not associated with changes in balance scores (BBS). Similarly, Menz, Morris & Lord (2006) did not find any significant association between footwear characteristics and risk of indoor and outdoor falls in older people. Tencer et al. (2004) observed no significant differences in heel collar height, heel width, sole thickness, critical tipping angle, sole flexibility, or coefficient of friction between individuals who fell and those who did not. However, a trend towards higher heels and a reduced sole contact area amongst those who experienced falls was noted. However, these associations were only marginally significant, and there was no clear threshold indicating a substantial increase in fall risk.. Even though these studies showed similar results, different methodologies where used which are outlined below in table 5.1. In summary, regardless of sample size, type of footwear tested and methods used to assess fall risk, these studies have not foud any significant association with footwear characteristics and risk of falling.

Table 5.1 Main similarities and differences between methodologies used in studies assessing footwear characteristics (Horgan et al., 2009; Menz, Morris & Lord, 2006; Tencer et al., 2009).

	This Study	**Horgan et al. (2009)**	**Menz, Morris & Lord (2006)**	**Tencer et al. (2009)**
Number of participants	41	100	176	654
Participants	Older adults living in long-term care	Older adults living in the community	Older adults living in a retirment village	Older adults living in the community
Footwear tested	Adequate footwear vs inadequate footwear	Participants' footwear vs no footwear	Footwear of fallers (n= 36) vs footwear of non fallers (n=139)	Footwear of fallers (n=327) vs footwear of non fallers (n=327)
Footwear features assessed	All Footwear characteristics mentioned in Footwear Assesment form and shoe fit (length and width)	All Footwear characteristics mentioned in Footwear Assesment form	All Footwear characteristics mentioned in Footwear Assesment form	Shoe measurements related to lateral stability, foot position sense and the shoe/surface interface
Methods used to assess balance/ risk of fall	Outcomes of FRT and TUG when using different footwear	BBS scores when barefooted and wearing footewar	Direct comparism between footwear characteristics of fallers vs non fallers	Nested case-control study: biomechanical measurments of shoes worn by those who reported a fall vs non fallers

These studies are inconsistent with multiple laboratory studies that found associatons between footwear characteristics and balance in older individuals (Menz, Lord, & McIntosh, 2001; Chien, Lu & Liu, 2014). These studies tend to focus on one specific footwear feature rather than footwear as a whole (Menant et al, 2008; Davis et al., 2016). Moreover, these studies focused on participants who were mostly independent, with the majority of them being mobile independently and having not experienced a fall in the past year (Menz, Auhl & Munteanu, 2017). Therefore, results in the current study may not directly align or be comparible.

Numerous laboratory studies have shown that gait and balance are influenced by footwear characteristics and fit (Davis et al., 2016; Doi et al., 2010). Factors such as dorsal fixation, and sole hardness were found to improve gait speed, increase step length, and reduce step width, indicating good balance control (Menant et al., 2009; Menz et al., 2017). Davis et al. (2016) observed that footwear with dorsal fixation improved minimum foot clearance and increased double support during gait compared to bed slippers. Rigid heel counters reduced step width and sway, suggesting improved balance control (Menz, Auhl & Munteanu, 2017). Elevated heels were associated with decreased walking stability, and the heel height-to-width ratio influenced lateral stability by affecting the tripping angle (Menant et al., 2008; Tencer et al., 2004). Shoe tread was investigated in various studies, and it was concluded that tread needs to provide friction in the antero-posterior direction and in the medio-lateral direction, since older adults have a high risk of slipping in the lateral direction (Yamaguchi & Masani, 2019).

However, some studies indicate that the association between gait and some footwear characteristics is not that clear (Doi et al., 2010). The effects of longitudinal sole rigidity and sole flexion point remain unclear with potential gait inefficiency linked to improper flexion points (Hall & Nester, 2004). Barton, Bonanno, & Menz, (2009) also believe that since the midfoot is required to form a rigid lever during propulsion, footwear stability in this area is an optimal motion control property. However, other studies believe that a rigid sole may limit metatarsophalangeal joint movement and therefore the hallux contribution to gait, thus increasing the predisposition to falls (Reints et al., 2017).

The lack of association between footwear characteristics and fall risk observed in this study, as well as in studies by Horgan et al. (2009), Menz, Morris & Lord (2006), and Tencer et al. (2009), may suggest that specific footwear characteristics play a minor role in falls prevention during daily activities. Also, this highlights the potential limitations of laboratory-based balance and gait investigations compared to real-life scenarios contributing to falls. Moreover, clinical balance test like the FRT and TUG may detect significant differences between distinct footwear types (such as walking shoes and high-heeled shoes) but not subtle design changes. Further research, particularly involving kinetic and kinematic movement analyses, is needed to better understand the impact of footwear on fall risk.

5.2.3 Evaluation of footwear worn at time of fall

Participants who experienced a fall in this study were predominantly found to be wearing footwear with several sub-optional features. Specifically, 45% wore footwear that was too long, 36% wore sandals and 33% wore bed slippers. Additionally, 63% of participants had footwear with heels higher than 2.5cm, 45% had footwear with no fixation and 30% had footwear with no heel counters. These footwear features have all been linked to loss of stability and balance in various laboratory studies (Jellema, et al., 2019; Menant & Lord, 2013). While numerous authors have assessed footwear features following a fall (Koepsell et al., 2004; Kelsey et al., 2010; Hourihan et al., 2000; O'Rourke et al., 2020; Sherrington & Menz, 2003), some of these studies are either dated or primarily focused on specific types of footwear. This study builds on the existing literature by providing a comprehensive analysis of multiple footwear characteristics and their association with falls.

Previous case reports and case series studies have shown that unsafe and unsuitable footwear significantly increases the risk of falls in older adults (Jellema et al., 2019). These studies have documented the footwear worn at the time of the fall and the fallers' beliefs about whether their footwear contributed to the incident (Kelsey et al., 2010; Haines et al., 2015), with the advantage of investigating un-biased, real-life scenarios, as opposed to laboratory studies (Davis et al., 2019). This information, however, may be limited to identifying which shoe styles older adults most commonly wear. In the current study, both types of tests were used in order to strengthen the overall methodology and depth of analysis. Phase 2 of this study assessed the footwear worn by participants at the time of their falls over a 9-month period. In this case, the footwear characteristics and fit of 76 participants were examined and discussed below.

- Footwear fit

Shoe-to- foot length: Only 26% of the study population wore shoes having the ideal 10-15mm gap between their foot and their shoes. Almost half (45%) of the participants who sustained a fall wore shoes that were too long for their feet. The highest percentage of participants (33%) was observed to be wearing shoes with a 15.5 to 20.5mm gap between their foot and their shoes. Wearing footwear that is too long (more than 15mm longer than the foot) has been associated with falling by tripping (Menant et al. 2008; Blazer, Jamrog & Schnack (2018). Indeed, in this study, it was noticed that the majority of participants who tripped were wearing shoes that were too long (n=17), however, since upon statistical analysis, the *p*-value (0.356) exceeded the 0.05 level of significance, no significant association was established between shoe fit, in terms of length, and type of fall. This study aligns with findings presented in a retrospective study conducted by O'Rourke et al., (2020). The authors linked wearing ill-fitting footwear (in terms of length) to falls since it was noticed that a large percentage (56%) of individuals who wore ill-fitting footwear reported a recent fall, compared to those who wore good-fitting shoes (39%), thus highlighting the role good-fitting footwear plays in fall prevention.

Shoe-to-foot width: In the current study population, almost half (45%) of the participants had their shoe-to-foot width within the ideal 0 to 7mm range. However, a significant portion (30%) had their shoes too narrow, while those with excessively wide shoes constituted the smallest category, making up 25% of the population. This observed trend aligns with the findings of Doi et al. (2010) who investigated the association of shoe fit with gait parameters in older individuals. They explain that ill-fitting shoes that are too tight in a particular foot region tend to affect the efficiency of the mechanical loading transmission between the foot and the shoe, which in turn increase the risk of falls (Blazer, Jamrog, & Schnack, 2018). Furthermore, shoes that are too loose result in a slower gait, shorter stride length, and an irregular gait pattern (Jellema et al., 2019). Doi et al., (2010) concluded that loose-fitting shoes produce regional instability, which most probably affects gait (Doi et al., 2010). Since studies, have linked ill-fitting shoe-to-foot length with falls by tripping (Menant et al., 2008), this current study's findings were statistically analysed to check for any correlation between ill-fitting shoe-to-foot width and type of fall sustained by the faller, however, no significant difference was observed since the *p*-value (0.305) exceeded the level of difference.

Combining data on both **shoe-to-foot length and width** revealed 25% of participants had shoes that were too long but had good width, while 15% had shoes that were too short and too narrow. Only 9% had shoes that fit well in both length and width. This aligns with an older study by Barbieri (1993) where it was observed that 52% of 25 patients fell because they were wearing ill-fitting shoes or slippers, suggesting a potential association between ill-fitting footwear and falls. However, larger sample sizes are needed for more robust conclusions. This potential association between ill-fitting footwear and falls was investigated only in a few studies. Keegan et al. (2004) found that wearing ill-fitting shoes increased the risk of tripping and consequential fractures at five sites in the lower limb in middle and old-aged people. Lopez Lopez & Becerro de Bengoa Vallejo (2015) explain that wearing shoes of the incorrect size corresponds with a lack of foot sensitivity, a phenomenon that is a major contributor to falls. Notably, Phase 1 of this study (An Overview of Older Individuals' footwear Habits – Section 4.2.4), a higher percentage of participants were wearing footwear having a good fit in both length and width, compared to Phase 2 (Evaluation of Footwear in Participants who Sustained a Fall – Section 4.6.8), which could indicate the importance of wearing good-fitting footwear in reducing falls. However, it is important to recognize that Phase 1 also included individuals with a history of falls. Therefore, one cannot attribute this higher incidence of good-fitting footwear in Phase 1, to any change in the outcome of falls.

Apart from shoe fit, the footwear of participants from Phase 2 (having sustained a fall) was also checked for its characteristics as described in the Footwear Assessment Form (Menz & Sherrington, 2000)

- Footwear characteristics

Footwear Type: Sandals were the most common shoe style worn by the participants who experienced a fall (36%), followed closely by bed slippers (33%). Studies have reported bed slippers as the most common type of footwear worn at the time of falls in older individuals (Najafi et al., 2013; Davis et al., 2016; Jellema et al., 2019). Bed slippers were also associated with the risk of injurious falls in older people in a study by Kerse et al., (2004). Moreover, Sherrington and Menz (2003) have associated falling by tripping with wearing bed slippers. Although, this study noted that falling by tripping was common in participants wearing sandals and bed slippers, however, no significant association could be made since the *p*-value (0.76) was greater than the 0.05 level of significance. Conversely, sandals were not commonly observed in participants during the time of fall in other studies. Sherrington & Menz (2003) found that only 8% of participants were wearing sandals during their sustained fall and Kelsey et al. (2010) found an even lower percentage, with only 4% wearing sandals during falls. The presence of participants wearing sandals during falls in this study might be attributed to the common preference of older adults for wearing sandals, as shown in Phase 1 of the study. Nevertheless, sandals might have several sub-optional features, such as an absence or a flexible heel counter and an unsafe method of fixation, which could have affected fall risk in this population. Moreover, Brenton- Rule, et al., (2014) found that sandals may negatively impact postural stability in their study of women with Rheumatoid Arthritis.

Heel Height: The most common heel height worn by participants who experienced a fall ranged from 2.6 to 5.0cm (63 %), which is more than the ideal 2.5cm heel height as described in the literature (Jellema et al., 2019). This aligns with a study by Menant et al. (2008) who noticed that shoes with heels higher than 2.5cm increase the risk of falling by 1.9-fold when compared to other types of footwear. Additionally, Tencer et al., (2004) noticed that fall risk is nearly double in persons wearing shoes with a heel height of 2.5 cm or greater.

Surprisingly, Sherrington & Menz (2003) found only a few participants wearing high heels at the time of their fall. However, the study does not clarify the definition of ‘high heels’—whether it refers to heels higher than 2.5 cm or higher than 5 cm. Only a small percentage of older adults wear heels higher than 5cm, as shown in Phase 1 of this study and several others (Vass et al., 2015). Therefore, the limited number of participants found wearing high heels during falls aligns with the infrequent use of heels higher than 5 cm among older adults.

Footwear Fixation: Almost half (45%) of the participants were wearing footwear with no fixation at the time of fall. Another 45% of participants used Velcro as a method of shoe fixation, while only a small number of participants used either straps, zips or laces. These findings are similar to those presented by Sherrington & Menz (2003), who noticed that 63% of participants who sustained a fall were wearing footwear with no fixation. These authors also reported that falls by tripping were the most common kind of fall induced by footwear with a lack of fixation. Although, this trend was also observed in this study, upon statistical analysis, no significant difference was found between footwear fixation and type of fall since the *p*-value (0.76) exceeded the 0.05 level of significance. Other studies have observed that footwear with no modes of fixation was commonly worn during fall-induced fractures (Hourihan et al, 2000; Keegan et al. 2004). Laboratory-led research results have shown how inadequate fixation tends to promote a shuffling gait and loss of balance and how footwear with no fixation is more likely to separate from the feet during gait, thus increasing falls risk (Davis et al, 2016; Maden et al., 2021).

Heel counter stiffness: Around one-third (30%) of participants had footwear with no heel counter at the time of fall. The majority (46%) of participants, had a heel counter with stiffness of more than 45°, providing minimal foot stability during gait. These findings are similar to those presented by Menz & Sherrington, where it was noticed that 43% of older adults who sustained a fall-induced hip fracture, had shoes with excessively flexible heel counters. Similarly, Hourihan et al., (2000) reported that 68% of 107 older people who were admitted to hospital following a fall-related hip fracture also had shoes with flexible heel counters at the time of fracture.

Longitudinal sole rigidity: This study shows that 17% of the participants had a rigid sole. Almost half of the participants (48%) had shoes with an outer sole rigidity of less than 45°. A study by Sherrington & Menz (2003) is the only known study that has examined longitudinal sole rigidity in participants who sustained a fall. Similar, to the current study 19% of participants had shoes with excessively stiff soles. This is thought to predispose the wearer to falls by inhibiting the toe-off Phase during the gait cycle (Sherrington & Menz; 2003; Jessup, 2007). However, Barton, Bonanno, & Menz (2009) believe that since the midfoot is required to form a rigid lever during propulsion, footwear stability in this area is an optimal motion control property. Given that only a small percentage of participants who experienced a fall were wearing shoes with rigid soles both in this study and the study by Sherrington & Menz (2003), it might suggest that rigid soles do not significantly contribute to falls in older individuals. However, further studies are needed to provide more definite answers.

Sole flexion point: The location of the participants' sole flexion point location was almost evenly distributed. Specifically, 49% of participants had a sole flexion point at the metatarsophangeal joints (MTPJs), while 51% of participants had a sole flexion point before the MTPJs. This finding is in line with results presented by Sherrington & Menz (2003) who found that 43% of participants who sustained a fall-related hip fracture were wearing shoes with soles that flexed before the MTPJs at the time of fall. This low incidence of sole flexion point variation might suggest that the location of the sole flexion point is not crucial to fall risk, however more studies on this topic might be needed. Similar to longitudinal sole rigidity, studies exploring the association of sole flexion point with falls are limited and have not been directly evaluated, however, there is a common belief that a shoe that flexes across the midsole increases the risk of falls by decreasing shoe stability (Jessup, 2007; Branton, Bonanno & Menz, 2009).

Tread pattern: One-third (33%) of the participants were wearing shoes with a textured tread pattern during the time of fall. While this is typically deemed beneficial for reducing slipping, it is worth noting that textured soles may pose a tripping hazard for some older individuals, particularly those with a shuffling gait due to the low toe clearance exhibited during gait (Menant & Lord, 2013). This trend was also noted in this study, where most participants who tripped were observed to be wearing textured soles. However, when analysing data, the *p*-value (0.076) exceeded the 0.05 level of significance, indicating that no significant association could be established between textured soles and type of fall. This was also observed during Phase 3 of this study, where it was noted that when performing the TUG test, some participants with a shuffling gait commented that the provided shoe, which had a textured sole, felt too heavy and gave them the sensation of getting ‘stuck to the ground’. As a result, they performed worse in the TUG test. Conversely, a smooth tread pattern has been identified to increase the risk of falls by slipping (Gupta & Chanda, 2023). This trend was not observed in this study, perhaps due to the textured ground noted in the premises, which is commonly found in older care residences (Valipoor et al., 2020).

Sole Hardness: Almost half of the participants (46%) were wearing footwear with a firm inner sole at the time of fall. Only 18% of participants in this study had shoes with a soft inner sole, a finding that aligns with results published by Sherrington & Menz (2003), where 20% of participants who experienced a fall were wearing footwear having excessively soft soles, making them susceptible to loss of balance. Research suggests that the use of soft midsoles may cause instability during gait by reducing afferent feedback from the sole of the foot (Aboutorabi, et al. 2015), predisposing the individual to falls, thus it is surprising that this study did not observe a higher incidence of participants wearing soft soled footwear. This may be due the low incidence of older adults wearing soft soles, as shown in Phase 1 of this study, where only 30% of participants were found to be wearing soft insoles. It is possible that typically older adults choose harder insoles because they feel more stable in them. In fact, many authors suggest footwear with thin, hard soles to provide greater proprioceptive feedback and reduce body sway velocity (Aboutorabi et al., 2015).

As discussed above, the current study aligns with the study findings by Sherrington & Menz (2003), where they assessed participants' footwear characteristics following a fall-related hip fracture. However, while the study by Sherrington & Menz (2003) found a statistical correlation between fall types and footwear characteristics, particularly falling by tripping and footwear with a lack of fixation, this study, did not find any significant associations. Nevertheless, some trends such as wearing textured soles and falling by tripping, were noted. The lack of significant association between footwear characteristics and type of falls, could be due to the study limitations such as the small sample size, which is described in more detail in section 5.5.

Studies have shown that even tough inadequate footwear may not cause fall related serious injuries, it can cause loss of confidence, fear of falling and a restriction in daily activity (Bay, et al., 2023). The current study did not measure fear of falling or the impact falls had on participants, however it was noted that some participants did not perform the TUG and FRT tests in Phase 3 of the study due to the consequences of their fall. In fact, 5.3% of the participants refused to participate in Phase 3 due to fear of falling. Moreover, 10.5% of participants became wheelchair dependant following the fall and 23.7% sustained a fracture from the fall itself, significantly impacting their daily activities.

The sub-optional footwear features noted in participants who sustained a fall, were also observed in Phase 1 of this study, where the footwear typically worn by older adults living in long-term care was assessed.

5.2.4 Evaluation of footwear characteristics and fit worn by residents living in a Maltese long-term elderly facility.

Concerningly, a significant proportion of the study population was observed wearing many of the previously mentioned suboptimal features; mainly bed slippers, footwear with a heel height of more than 2.5cm, and footwear with no heel counters or flexible heel counters. Almost half of the study population were found to be wearing shoes with a sole rigidity of more than 45° and footwear with smooth tread patterns. Moreover, most of the participants were found to be wearing footwear of the incorrect length; mostly footwear which is too short for their feet. This is surprising when considering that these participants often interact with nurses and other healthcare professionals who should provide guidance on safe footwear. Nevertheless, this study's findings are similar to other published international studies where many older adults were found wearing footwear with a number of unsafe features (Chari et al., 2016; Jessup, 2007; O’ Rourke et al., 2020; Vass et al.; 2015). Contrary to being solely an issue of inadequate access to suitable footwear, the choice of footwear among older adults seems influenced by symptoms, clinical conditions, personal preferences, and a desire for independence (Chari et al., 2016). Moreover, the high prevalence of suboptimal footwear features reported here is consistent with previous studies that observed that older people primarily base their footwear choices on comfort rather than safety (Sherrington & Menz, 2003). Interestingly, patients admitted for hip fractures following falls may persist in wearing inappropriate footwear in the hospital, reflecting a lack of awareness, as observed in a study by Jessup (2007). This was also observed in this current study since 53% of this population had a history of falls in the previous year, yet many participants opted for unsafe footwear.

5.3 Analysis of falls that occurred in the study period

Details about the sustained falls, along with details about the participants’ intrinsic and extrinsic risk factors, that may have contributed to falls were analysed and discussed below.

- Extrinsic risk factors

This study found that most fall incidents (51%) involved participants who used an assistive walking aid for ambulation, while 49% walked unaided. These findings are consistent with

Jensen et al. (2022), who reported that 40% of fallers living in residential care use a walking aid for ambulation. This presents a concerning contradiction as older adults usually use walking aids to prevent fall risks (Sakano et al., 2023). However, recent studies found that the use of walking aids is associated with a 2.6-fold increased risk of falls, possibly due to the inappropriate use of walking aids or due to multi-footed walking aids posing a trip hazard (Thies, et al., 2020). Indeed, some studies have identified the use of walking frames as a risk factor (Whitney et al., 2012). Moreover, a history of falls emerged as a common risk factor across various studies, including this one, where 72% of fallers had sustained a fall in the previous year.

- Intrinsic risk factors

Apart from the use of walking aids, this study identified several intrinsic risk factors making participants susceptible to falls. The most common risk factor was polypharmacy, with 81% of the fallers taking more than four medications. Other significant risk factors included depression (35%), visual impairment (23%), and lower limb arthritis (22%). Similarly to these findings, Jensen et al. (2022) identified depression to be common in 40% of fallers, followed by a history of stroke in 28% and osteoarthritis in 24% of fallers. Dementia was the most common fall risk factor making up 52% of fallers. Whitney et al. (2012) also observed dementia and impaired cognition to be prevalent among elderly care fallers. This study highlighted that polypharmacy, especially the use of antidepressants and anxiolytics, increased the risk of falls. Although dementia is a well-recognized risk factor (Baker et al., 2011; Byun et al., 2018), it is worth noting that this study did not include residents with dementia due to ethical and safety concerns as outlined in section 3.10.

- Season and day of the falls

This study also noted that most falls occurred during the summer period, with August experiencing the highest frequency (21%), followed by July (15%) and September (12%). Conversely, January and March had the lowest incidence of falls, each accounting for 5% of falls. This pattern mirrors observations by Kerse et al. (2004), indicating that late summer, especially September and October, saw the highest number of falls. This phenomenon may be attributed to the common practice of wearing unsupportive footwear such as sandals or footwear lacking a heel counter, particularly during the summer period. These footwear features have been associated with an increased risk of falls in several studies (Jellema et al., 2019). Moreover, during summer, older adults are more likely to participate in outdoor activities, thus putting them at more risks of falling. Additionally, falls can be more common during summer, often due to dehydration, which is a prevalent concern among older individuals (Hussain Itthadi, 2022).

This study also investigated the time of the day when falls occurred. The majority of falls (58%) occurred in the morning, followed by the afternoon (29%). Moreland et al. (2021) noted a similar trend in older adults living in residential care, noting that most falls occur during periods of maximum activity in the morning or afternoon, with only 20% occurring between 9 p.m. and 7 a.m. Similarly, this study identified a parallel pattern, indicating that participants primarily engaged in ambulation during the morning, often under the supervision of healthcare professionals or for recreational purposes. Moreover, Rapp et al. (2012) found that falls varied throughout the day, with peaks between 10 am and midday and between 2 pm and 8 pm, coinciding with times of increased resident activity. However, Jensen et al. (2022) noted that 28% of falls happen at night and the period between 12 pm and 3 pm being the most common for falls. The falls may be attributed to potential drowsiness among participants, likely resulting from sleepiness.

- Location of falls

The bathroom emerged as the most prevalent location for falls in this study (29%), closely followed by the bedroom (28%). These findings resonate with Jensen et al. (2022), who reported a similar incidence of falls in the bathroom at about 28%. Additionally, Rapp et al. (2012) and Moreland et al. (2021) identified the bedroom (25%) and bathrooms (23%) as frequent sites for falls in home settings. The prevalence of falls in the bathroom and bedroom could be attributed to common clutter found in these areas, such as wheelchairs and transfer benches, as observed in this study during data collection. Indeed, tripping incidents were notably more common in the bathroom in this study. Moreover, older adults who are especially incontinent may rush to use the bathroom, thus increasing their risk of falling.

- Type of falls

Falling due to tripping and loss of balance were the most prevalent, each accounting for 34% of falls in this study. This aligns with findings by Koepsell (2004), who reported that about 36% of falls involved tripping on something, while Sherrington & Menz (2003) identified tripping as the most reported type of fall, followed by loss of balance.

- Injuries sustained from falls

When examining the injuries sustained, bruises were the most common (63%), followed by skin cuts/lacerations (38%). Similarly, Koepsell (2004) reported that 65% of fall-related injuries were contusions or lacerations, and serious injuries like fractures and head injuries were not that common. Additionally, Kerse et al. (2004) found that 17% of fallers experienced serious injuries such as sprains, dislocations, fractures, or head injuries. Jensen et al. (2002) reported that 28% of fallers sustained at least one injury, with 7% experiencing serious injuries like fractures in nursing home settings. This study tried to investigate any potential correlation between the type of falls and the resulting injuries. The findings revealed that bruises were the prevailing injury among participants who experienced tripping or loss of balance. However, with a p-value of 0.969 exceeding the significance threshold of 0.05, the analysis indicates no significant association between the type of fall and the injuries sustained within this population.

5.4 Clinical Relevance of Findings

- In light of the results presented in this study, footwear can positively affect balance and reduce the risk of falling in older adults living in long-term care. Therefore, all healthcare providers working with older adults should assess the appropriateness of footwear being worn by the residents. When determining the appropriateness of footwear, a number of factors need to be considered. These include shoe fit, sole stiffness, heel counter, footwear fixation and sole tread.

- Patients admitted to an older care institution should undergo assessments of their foot conditions and footwear, with appropriate measures taken to address these factors. Considering that a significant proportion of participants in this study exhibited multiple other risk factors linked to falls, there is a need for increased awareness among healthcare professionals regarding all fall-risk factors. Such factors, most importantly those which can be modifiable, such as footwear should be addressed.

- Introducing safe footwear suitable for hospitals or geriatric cares. This approach could be cost-effective and low-tech means of enhancing safety. As a result, fall prevention programs may need to define what ‘safe footwear’ is and highlight its importance.

Decisions about footwear should involve a multidisciplinary team, including podiatry services when necessary, and align with patient mobility priorities and preferences.

- Clinicians sometimes recommend wide shoes to accommodate certain conditions such as claw toes, however, caution should be taken to ensure that this will not jeopardize the shoe-fit in terms of length, as research has shown that balance can be impaired when wearing shoes which are too long for the feet (Doi et al., 2010). Moreover, clinicians may sometimes recommend footwear with a soft sole to cushion the foot, yet soft soles can impair balance as shown in studies (Jellema et al., 2019). Thin, hard soles have shown to provide improved proprioception and reduce body sway (Menant et al., 2008); however, this may increase the risk of foot pathologies particularly in individuals with insensate feet. Therefore, a balanced approach should be adopted, opting for firm soles (Shore A30-49) that provide adequate support without compromising stability.

5.5 Limitations of this study

Every research study exhibits weaknesses and limitations. It is important to acknowledge and highlight any shortcomings so that future research in the field, can reduce these limitations as much as possible to produce more valid results.

5.5.1 Study design

- Exclusion criteria of study

This study excluded residents with dementia and other severe forms of cognitive impairment from participating in the study. Considering that these individuals are more prone to falls (Fernando et al., 2017), the falls recorded in this study might not have been full representative of a geriatric population living in long-term care. Excluding residents with dementia has also restricted the number of falls investigated, as individuals with dementia comprise a significant proportion of older adults residing in geriatric care facilities.

- Inaccurate reporting

It is possible that the intermediaries may not have reported all falls that occurred in the residence to the researcher. This could be due to a breakdown in communication between the nursing officer and intermediaries, or between intermediaries and the researcher. Moreover, it is possible that some nurses felt that they are to blame for the fall, so they failed to document such fall.

- Cause of falls/ fractures

In cases of fractures, particularly in individuals with osteoporosis, it can be challenging to determine which occurred first: the fracture or the fall. Consequently, it was sometimes unclear whether the fracture resulted from the fall or if the fall was caused by the fracture.

5.5.2 Methodology: Definitions and tools

- Definition of shoe fit

This study measured shoe fit in terms of length and width. Depth, which is another important parameter for shoe fit, was not taken into consideration in this study mostly because due to lack of literature on the recommended shoe-to-foot depth for achieving a good fit and due to the challenges associated with measuring footwear depth accurately.

- Tools used for foot/footwear measurements

As discussed in section 3.7, there is not a standard technique for measuring foot and footwear dimensions. This study attempted at using the most reliable and valid tools for measurements. However, even though it has been used in various studies, the SATRA shoe stick has not been properly tested for validity and reliability. Thus, some human errors could have occurred during foot and footwear measurement.

- Performing TUG and FRT with the researcher's footwear

Social desirability bias may have influenced the results, as participants were aware of being tested with different footwear, potentially leading them to subconsciously perform better when wearing the researcher's footwear. Moreover, even though the participants were asked to walk for a few minutes with the provided footwear, this might not have been enough for them to get acclimatised to the new footwear. Furthermore, some participants commented that they felt the provided footwear was too heavy, particularly since they typically make use of lightweight footwear such as sandals or bed slippers. This could have negatively affected their performance when wearing the researcher's footwear.

- Rocker sole present in the researcher's footwear

The provided footwear (researcher's footwear) had a rocker sole and was not flat. This could have affected the clinical balance tests carried out, particularly the FRT. This was noted in a study conducted by Vieira et al. (2014) where it was noted that front directional control of the centre of gravity was significantly worse when wearing rocker-soled footwear when compared to flat soles. Therefore, balance and stability might have been affected by the presence of a rocker-sole and not solely by footwear characteristics and fit.

5.5.3 Data results

This study analysed data of 76 falls for Phase 2, and of 41 falls for Phase 3. This small sample size and various independent variables (all footwear characteristics and fit) limited the accuracy of the statistical tests used during Phase 3 of this study, and consequently reduced the statistical power of the analysis.

5.6 Recommendations for Future Research

Although previous studies have investigated the relationship between footweaj,cr and falls in older adults, this study uniquely focuses on the specific footwear worn at the time of the fall and compares it to adequate footwear using balance and stability tests. Considering the limitations of the study discussed above, the following recommendations are being suggested for future research:

- Carrying the study with a larger sample size

This can be done by prolonging the data collection period and including residents with dementia. Also, multiple geriatric long-term facilities settings can be included in other studies.

- Kinematic studies

Further studies with detailed footwear assessments are needed to clearly demonstrate how specific footwear characteristics affect balance and gait in the older population. This can be done by conducting kinematic studies instead of clinical tests such as FRT and TUG.

- Evaluation of foot problems

A similar study but taking into account the foot problems such as pain and pathologies commonly associated with old age may provide a more complex insight about the importance of podiatry in reducing falls in older adults.

- Further studies on consequences of falls

The relationship between footwear and psychological consequences of falls along with healthcare costs due to fall related complications (e.g. hip fractures) should also be investigated to shed more light on the importance of safe footwear.

- Investigating Maltese health workers knowledge on footwear

Unfortunately, a study conducted by Aquilina (2008) revealed a lack of awareness about footwear being an extrinsic risk factor for falls amongst Maltese nurses. Based on this, investigating the knowledge of health care workers about adequate footwear is needed.

- National guidelines on fall prevention programmes

No national guidelines about fall prevention are present in Malta, which could lead to a lack of structured assessment being carried out by the Maltese multidisciplinary team to identify the cause of falls and prevent further fall accidents. Therefore, national guidelines would help the whole multidisciplinary team to collectively contribute towards fall prevention in older adults.

Chapter 6:

Conclusion

The aim of this study was to investigate the relationship between footwear design and risk of falling in a sample of older adults living in a long-term care facility. This was done by dividing the study into 3 Phases: Phase 1: Evaluation of footwear characteristics and fit worn by a sample of residents living in a Maltese long-term elderly facility to provide an overview of footwear typically worn by this population. Phase 2: Evaluation of footwear worn at the time of fall. Phase 3: Evaluating the functional stability and balance of participants when wearing the footwear worn at the time of fall and when wearing 'adequate' footwear as suggested by the literature.

This is the first known study to have been conducted in Malta which has investigated falls related to footwear in the older population. Additionally, the majority of published research on this subject has focused on older individuals residing within the community. However, this study specifically targeted the most vulnerable older adults residing in long-term care facilities, who are at higher risk of falling. Unlike the majority of other studies, this study was conducted using two different methodologies; an observational approach (Phase 1 and 2 of the study) and an experimental approach (Phase 3 of the study), in order to strengthen the methodology and analysis of results.

Results of this study have demonstrated that inadequate footwear increases the risk of falling in a geriatric population living in a long-term care facility. This is because the footwear worn at the time of fall had negatively affected the participants' balance during walking. However, the participants' stability over a fixed base of support was not affected when wearing 'adequate' footwear which could reflect the importance of adequate footwear during walking. Although, none of the footwear characteristics were found to significantly impact any changes in stability and balance during clinical balance tests (TUG and FRT), participants demonstrated significantly improved performance on ambulatory tests when wearing footwear having ideal characteristics. It was also observed that the participants who experienced a fall in this study were wearing footwear with many sub-optional features, mainly footwear that is too long (45%), sandals (36%) and bed slippers (33%), heels which are longer than 2.5cm (63%) and footwear with no fixation (45%) and no heel counters (30%).

Various studies have shown how these footwear characteristics negatively affect balance in older adults, thus increasing their risk of falls (Jellema et al., 2019). However, when individually assessing each footwear characteristic and fit variables, none of them were found to play a significant role in improving balance and stability. This is because they did not significantly impact the Time Up and GO (TUG) and Functional Reach Test (FRT) scores, which correlates to the findings of other studies (Horgan et al., 2009; Menz, Morris & Lord, 2006; Tencer et al., 2009). This could mean that clinical balance tests such as the TUG, FRT and Berg Balance Scale (BBS) are capable of detecting major changes between different types of footwear (e.g. adequate and not adequate) but may not be capable of identifying subtle modifications in footwear design. Therefore, kinematic studies might be more applicable in this case.

This study suggests that the relationship between footwear and balance is complex and is influenced by various factors such as patient frailty and type of balance test applied. Nonetheless, despite falls being multifactorial, it is evident that footwear significantly contributes to falls in older adults living in long-term care.

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Appendices

Appendix 1: Email from FREC approving study

R

Research Ethics HEALTHSCI <research-ethics.healthsci@um.edu.mt> 8 Feb 2022, 15:38

to Rita, Stephen, me

Dear Annalise,

Further to the correspondence below, please note that UREC-DP has reviewed your application and this was found to be consistent with the University of Malta Research Code of Practice. Approval is therefore granted.

Good Luck with your study!

Sincere Regards,
Christabel

Christabel Vella
FREC Secretary

University of Malta
Faculty of Health Sciences
Room 76, Block A, Level 1
Mater Dei Hospital

https://www.um.edu.mt/healthsciences/students/researchethics

Facebook Twitter

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Appendix 2: Phase 1 Information and Consent Form in English

L-Università ta' Malta

Participants` Information Sheet

Dear Participant,

My name is Annalise Muscat and I am currently reading for a Masters Degree in Podiatry at the University of Malta. As part of my course requirements, I am conducting a research study entitled,
'The evaluation of footwear worn at a time of fall at a Maltese long- term elderly residence.'

The aim of this study is to evaluate the shoe fit and footwear characteristics worn by residents at a long-term elderly facility care. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and the fear of falling can lead to loss of mobility and reduction in quality of life. Your participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention. Furthermore, all data collected from this research shall be used solely for the purpose of this study.

In this study, I as the researcher, will investigate the participants' frequently used footwear for its characteristics and fit. You are being invited to participate in this study. If you agree to participate, you will meet the researcher once, for approximately 30 minutes. The meeting will be held either at the Podiatry Clinic or at your ward.

During the visit I, as the researcher will:

- Ask some general questions about you, such as age, mobility status, medical conditions and medications. These details will be retrieved from your medical file, if you are not able to provide them.

- Assess your footwear for its characteristics according to the Footwear Assessment Form. This is a simple 8-point form which incorporates details such as the shoe type, heel height, heel counter stiffness, sole rigidity, fixation, sole flexion point, sole hardness, and outsole of shoe pattern.

- Assess your footwear for its fit. This will be done by measuring and comparing the size for the shoe to your foot, both in terms of length and width. Footwear length will be measured by means of an internal shoe size gauge, whilst width will be measured using a calliper with outward pointed ends. These dimensions will then be compared to your foot measurements recorded using a measuring device named Brannock device. Here you will be asked to stand up and place your bare feet on the measuring device. Your feet length and width will be measured. Your feet measurements will then be compared to your footwear measurements.

Your footwear will not be damaged during assesment. You are not obliged to participate in this study and you may withdraw from the study at any time without giving a reason. This will not have any negative repercussions on you and no loss of benefits to which you are entitled will be involved. Any data collected will be erased. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be revealed in any publications, reports or presentations arising from this research. Only data necessary for this research will be shared. All data collected will be pseudonymised meaning that the data will be assigned codes and that this data will be stored securely and separately from any codes and personal data.

This data may only be accessed by the researcher. The academic supervisors and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes. The data files will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard.

Participation in this study is completely voluntary and you are free to accept or refuse to take part without giving a reason. A copy of the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning you to be erased. Once the study is completed and the results are published, the data will be retained in anonymous form. Any personal details will be destroyed.

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on 99401719 or by e-mail annalise.vassallo.10@um.edu.mt or my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt or 23401154.

Yours Sincerely,

Muscat

Ms. Annalise Muscat

Researcher

Dr. Stephen Mizzi

Research Supervisor

Participants` Consent Form

The evaluation of footwear worn at a time of fall at a Maltese long- term elderly residence.

I, the undersigned, give my consent to take part in the study conducted by Annalise Muscat. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in a study, in which the researcher will ask some general medical information about me and perform tests to investigate my footwear's characteristics and fit. These tests will not put my health and safety at risk.
3. I am aware that the meeting will take approximately 30 minutes. I understand that the meeting is to be conducted at St. Vincent de Paul Residence, either in the Podiatry Clinic or in my ward, at a time that is convenient for me.
4. I am aware that data will be written on the prepared record forms.
5. I am aware that the data collected will be coded and that this data will be stored securely and separately from any codes and personal data.
6. I am aware that the researcher is the only person who has access to this data. The academic supervisors and examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes.
7. I am also aware that data files will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard and kept until results are published.
8. I am aware that my identity and personal information will not be revealed in any publications, reports or presentations arising from this research.

9. I also understand that I am free to accept, refuse or stop participation at any time without giving any reason. This will have no negative repercussions on myself and that any data collected form me will be erased.
10. I also understand that my contribution will serve to understand the role of footwear in reducing falls amongst the older population living in a long- term facility.
11. I understand that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.
12. I also understand that once the study is completed and results are published the data will be retained in anonymous form. Any personal details will be destroyed.
13. I will be provided with a copy of the information letter and consent form for future reference.
14. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: ____

Signature: ____

Date: ____

Annalise Muscat

Researcher

Mob. No. 99401719

Dr. Stephen Mizzi

Research Supervisor

Tel. No. 2340 1154

Appendix 3: Phase 2 Information and Consent Form in English

Participants` Information Sheet

Dear Participant,

My name is Annalise Muscat and I am currently reading for a Masters Degree in Podiatry at the University of Malta. As part of my course requirements, I am conducting a research study entitled,

'The evaluation of footwear worn at a time of fall at a Maltese long- term elderly residence.'

The aim of this study is to evaluate the shoe fit and footwear characteristics worn by residents at a long-term elderly facility care. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and the fear of falling can lead to loss of mobility and reduction in quality of life. Your participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention. Furthermore, all data collected from this research shall be used solely for the purpose of this study.

Following your recent fall sustained whilst walking, you are being invited to participate in a study, where you provide me with your footwear worn at the time of fall, and it will be investigated for its characteristics and fit. If you agree to participate, you will meet the researcher once, at St. Vincent de Paul Residence either at the Podiatry Clinic or in your ward, at a time that is convenient for you, for approximately 30 minutes.

During the visit I, as the researcher will:

- Ask some general questions about you, such as age, mobility status medical conditions and medications. Details about your fall, such as location, time of fall and any injuries sustained will also be asked. These details will be retrieved from your medical file, if you are not able to provide them. Your medical parameters taken following your fall (such as blood pressure, body temperature and glucose levels) will be retrieved from your medical file.

- Assess the footwear worn at the time of your fall, for its characteristics according to the Footwear Assessment Form. This is a simple 8-point form which incorporates details such as the shoe type, heel height, heel counter stiffness, sole rigidity, fixation, sole flexion point, sole hardness, and outersole pattern.
- Assess footwear for its fit. This will be done by measuring the shoe size and your feet's length and width. Footwear length will be measured by means of an internal shoe size gauge, whilst width will be measured using a calliper with outward pointed ends. These dimensions will then be compared to your foot measurements recorded using the Brannock device. Here you will be asked to stand up and place your bare feet on the measuring device so the length and width will be measured.

Later on, you might be asked to participate in another part of the study, where further testing will be done to determine your balance and stability when wearing your footwear. In this case, another information letter and consent form will be provided, and all details will be explained.

Your footwear will not be damaged during assesment. You are not obliged to participate in this study and you may withdraw from the study at any time without giving a reason. This will not have any negative repercussions on you and no loss of benefits to which you are entitled will be involved. Any data collected will be erased. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be revealed in any publications, reports or presentations arising from this research. Only data necessary for this research will be shared. All data collected will be pseudonymised meaning that the data will be assigned codes and that this data will be stored securely and separately from any codes and personal data.

This data may only be accessed by the researcher. The academic supervisors and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes. The data files will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard.

Participation in this study is completely voluntary and you are free to accept or refuse to take part without giving a reason. A copy of the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning you to be erased. Once the study is completed and the results are published, the data will be retained in anonymous form. Any personal details will be destroyed.

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on 99401719 or by e-mail annalise.vassallo.10@um.edu.mt or my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt or 23401154.

Yours Sincerely,

Ms. Annalise Muscat	**Dr. Stephen Mizzi**
Researcher	Research Supervisor
99401719	23401154

Participants` Consent Form

The evaluation of footwear worn at a time of fall at a Maltese long- term elderly residence.

I, the undersigned, give my consent to take part in the study conducted by Annalise Muscat. The purpose of this document is to specify the terms of my participation in this research study.

15. I have been given written and verbal information about the purpose of the study and all questions have been answered.
16. I understand that I have been invited to participate in a study, in which the researcher will ask some general questions about me and my recently sustained fall, and perform tests to investigate my footwear's characteristics and fit. These tests will not put my health and safety at risk.
17. I am aware that the meeting will take approximately 30 minutes. I understand that the meeting is to be conducted at St. Vincent De Paul Residence, either at the Podiatry clinic or at my ward, at a time that is convenient for me.
18. I am aware that data will be written on the prepared record forms.
19. I am aware that the data collected will be coded and that this data will be stored securely and separately from any codes and personal data.
20. I am aware that the researcher is the only person who has access to this data. The academic supervisors and examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes.
21. I am also aware that data files will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard and kept until results are published.
22. I am aware that my identity and personal information will not be revealed in any publications, reports or presentations arising from this research.

23. I also understand that I am free to accept, refuse or stop participation at any time without giving any reason. This will have no negative repercussions on myself and that any data collected form me will be erased.

24. I also understand that my contribution will serve to understand the role of footwear in reducing falls amongst the older population living in a long- term facility.

25. I understand that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.

26. I also understand that once the study is completed and results are published the data will be retained in anonymous form. Any personal details will be destroyed.

27. I will be provided with a copy of the information letter and consent form for future reference.

28. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: ____

Signature: ____

Date: ____

Annalise Muscat	**Dr. Stephen Mizzi**
Researcher	Research Supervisor
99401719	23401154

Appendix 4: Phase 3 Information and Consent Form in English

L-Università ta' Malta

Participants` Information Sheet

Dear Participant,

My name is Annalise Muscat and I am currently reading for a Masters Degree in Podiatry at the University of Malta. As part of my course requirements, I am conducting a research study entitled,

'The evaluation of footwear worn at a time of fall at a Maltese long- term elderly residence.'

The aim of this study is to evaluate the shoe fit and footwear characteristics worn by residents at a long-term elderly facility care. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and the fear of falling can lead to loss of mobility and reduction in quality of life. Your participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention. Furthermore, all data collected from this research shall be used solely for the purpose of this study.

Following your participation at an earlier stage of the study, where you were assessed following your sustained fall, you are now being invited to participate in the final part of the study. Your balance and stability will be tested while wearing your own footwear and also while wearing a shoe with a good fit, including an appropriate fastening system, rubber sole and a low heel height, to ensure good stability which will be provided by the researcher accoriding to size. If you agree to participate, you will meet the researcher once, at St. Vincent de Paul Residence either at the Podiatry Clinic or in your ward, at any time that is convenient for you, for approximately 30 minutes.

During the visit, you will be asked to perform 2 tests. The first being the Functional Reach Test (FRT). Here, you will be asked to stand up next to a yardstick attached to a wall and you will be instructed to outstretch your arm in a maximal forward reach (without taking a step or losing balance), while maintaining a fixed base of support. You will be asked to repeat this for another 2 times.

The other test is the Touch Up and Go (TUG). You will be asked to stand up from a seated position, walk 3 meters, turn around and walk back to the chair and sit down. The time taken to complete this test will be recorded. Results taken when wearing your footwear and the provided footwear by the researcher will be compared.

Your footwear won't be damaged during assessment. During both tests, a qualified podiatrist will accompany to ensure your safety. Your participation in this study will be terminated if it is noted that you are at risk of losing your balance. You are free to stop at any given time, without providing any explanation. Any data collected will be erased. Furthermore, refusal of participation or withdrawal from the study will not have any negative repercussions on you and no loss of benefits to which you are otherwise entitled will be involved.

I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be revealed in any publications, reports or presentations arising from this research. Only data necessary for this research will be shared. All data collected will be pseudonymised meaning that the data will be assigned codes and that this data will be stored securely and separately from any codes and personal data.

This data may only be accessed by the researcher. The academic supervisors and the examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes. The data files will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard.

Participation in this study is completely voluntary and you are free to accept or refuse to take part without giving a reason. A copy of the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning you to be erased. Once the study is completed and the results are published, the data will be retained in anonymous form. Any personal details will be destroyed.

This study has been approved by the Research Ethics Committee of the Faculty of Health Sciences at the University of Malta.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on 99401719 or by e-mail annalise.vassallo.10@um.edu.mt or my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt or 23401154.

Yours Sincerely,

Muscat

Ms. Annalise Muscat
Researcher

Dr. Stephen Mizzi
Research Supervisor

L-Università ta' Malta

Participants` Consent Form

The evaluation of footwear worn at a time of fall at a Maltese long- term elderly residence.

I, the undersigned, give my consent to take part in the study conducted by Annalise Muscat. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in a study, in which the researcher will ask me to perform 2 tests in order to assess for balance and stability. This will be done by performing the tests with my footwear worn during my previous fall and the footwear provided by the researcher. Precautions will be taken to ensure my health and safety.
3. I am aware that the meeting will take approximately 30 minutes. I understand that the meeting is to be conducted at St. Vincent de Paul Residence, either at the Podiatry Clinic or in my room, at my ward, at a time that is convenient for me.
4. I am aware that data will be written on the prepared record forms.
5. I am aware that the data collected will be coded and that this data will be stored securely and separately from any codes and personal data.
6. I am aware that the researcher is the only person who has access to this data. The academic supervisors and examiners will typically have access to coded data only. There may be exceptional circumstances which allow the supervisor and examiners to have access to personal data too, for verification purposes.

7. I am also aware that data files will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard and kept until results are published.

8. I am aware that my identity and personal information will not be revealed in any publications, reports or presentations arising from this research.

9. I also understand that I am free to accept, refuse or stop participation at any time without giving any reason. This will have no negative repercussions on myself and that any data collected form me will be erased.

10. I also understand that my contribution will serve to understand the role of footwear in reducing falls amongst the older population living in a long- term facility.

11. I understand that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.

12. I also understand that once the study is completed and results are published the data will be retained in anonymous form. Any personal details will be destroyed.

13. I will be provided with a copy of the information letter and consent form for future reference.

14. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: ______________________________

Signature: ______________________________

Date: ______________________________

Muscat

Annalise Muscat

Researcher

99401719

Dr. Stephen Mizzi

Research Supervisor

23401154

Appendix 5: Phase 1 Information and Consent Form in Maltese

L-Università ta' Malta

Formula ta’ Informazzjoni għall-Parteċipanti

Għażiż/a Parteċipant/a,

Jiena Annalise Muscat fil-preżent qed insegwi il- ‘Masters’ fil- Podjatrija, f’ l-Universita’ ta’ Malta. Bħala parti mir-rekwiżiti tal-kors, qed nagħmel riċerka bit-titlu,

‘The evaluation of footwear worn at a time of fall at a Maltese long- term elderly residence.’

L-għan ta’ dan l-istudju hu li ninvestiga il- qies u l- karatteristici taż- żraben milbusa min persuni li qedgħin f’ residenza għal kura fit- tul. Huwa stmat li persuna minn kull tlieta ta’ 65 sena jew aktar jaqgħu kull sena. Dan jiżdied għal wieħed minn kull tnejn għal dawk li għandhom 80 sena 'l fuq. Il-waqgħat huma raġuni komuni għad-dħul fl-isptar fil-popolazzjoni anzjana u l-biża’ li jaqgħu tista’ twassal għal telf ta’ mobilità u tnaqqis fil-kwalità tal-ħajja. Il-parteċipazzjoni tiegħek f'dan l-istudju tgħinna niksbu ftehim aħjar dwar il-qies u il-karatteristiċi taż-żraben fost kampjun ta' popolazzjoni anzjana Maltija, u r-relazzjoni tagħha, jekk hemm, mal-waqgħat. Dan eventwalment se jibbenefika lill-popolazzjoni anzjana fil-prevenzjoni tal-waqgħat. Kull informazzjoni miġbura tintuża biss għall-għan jew l-għanijiet ta’ dan l-istudju.

F'dan l-istudju, jien bħala r-riċerkatrici, se ninvestiga ż- żarbun l- iktar użat tal-parteċipanti għall-karatteristiċi u qies tiegħu. Qed tiġi mistieden tipparteċipa f'dan l-istudju. Jekk taqbel li tipparteċipa, tiltaqa’ mar-riċerkatrici darba, fir-Residenza San Vinċenz de Paul jew fil-Klinika tal-Podjatrija ġewwa r- residenza San Vincenz de Paul, għal madwar 30 minuta.

Waqt din il-laqgħa jiena, bħala r- riċerkatrici nkun nista’:

• Nsaqsi xi mistoqsijiet ġenerali dwarek, bħall-età, mobilità tiegħek , il-kundizzjonijiet mediċi u l-mediċini li tieħu. Dawn id-dettalji se jiġu rkuprati mill-fajl mediku tiegħek, jekk ma tkunx tista' tipprovdihom.

• Iż- żarbun tiegħek ser jiġi vvalutat mir-riċerkatrici (lili nnifsi) għall-karatteristiċi tiegħu skont il- 'Footwear Assesment Form'. Din hija formula sempliċi ta' 8 punti li tinkorpora dettalji bħat-tip ta' żarbun, għoli ta' l-għarqub, ebusija ta' madwar l- għarqub, riġidità tal-qiegħ lonġitudinali, mod kif jinqafel iż- żarbun, punt ta' flessjoni tal- qiegħ, ebusija tal- qiegħ, u id-disinn ta' qiegħ iż- żarbun.

• Iż- żarbun imbagħad jiġi eżaminat għal qies tiegħu f' saqajk. Dan se jsir billi jitkejjel u jitqabbel id-daqs taż-żarbun mas-sieq tiegħek, kemm f'termini ta' tul kif ukoll wisa'. It-tul taż-żarbun se jitkejjel permezz ta' gauge intern, filwaqt li l-wisa' se titkejjel permezz ta' kaliper bit-truf bil-ponta 'l barra. Dawn id-dimensjonijiet imbagħad jitqabblu mal-kejl tas-sieq tiegħek irreġistrat bl-użu ta' apparat tal-kejl imsejjaħ apparat Brannock. Hawnhekk se tintalab toqgħod bilwieqfa u tpoġġi saqajk fuq l-apparat Brannock biex jitkejlu t-tul u l-wisa' ta' saqajk.

Iż- żarbun tiegħek mhux ħa ssirilu ħsara waqt il-valutazzjoni. M'intix obbligat li tipparteċipa f'dan l-istudju u tista' tirtira mill-istudju fi kwalunkwe ħin mingħajr ma tagħti raġuni. Dan ma jkollu ebda riperkussjonijiet negattivi fuqek u mhux ħa jkollok l-ebda telf ta' benefiċċji li inti intitolat għalihom. F' dan il- każ, l-informazzjoni li tinġabar mingħandek titħassar. Nassigurak li se tinżamm il-kunfidenzjalità matul l-istudju kollu u l-identità tiegħek u kull informazzjoni personali miġbura mhux se jiġu żvelati mkien fit-teżi, ir-rapporti, il-preżentazzjonijiet u/jew il-pubblikazzjonijiet li jistgħu jirriżultaw minnha. Id-data meħtieġa għal din ir-riċerka biss tiġi ppubblikata. Kull tagħrif miġbur se jiġi psewdonomizzat, jiġifieri id-data kollha se tkun protetta permezz ta' sistema ta' kodiċi u miżmuma separatament mill-informazzjoni personali.

Ir- Riċerkatriċi biss ser ikollha aċċess għall-informazzjoni miġbura, filwaqt li s- is-Superviżuri akkademiċi u l-eżaminaturi se jkollhom biss aċċess għal data kkodifikata. Is-Superviżuri akkademiċi u l-eżaminaturi jista jkollhom bżonn aċċess għall-informazzjoni miġbura għal skop ta' verifika.

Id-data kollha se tinħażen fuq il-kompjuter personali tar- Riċerkatriċi permezz ta' kodifikazzjoni tad-data (data encryption) u li hi protetta b'password. Barra minn hekk, il-materjal stampat se jinqafel f'post sigur.

Il-parteċipazzjoni tiegħek f'dan l-istudju hija għażla għal kollox volontarja u inti ħieles/ħielsa li taċċetta jew tirrifjuta li tieħu sehem mingħajr ma jkun hemm konsegwenzi fil-konfront tiegħek. Se tingħata kopja tal-ittra ta' informazzjoni u tal-formula ta' kunsens sabiex tkun tista' taċċessahom fil-futur. Barra minn hekk, skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, inti għandek id-dritt li taċċessa, tirretifika, u fejn japplika titlob sabiex titħassar id-data li tikkonċerna lilek. L-informazzjoni personali kollha se titħassar hekk kif jintemm dan l-istudju ta' riċerka u jkunu ppubblikati r-riżultati miksuba.

Dan l-istudju ġie approvat mill-Kumitat għall-Etika fir-Riċerka fi ħdan il-Fakultà tax-Xjenzi tas-Saħħa fl-Università ta' Malta.

Grazzi ħafna tal-ħin u s-sehem tiegħek f'dan l-istudju. F'każ li jkollok xi mistoqsijiet jew tixtieq tiċċara xi ħaġa, tista' ċċempilli fuq 99401719 jew tibgħatli email fuq annalise.vassallo.10@um.edu.mt. Tista' wkoll tikkuntattja lis-Superviżur Dr. Stephen Mizzi fuq 23401154 jew billi tibgħat email fuq stephen.mizzi@um.edu.mt

Dejjem tiegħek,

Annalise Muscat

Dr. Stephen Mizzi

L-Università ta' Malta

Formula ta' Kunsens tal-Parteċipanti

'The evaluation of footwear worn at a time of fall at a Maltese long- term elderly residence.'

Jien, hawn taħt iffirmat/a, nagħti l-kunsens tiegħi biex nieħu sehem fl-istudju mmexxi minn Annalise Muscat. L-għan ta' dan id-dokument hu li jiġu speċifikati t-termini tal-parteċipazjoni tiegħi f'dan l-istudju ta' riċerka.

1. Jien ingħatajt informazzjoni miktuba u verbali dwar l-għan tal-istudju u l-mistoqsijiet kollha twieġbu.
2. Nifhem li se nkun qed nipparteċipa fi studju, fejn ir- Riċerkatriċi ħa tistaqsi xi informazzjoni medika ġenerali dwari u twettaq testijiet biex tinvestiga l-karatteristiċi u l-qies taż-żarbun tiegħi. Dan mhux se jpoġġi s-saħħa u s-sigurtà tiegħi f'riskju.
3. Naf li l-istudju se jieħu madwar 30 minuta. Nifhem, li l-laqgħa se ssir gewwa s- sala tieghi jew gewwa l- klinika tal- Podjatrija, ġewwa r- residenza San Vincenz de Paul, f' ħin konvenjenti għalija.
4. Jien konxju/a li se jinkitbu r-risposti fuq formuli apposta.
5. Naf ukoll li se ssir kodifikazzjoni tad-data u din se tinżamm separatament mill-informazzjoni personali.
6. Naf ukoll li r- Riċerkatriċi hi l-unika persuna li se jkollha aċċess għal din l-informazzjoni, filwaqt li s-Superviżuri akkademiċi u l-eżaminaturi se jkollhom aċċess għal data kkodifikata biss. Is-Superviżuri akkademiċi u l-eżaminaturi jista jkollhom bżonn aċċess għall-informazzjoni miġbura għal skop ta' verifika.
7. Barra min hekk, naf li id-data se jinħażnu fuq il-kompjuter personali tar- Riċerkatriċi permezz ta' kodifikazzjoni tad-data (data encryption) u li hi protetta b'password. Barra minn hekk, naf li l-materjal stampat se jitqiegħed f'post sikur u se jinżamm sakemm joħorġu r-riżultati.
8. Naf li l-identità tiegħi u l-informazzjoni personali mhuma se jinkixfu mkien fit-teżi, fir-rapporti, fil-preżentazzjonijiet u/jew fil-pubblikazzjonijiet li jistgħu jirriżultaw minnha.

9. Nifhem ukoll li jien liberu/a li naċċetta, nirrifjuta jew inwaqqaf il-parteċipazzjoni f'kull ħin bla ma nagħti raġuni. Dan mhux ħa jkollu riperkussjonijiet negattivi fuqi. Nifhem ukoll li la darba nirtira minn dan l-istudju, l-informazzjoni miġbura se titħassar.
10. Nifhem ukoll li l-kontribuzzjoni tiegħi ser isservi biex jinfthiem ir-rwol żraben fit-tnaqqis tal-waqgħat fost il-popolazzjoni anzjana li tgħix f'faċilità fit-tul.
11. Nifhem ukoll, li skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, jiena għandi d-dritt li naċċessa, nirretifika, u fejn japplika nitlob sabiex titħassar id-data li tikkonċernani.
12. Naf ukoll li meta jintemm l-istudju u r-riżultati jkunu ppubblikati, l-informazzjoni personali miġbura titħassar.
13. Fl-aħħar nett, naf ukoll li se ningħata kopja tal-ittra ta' informazzjoni u tal-formula ta' kunsens sabiex inkun nista' naċċessahom fil-futur.
14. Jien qrajt u fhimt il-punti u d-dikjarazzjonijiet f'din il-formula. Inħossni sodisfatt/a bit-tweġibiet li ngħatajt għall-mistoqsijiet li kelli, u qed naċċetta minn jeddi li nipparteċipa f'dan l-istudju.

Parteċipant:___________________________________

Firma:_______________________________________

Data:____

Isem ir- Riċerkatriċi:

Annalise Muscat

Firma: ___________________

Data: _____26/12/21_____

Isem is-Superviżur tar-riċerka:

Dr. Stephen Mizzi

Firma: _____________________

Data:__26th December, 2021_

Appendix 6: Phase 2 Information and Consent form in Maltese

L-Università ta' Malta

Formula ta' Informazzjoni għall-Parteċipanti

Għażiż/a Parteċipant/a,

Jiena Annalise Muscat fil-preżent qed insegwi il- 'Masters' fil- Podjatrija, f' l-Universita' ta' Malta. Bħala parti mir-rekwiżiti tal-kors, qed nagħmel riċerka bit-titlu,

'The evaluation of footwear worn at a time of fall at a Maltese long- term elderly residence.'

L-għan ta' dan l-istudju hu li ninvestiga il- qies u l- karatteristici taż- żraben milbusa min persuni li qedghin f' residenza għal kura fit- tul. Huwa stmat li persuna minn kull tlieta ta' 65 sena jew aktar jaqgħu kull sena. Dan jiżdied għal wieħed minn kull tnejn għal dawk li għandhom 80 sena 'l fuq. Il-waqgħat huma raġuni komuni għad-dħul fl-isptar fil-popolazzjoni anzjana u l-biża' li jaqgħu tista' twassal għal telf ta' mobilità u tnaqqies fil-kwalità tal-ħajja. Il-parteċipazzjoni tiegħek f'dan l-istudju tgħinna niksbu ftehim aħjar dwar il-qies u il-karatteristiċi taż-żraben fost kampjun ta' popolazzjoni anzjana Maltija, u r-relazzjoni tagħha, jekk hemm, mal-waqgħat. Dan eventwalment se jibbenefika lill-popolazzjoni anzjana fil-prevenzjoni tal-waqgħat. Kull informazzjoni miġbura tintuża biss għall-għan jew l-għanijiet ta' dan l-istudju.

Wara l-waqgħa riċenti tiegħek li sostnejt waqt il-mixi, qed tiġi mistieden tipparteċipa fi studju, fejn tipprovdini biż-żarbun li ntlibes fil-ħin tal-waqgħa, u se jiġi investigat għall-karatteristiċi u l-qies tiegħu. Jekk taqbel li tipparteċipa, tiltaqa' mar-riċerkatrici darba, fir-Residenza San Vinċenz de Paul; jew fil-Klinika tal-Podjatrija jew fis-sala tiegħek, f'ħin li jkun konvenjenti għalik, għal madwar 30 minuta. Iż- żarbun tiegħek jiġi rritornat lilek fi tmiem il-laqgħa.

Matul il- laqgħa, jiena bħala r-riċerktici ser:

• Nsaqsi xi mistoqsijiet ġenerali dwarek, bħall-età, mobilita' tiegħek, kundizzjonijiet mediċi u mediċini li tieħu. Se jintalbu wkoll dettalji dwar il-waqgħa tiegħek, bħall-post u l-ħin tal-waqgħa u kwalunkwe ferimenti li ġarrabt. Jekk ma tkunx tista' tipprovdihom, dawn id-dettalji se jiġu rkuprati mill-fajl mediku tiegħek. Il-parametri mediċi tiegħek meħuda wara l-waqgħa tiegħek (bħal pressjoni tad-demm, temperatura tal-ġisem u livelli ta' glukożju) se jiġu rkuprati mill-fajl mediku tiegħek.

• Iż-żarbun li kien ntilbes fiż-żmien tal-waqgħa tiegħek, jiġi evalwat għall-karatteristiċi tiegħu skont il- 'Footwear Assesment Form'. Din hija formola sempliċi ta' 8 punti li tinkorpora dettalji bħat-tip ta' żarbun, għoli ta 'l-għarqub, ebusija ta' madwar l-għarqub, riġidità tal-qiegħ lonġitudinali, il- mod kif jinqafel iż-żarbun, punt ta' flessjoni tal-qiegħ, ebusija tal- qiegħ u d-disinn ta' qiegħ iż-żarbun.

• Iż- żarbun imbagħad jiġi eżaminat għal qies tiegħu f' saqajk. Dan se jsir billi tkejjel id-daqs taż-żarbun u t-tul u l-wisa' saqajk. It-tul taż-żarbun se jitkejjel permezz ta' gauge intern, filwaqt li l-wisa' se titkejjel permezz ta' kaliper bit-truf bil-ponta 'l barra. Dawn id-dimensjonijiet imbagħad jitqabblu mal-kejl tas-sieq tiegħek irreġistrat bl-użu ta 'apparat tal-kejl imsejjaħ apparat Brannock. Hawnhekk se tintalab toqgħod bilwieqfa u tpoġġi saqajk fuq l-apparat tal-kejl. It-tul u l-wisa' saqajk se jitkejlu.

Aktar tard, tista' tintalab tipparteċipa f'parti oħra tal-istudju, fejn se jsiru aktar testijiet biex jiddeterminaw il-bilanċ u l-istabbiltà tiegħek meta tilbes iż-żarbun tiegħek. F'dan il-każ, se jiġu pprovduti ittra ta' informazzjoni oħra u formola ta' kunsens, u d-dettalji kollha jiġu spjegati.

Iż- żarbun tiegħek mhux ħa ssirilu ħsara waqt il-valutazzjoni. M'intix obbligat li tipparteċipa f'dan l-istudju u tista' tirtira mill-istudju fi kwalunkwe ħin mingħajr ma tagħti raġuni. Dan ma jkollu ebda riperkussjonijiet negattivi fuqek u mhux ħa jkollok l-ebda telf ta' benefiċċji li inti intitolat għalihom. F' dan il- każ, l-informazzjoni li tinġabar mingħandek titħassar. Nassigurak li se tinżamm il-kunfidenzjalità matul l-istudju kollu u l-identità tiegħek u kull informazzjoni personali miġbura mhux se jiġu żvelati mkien fit-teżi, ir-rapporti, il-preżentazzjonijiet u/jew il-pubblikazzjonijiet li jistgħu jirriżultaw minnha. Id-data meħtieġa għal din ir-riċerka biss tiġi ppubblikata. Kull tagħrif miġbur se jiġi psewdonomizzat, jiġifieri id-data kollha se tkun protetta permezz ta' sistema ta' kodiċi u miżmuma separatament mill-informazzjoni personali.

Ir- Riċerkatriċi biss ser ikollha aċċess għall-informazzjoni miġbura, filwaqt li s- is-Superviżuri akkademiċi u l-eżaminaturi se jkollhom biss aċċess għal data kkodifikata. Is-Superviżuri akkademiċi u l-eżaminaturi jista jkollhom bżonn aċċess għall-informazzjoni miġbura għal skop ta' verifika.

Id-data kollha se tinħażen fuq il-kompjuter personali tar- Riċerkatriċi permezz ta' kodifikazzjoni tad-data (data encryption) u li hi protetta b'password. Barra minn hekk, il-materjal stampat se jinqafel f'post sigur.

Il-parteċipazzjoni tiegħek f'dan l-istudju hija għażla għal kollox volontarja u inti ħieles/ħielsa li taċċetta jew tirrifjuta li tieħu sehem mingħajr ma jkun hemm konsegwenzi fil-konfront tiegħek. Se tingħata kopja tal-ittra ta' informazzjoni u tal-formula ta' kunsens sabiex tkun tista' taċċessahom fil-futur. Barra minn hekk, skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, inti għandek id-dritt li taċċessa, tirretifika, u fejn japplika titlob sabiex titħassar id-data li tikkonċerna lilek. L-informazzjoni personali kollha se titħassar hekk kif jintemm dan l-istudju ta' riċerka u jkunu ppubblikati r-riżultati miksuba.

Dan l-istudju ġie approvat mill-Kumitat għall-Etika fir-Riċerka fi ħdan il-Fakultà tax-Xjenzi tas-Saħħa fl-Università ta' Malta.

Grazzi ħafna tal-ħin u s-sehem tiegħek f'dan l-istudju. F'każ li jkollok xi mistoqsijiet jew tixtieq tiċċara xi ħaġa, tista' ċċempilli fuq 99401719 jew tibgħatli email fuq annalise.vassallo.10@um.edu.mt. Tista' wkoll tikkuntattja lis-Superviżur Dr. Stephen Mizzi fuq 23401154 jew billi tibgħat email fuq stephen.mizzi@um.edu.mt.

Dejjem tiegħek,

Muscat

Isem ir- Riċerkatrici

Annalise Muscat

Isem is- Superviżur tar-Riċerka

Formula ta' Kunsens tal-Parteċipanti

'The evaluation of footwear worn at a time of fall at a Maltese long- term elderly residence.'

Jien, hawn taħt iffirmat/a, nagħti l-kunsens tiegħi biex nieħu sehem fl-istudju mmexxi minn Annalise Muscat. L-għan ta' dan id-dokument hu li jiġu speċifikati t-termini tal-parteċipazjoni tiegħi f'dan l-istudju ta' riċerka.

1. Jien ingħatajt informazzjoni miktuba u verbali dwar l-għan tal-istudju u l-mistoqsijiet kollha twieġbu.
2. Nifhem li se nkun qed nipparteċipa fi studju, fejn ir- Riċerkatriċi ħa tistaqsi xi informazzjoni medika ġenerali dwari u dwar il- waqgħa tiegħi u twettaq testijiet biex tinvestiga l-karatteristiċi u l-qies taż-żarbun tiegħi. Dan mhux se jpoġġi s-saħħa u s-sigurtà tiegħi f'riskju.
3. Naf li l-istudju se jieħu madwar 30 minuta. Nifhem, li l-laqgħa se ssir ġewwa s- sala tiegħi jew ġewwa l- klinika tal- Podjatrija, ġewwa r- residenza San Vincenz de Paul, f' ħin konvenjenti għalija.
4. Jien konxju/a li se jinkitbu r-risposti fuq formuli apposta.
5. Naf ukoll li se ssir kodifikazzjoni tad-data u din se tinżamm separatament mill-informazzjoni personali.
6. Naf ukoll li r- Riċerkatriċi hi l-unika persuna li se jkollha aċċess għal din l-informazzjoni, filwaqt li s-Superviżuri akkademiċi u l-eżaminaturi se jkollhom aċċess għal data kkodifikata biss. Is-Superviżuri akkademiċi u l-eżaminaturi jista jkollhom bżonn aċċess għall-informazzjoni miġbura għal skop ta' verifika.
7. Barra min hekk, naf li id-data se jinħażnu fuq il-kompjuter personali tar- Riċerkatriċi permezz ta' kodifikazzjoni tad-data (data encryption) u li hi protetta b'password. Barra minn hekk, naf li l-materjal stampat se jitqiegħed f'post sikur u se jinżamm sakemm joħorġu r-riżultati.

8. Naf li l-identità tiegħi u l-informazzjoni personali mhuma se jinkixfu mkien fit-teżi, fir-rapporti, fil-preżentazzjonijiet u/jew fil-pubblikazzjonijiet li jistgħu jirriżultaw minnha.

9. Nifhem ukoll li jien liberu/a li naċċetta, nirrifjuta jew inwaqqaf il-parteċipazzjoni f'kull ħin bla ma nagħti raġuni. Dan mhux ħa jkollu riperkussjonijiet negattivi fuqi. Nifhem ukoll li la darba nirtira minn dan l-istudju, l-informazzjoni miġbura se titħassar.

10. Nifhem ukoll li l-kontribuzzjoni tiegħi ser isservi biex jinfthiem ir-rwol żraben fit-tnaqqis tal-waqgħat fost il-popolazzjoni anzjana li tgħix f'faċilità fit-tul.

11. Nifhem ukoll, li skont ir-Regolam enti Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, jiena għandi d-dritt li naċċessa, nirretifika, u fejn japplika nitlob sabiex titħassar id-data li tikkonċernani.

12. Naf ukoll li meta jintemm l-istudju u r-riżultati jkunu ppubblikati, l-informazzjoni personali miġbura titħassar.

13. Fl-aħħar nett, naf ukoll li se ningħata kopja tal-ittra ta' informazzjoni u tal-formula ta' kunsens sabiex inkun nista' naċċessahom fil-futur.

14. Jien qrajt u fhimt il-punti u d-dikjarazzjonijiet f'din il-formula. Inħossni sodisfatt/a bit-tweġibiet li ngħatajt għall-mistoqsijiet li kelli, u qed naċċetta minn jeddi li nipparteċipa f'dan l-istudju.

Parteċipant: ______________________________

Firma: ______________________________

Data: ______________________________

Isem ir-Riċerkatur:

Annalise Muscat

Firma: ____________________

Data: 26/12/2021__________

Isem is- Superviżur:

Dr. Stephen Mizzi

Firma: ____________________

Data: 26th December, 2021

Appendix 7: Phase 3 Information and Consent Form in Maltese

Formula ta' Informazzjoni għall-Parteċipanti

Għażiż/a Parteċipant/a,

Jiena Annalise Muscat fil-preżent qed insegwi il- 'Masters' fil- Podjatrija, f' l-Universita' ta' Malta. Bħala parti mir-rekwiżiti tal-kors, qed nagħmel riċerka bit-titlu,

'The evaluation of footwear worn at a time of fall at a Maltese long- term elderly residence.'

Huwa stmat li persuna minn kull tlieta ta' 65 sena jew aktar jaqgħu kull sena. Dan jiżdied għal wieħed minn kull tnejn għal dawk li għandhom 80 sena 'l fuq. Il-waqgħat huma raġuni komuni għad-dħul fl-isptar fil-popolazzjoni anzjana u l-biża' li jaqgħu tista' twassal għal telf ta' mobilità u tnaqqis fil-kwalità tal-ħajja. Il-parteċipazzjoni tiegħek f'dan l-istudju tgħinna niksbu ftehim aħjar dwar il-qies u il- karatteristiċi taż-żraben fost kampjun ta' popolazzjoni anzjana Maltija, u r-relazzjoni tagħha, jekk hemm, mal-waqgħat. Dan eventwalment se jibbenefika lill-popolazzjoni anzjana fil-prevenzjoni tal-waqgħat. Kull informazzjoni miġbura tintuża biss għall-għan jew l-għanijiet ta' dan l-istudju.

Wara l-parteċipazzjoni tiegħek fi stadju aktar bikri tal-istudju, fejn ġejt eżaminat wara l-waqgħa tiegħek, issa qed tiġi mistieden biex tipparteċipa fl-aħħar parti tal-istudju. Hawnhekk se tiġi ttestjat għall-bilanċ u l-istabbiltà meta tilbes iż-żarbun li pprovdejtilna aktar kmieni, u meta tilbes żarbun ieħor ipprovdut mir-riċerkatriċi. Jekk taqbel li tipparteċipa, tiltaqa' mar-riċerkatriċi darba, fir-Residenza San Vinċenz de Paul, fil-Klinika tal-Podjatrija, f'ħin li jkun konvenjenti għalik, għal madwar 30 minuta.

Matul iż-żjara jien, bħala r-riċerkatriċi, ser nagħtik par żarbun skond id-daqs tiegħek. Dan ż-żarbun għandu karatteristiċi tajbin bħal għarqub sod u qiegħ iebes, li jiżgura stabbiltà tajba. Inti tintalab tagħmel 2 testijiet, it-tnejn li huma waqt li tilbes iż-żarbun li lbist waqt il-waqgħa preċedenti tiegħek u ż-żarbun ipprovdut mir-riċerkatriċi. L-ewwel test jissejjaħ Functional Reach Test (FRT). Hawnhekk, inti tintalab toqgħod bilwieqfa ħdejn riga mwaħħla ma' ħajt u tingħata struzzjonijiet biex tifrex dirgħajk 'l quddiem kemm tista (mingħajr ma tieħu pass 'l quddiem jew titlef il-bilanċ), filwaqt li żżomm sod kemm tista. Inti tintalab tirrepeti dan għal 2 darbiet oħra.

It-test l-ieħor jissejjaħ Touch Up and Go (TUG). Inti se tintalab toqgħod bilqiegħda, timxi 3 metri, iddur u timxi lura lejn is-siġġu u toqgħod bilqiegħda. Il-ħin meħud biex jitlesta dan it-test jiġi rreġistrat. Ir-riżultati meħuda meta tilbes iż-żarbun tiegħek u ż-żarbun ipprovdut mir-riċerkatrici se jiġu mqabbla.

Matul iż-żewġ testijiet, inti ser tkun akkumpanjat min podjatra kwalifikata biex tiżgura s-sigurtà tiegħek. Ir-riċerkatriċi twaqqafek milli tkompli t-test jekk jigi nnutat li qiegħed f'riskju li titlef il-bilanċ tiegħek. Inti liberu/a li twaqqaf it-testijiet f' kwalunkwe ħin, mingħajr ma tipprovdi ebda spjegazzjoni. Barra minn hekk, iċ-ċaħda tal-parteċipazzjoni jew l-irtirar mill-istudju ma jkollhom l-ebda riperkussjonijiet negattivi fuqek u ma jkollok l-ebda telf ta' benefiċċji li inti intitolat għalihom.

Nassigurak li se tinżamm il-kunfidenzjalità matul l-istudju kollu u l-identità tiegħek u kull informazzjoni personali miġbura mhux se jiġu żvelati mkien fit-teżi, ir-rapporti, il-preżentazzjonijiet u/jew il-pubblikazzjonijiet li jistgħu jirriżultaw minnha. Id-data meħtieġa għal din ir-riċerka biss tiġi ppubblikata. Kull tagħrif miġbur se jiġi psewdonomizzat, jiġifieri id-data kollha se tkun protetta permezz ta' sistema ta' kodiċi u miżmuma separatament mill-informazzjoni personali.

Ir- Riċerkatriċi biss ser ikollha aċċess għall-informazzjoni miġbura, filwaqt li s- is-Superviżuri akkademiċi u l-eżaminaturi se jkollhom biss aċċess għal data kkodifikata. Is-Superviżuri akkademiċi u l-eżaminaturi jista jkollhom bżonn aċċess għall-informazzjoni miġbura għal skop ta' verifika.

Id-data kollha se tinħażen fuq il-kompjuter personali tar- Riċerkatriċi permezz ta' kodifikazzjoni tad-data (data encryption) u li hi protetta b'password. Barra minn hekk, il-materjal stampat se jinqafel f'post sigur.

Il-parteċipazzjoni tiegħek f'dan l-istudju hija għażla għal kollox volontarja u inti ħieles/ħielsa li taċċetta jew tirrifjuta li tieħu sehem mingħajr ma jkun hemm konsegwenzi fil-konfront tiegħek. Se tingħata kopja tal-ittra ta' informazzjoni u tal-formula ta' kunsens sabiex tkun tista' taċċessahom fil-futur. Barra minn hekk, skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, inti għandek id-dritt li taċċessa, tirretifika, u fejn japplika titlob sabiex titħassar id-data li tikkonċerna lilek. L-informazzjoni personali kollha se titħassar hekk kif jintemm dan l-istudju ta' riċerka u jkunu ppubblikati r-riżultati miksuba.

Dan l-istudju ġie approvat mill-Kumitat għall-Etika fir-Riċerka fi ħdan il-Fakultà tax-Xjenzi tas-Saħħa fl-Università ta' Malta.

Grazzi ħafna tal-ħin u s-sehem tiegħek f'dan l-istudju. F'każ li jkollok xi mistoqsijiet jew tixtieq tiċċara xi ħaġa, tista' ċċempilli fuq 99401719 jew tibgħatli email fuq annalise.vassallo.10@um.edu.mt. Tista' wkoll tikkuntattja lis-Superviżur Dr. Stephen Mizzi fuq 23401154 jew billi tibgħat email fuq stephen.mizzi@um.edu.mt.

Dejjem tiegħek,

Annalise Muscat

Dr. Stephen Mizzi

Formula ta' Kunsens tal-Parteċipanti

'The evaluation of footwear worn at a time of fall at a Maltese long- term elderly residence.'

Jien, hawn taħt iffirmat/a, nagħti l-kunsens tiegħi biex nieħu sehem fl-istudju mmexxi minn Annalise Muscat. L-għan ta' dan id-dokument hu li jiġu speċifikati t-termini tal-parteċipazjoni tiegħi f'dan l-istudju ta' riċerka.

1. Jien ingħatajt informazzjoni miktuba u verbali dwar l-għan tal-istudju u l-mistoqsijiet kollha twieġbu.
2. Nifhem li se nkun qed nipparteċipa fi studju, fejn ir- Riċerkatriċi se titlobni nwettaq 2 testijiet sabiex tivvaluta l-bilanċ u l-istabbiltà tiegħi. Dan se jsir billi nwettaq it-testijiet biż-żarbun li ntlibes waqt il-waqgħa preċedenti tiegħi u ż-żarbun ipprovdut mir-riċerkatur. Se jittieħdu prekawzjonijiet biex niżguraw is-saħħa u s-sigurtà tiegħi waqt dawn it-testijiet.
3. Naf li l-istudju se jieħu madwar 30 minuta. Nifhem, li l-laqgħa se ssir ġewwa l- klinika tal- Podjatrija, ġewwa r- residenza San Vincenz de Paul, f' ħin konvenjenti għalija.
4. Jien konxju/a li se jinkitbu r-risposti fuq formuli apposta.
5. Naf ukoll li se ssir kodifikazzjoni tad-data u din se tinżamm separatament mill-informazzjoni personali.
6. Naf ukoll li r- Riċerkatriċi hi l-unika persuna li se jkollha aċċess għal din l-informazzjoni, filwaqt li s-Superviżuri akkademiċi u l-eżaminaturi se jkollhom aċċess għal data kkodifikata biss. Is-Superviżuri akkademiċi u l-eżaminaturi jista jkollhom bżonn aċċess għall-informazzjoni miġbura għal skop ta' verifika.
7. Barra min hekk, naf li id-data se jinħażnu fuq il-kompjuter personali tar- Riċerkatriċi permezz ta' kodifikazzjoni tad-data (data encryption) u li hi protetta b'password. Barra minn hekk, naf li l-materjal stampat se jitqiegħed f'post sikur u se jinżamm sakemm joħorġu r-riżultati.
8. Naf li l-identità tiegħi u l-informazzjoni personali mhuma se jinkixfu mkien fit-teżi, fir-rapporti, fil-preżentazzjonijiet u/jew fil-pubblikazzjonijiet li jistgħu jirriżultaw minnha.
9. Nifhem ukoll li jien liberu/a li naċċetta, nirrifjuta jew inwaqqaf il-parteċipazzjoni f'kull ħin bla ma nagħti raġuni. Dan mhux ħa jkollu riperkussjonijiet negattivi fuqi. Nifhem ukoll li la darba nirtira minn dan l-istudju, l-informazzjoni miġbura se titħassar.
10. Nifhem ukoll li l-kontribuzzjoni tiegħi ser isservi biex jinfthiem ir-rwol żraben fit-tnaqqis tal-waqgħat fost il-popolazzjoni anzjana li tgħix f'faċilità fit-tul.

11. Nifhem ukoll, li skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, jiena għandi d-dritt li naċċessa, nirretifika, u fejn japplika nitlob sabiex titħassar id-data li tikkonċernani.

12. Naf ukoll li meta jintemm l-istudju u r-riżultati jkunu ppubblikati, l-informazzjoni personali miġbura titħassar.

13. Fl-aħħar nett, naf ukoll li se ningħata kopja tal-ittra ta' informazzjoni u tal-formula ta' kunsens sabiex inkun nista' naċċessahom fil-futur.

14. Jien qrajt u fhimt il-punti u d-dikjarazzjonijiet f'din il-formula. Inħossni sodisfatt/a bit-tweġibiet li ngħatajt għall-mistoqsijiet li kelli, u qed naċċetta minn jeddi li nipparteċipa f'dan l-istudju.

Parteċipant: ________________________________

Firma:_____________________________________

Data:______________________________________

Isem ir- Ricerkatriċi:

Annalise Muscat

Firma:

Data: _______26/12/2021________

Isem is- Superviżur tar- riċerka:

Dr. Stephen Mizzi

Firma:

Data: ___26th December, 2021

Appendix 8: Phase 1 Record Sheet

Phase 1 Record Sheet

Date: ________________

Participant Number: _____

1. Gender — Male/ Female
2. Age — ___________
3. Mobility Status: — Walks Unaided/Uses Assistive Device
4. Barthel Index Score: ___________
5. Medical Conditions:

Visual Impairment	Hypotension
Parkinson's	Incontinence
History of Stroke	Depression
Lower limb Arthritis	Peripheral Neuropathy
Polypharmacy	Others ____________

6. History of Falls — Yes/No

7. Footwear measurements (mm)

- Shoe Length — Left _________ Right _________
- Shoe Width — Left _________ Right _________

8. Foot measurements (mm)

- Foot Length — Left _________ Right _________
- Foot Width — Left _________ Right _________

Difference in Foot-to-Shoe Length: Left ________ Right _________

Difference in Foot-to-Shoe Width: Left ________ Right _________

FOOTWEAR ASSESSMENT FORM

General shoe style / covering

- ☐ barefoot
- ☐ mule
- ☐ slipper
- ☐ walking shoe
- ☐ surgical footwear
- ☐ socks only
- ☐ high heel
- ☐ sandal
- ☐ Oxford shoe
- ☐ stockings only
- ☐ courtshoe
- ☐ mocassin
- ☐ Ugg bot
- ☐ backless slipper
- ☐ boot
- ☐ athletic shoe
- ☐ thong / flip-flop

Heel height

☐ 0 to 2.5 cm ☐ 2.6 to 5.0 cm ☐ >5.0 cm

Fixation

☐ none ☐ laces ☐ straps/buckles ☐ Velcro ☐ zips

Heel counter stiffness

☐ minimal (rigid) ☐ <45° ☐ >45°

Longitudinal sole rigidity

☐ minimal (rigid) ☐ <45° ☐ >45°

Sole flexion point

☐ at MTPJs ☐ before MTPJs

Tread pattern

☐ textured ☐ smooth ☐ partly worn ☐ fully worn

Sole hardness

☐ soft ☐ firm ☐ hard

Appendix 9: Phase 2 Record Sheet

Phase 2 Record Sheet

Date: ________________

Participant Number: _____

9. Gender Male/ Female

10. Age ___________

11. Mobility Status: Walks Unaided/Uses Assistive Device

12. Barthel Index Score: ___________

13. Medical Conditions:

Visual Impairment	Hypotension
Parkinson's	Incontinence
History of Stroke	Depression
Lower limb Arthritis	Peripheral Neuropathy
Polypharmacy	Others ____________

14. Date of Fall: ____________

15. History of falls in past year: Yes No

16. Any injuries sustained during the fall:

Bruises	Skin cuts/ Lacerations
Sprains	Pulled/Torn Muscles
Fractures/Dislocations	Head Injury

Others __________ No Injuries

17. Reasons for Fall:

Slipped Tripped

Legs gave way Loss of Balance

Others _____________ Unknown

9. Time of Fall: Morning Afternoon Evening

10. Location of Fall: ___________________________

11. Ground conditions: Dry Wet

12. Was participant wearing his usual footwear during time of fall?

Yes No

13. Footwear measurements (mm)

- Shoe Length: Left ________ Right _________
- Shoe Width: Left ________ Right _________

14. Foot measurements (mm)

- Foot Length: Left _________ Right _________
- Foot Width: Left _________ Right _________

Difference in Foot-to-Shoe Length: Left ________ Right ________

Difference in Foot-to-Shoe Width: Left ________ Right ________

FOOTWEAR ASSESSMENT FORM

General shoe style / covering

- ☐ barefoot
- ☐ mule
- ☐ slipper
- ☐ walking shoe
- ☐ surgical footwear
- ☐ socks only
- ☐ high heel
- ☐ sandal
- ☐ Oxford shoe
- ☐ stockings only
- ☐ courtshoe
- ☐ mocassin
- ☐ Ugg bot
- ☐ backless slipper
- ☐ boot
- ☐ athletic shoe
- ☐ thong / flip-flop

Heel height

☐ 0 to 2.5 cm ☐ 2.6 to 5.0 cm ☐ >5.0 cm

Fixation

☐ none ☐ laces ☐ straps/buckles ☐ Velcro ☐ zips

Heel counter stiffness

☐ minimal (rigid) ☐ <45° ☐ >45°

Longitudinal sole rigidity

☐ minimal (rigid) ☐ <45° ☐ >45°

Sole flexion point

☐ at MTPJs ☐ before MTPJs

Tread pattern

☐ textured ☐ smooth ☐ partly worn ☐ fully worn

Sole hardness

☐ soft ☐ firm ☐ hard

Appendix 10: Phase 3 Record Sheet

Phase 3 Record Sheet

Date ____________

Participant Number ______

Date of Fall _____________

Functional Reach Test

1. Using footwear worn at time of fall

	Trial 1 (Practice)	Trial 2	Trial 3	**Average** (Trial 2 and 3 only)
Distance (mm)				

2. Using researcher's footwear

	Trial 1 (Practice)	Trial 2	Trial 3	**Average** (Trial 2 and 3 only)
Distance (mm)				

3. Use of mobility assistive device during the test: Yes No

Time Up and Go test

1. Time needed (s) with footwear worn at time of fall: _____________
2. Time needed (s) with researcher's footwear: _____________
3. Use of mobility assistive device during the test: Yes No

Appendix 11: Residence CEO Request and Approval for Participant Recruitment

L-Università ta' Malta

Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Approval for Masters Study

2 messages

Annalise Vassallo <annalise.vassallo.10@um.edu.mt> 27 October 2021 at 10:34
To: josianne.cutajar@gov.mt

Dear Dr. Cutajar,

I am a state registered podiatrist, currently reading for an M.Sc. (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

I am aware that I will have to strictly adhere to all ethical issues, especially relating to confidentiality and informed consent. I will also consult my research supervisor Dr. Stephen Mizzi throughout the research process. Moreover, I will also be seeking approval from the Faculty of Health Sciences and the University of Malta Research Ethics Committee.

I would be grateful if you would allow me to recruit patients from St. Vincent de Paul Long Term Care Facility, to carry out this study. Data collection will start on March 2022 till March 2023. Recruited participants will be ambulatory and not suffering from any cognitive difficulties which prevent them from understanding their participation in the study. This study will be divided into three phases. Phase 1 will be a scoping study where around 200 consenting participants will have their footwear assessed for appropriateness, namely fit and style. Phase 2 will be held over a period of 9 months where the Senior Nursing Managers will inform the researcher of any falls happening over that time, at all wards, excluding dementia wards. The nature of the falls will be recorded, and the footwear worn by the residents during the time of fall, will be assessed and recorded. Around 50% of participants recruited during phase 2 and who consent will be invited to participate in phase 3 of this study. During this phase, participant's balance and stability will be assessed using Functional Reach Test and the Touch Up and Go Test. All precautions will be taken to ensure the residents' health and safety.
The motive of the study is mainly for research purposes. The residents' participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention.

Should you require further information, you can contact me via mobile on 99401719 or via email on annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Cutajar Josianne at MSCA-SVP <josianne.cutajar@gov.mt> 27 October 2021 at 20:53
To: Annalise Vassallo <annalise.vassallo.10@um.edu.mt>, Fiorentino Ronald at MSCA-SVP <ronald.fiorentino@gov.mt>, Briffa Valerie at MSCA-SVP <valerie.briffa@gov.mt>

Dear Annalise

Thank you for choosing SVP as part of your research.

https://mail.google.com/mail/u/0/?ik=8ab79c7e69&view=pt&search=all&permthid=thread-a%3Ar6031213561742851338simpl=msg-a%3Ar61138... 1/2

You have my go ahead once our DPO Ms Briffa and Dr Fiorentino from office of medical superintendent give you the green light

Good luck

jos

Josianne Cutajar
Chief Executive Officer
Ceo Office
St Vincent de Paul Long Term Care Facility

t +356 21443356 e josianne.cutajar@gov.mt
www.family.gov.mt | www.publicservice.gov.mt

MINISTRY FOR THE FAMILY, CHILDREN'S RIGHTS AND SOCIAL SOLIDARITY

ST VINCENT DE PAUL LONG TERM CARE FACILITY, TRIQ L-INGIERED, LUQA, MALTA

From: Annalise Vassallo <annalise.vassallo.10@um.edu.mt>
Sent: Wednesday, 27 October 2021 10:35
To: Cutajar Josianne at MSCA-SVP <josianne.cutajar@gov.mt>
Subject: Approval for Masters Study

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Appendix 12: Residence Medical Superintendent Request and Approval for Participant Recruitment

26th October, 2021
Annalise Muscat
Australia, Flat 1
Triq Hal Ghaxaq,
Gudja GDJ 2031

Dear Dr. Fiorentino,

I am a state registered podiatrist, currently reading for an M.Sc. (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

I am aware that I will have to strictly adhere to all ethical issues especially relating to confidentiality and informed consent. I will also consult my research supervisor Dr. Stephen Mizzi throughout the research process. Moreover, I will also be seeking approval from the Faculty of Health Sciences and the University of Malta Research Ethics Committee.

I would be grateful if you would allow me to recruit patients from St. Vincent de Paul Long Term Care Facility, to carry out this study. Data collection will start on March 2022 till March 2023. Recruited participants will be ambulatory and not suffering from any cognitive difficulties which prevent them from understanding their participation in the study. This study will be divided into three phases. Phase 1 will be a scoping study where around 200 consenting participants will have their footwear assessed for appropriateness, namely fit and style. Phase 2 will be held over a period of 9 months where the Senior Nursing Managers will inform the researcher of any falls happening over that time, at all wards, excluding dementia wards. The nature of the falls will be recorded, and the footwear worn by the residents during the time of fall, will be assessed and recorded. Around 50% of participants recruited during phase 2 and who consent will be invited to participate in phase 3 of this study. During this phase, participant's balance and stability will be assessed using Functional Reach Test and the Touch Up and Go Test. All precautions will be taken to ensure the residents' health and safety. The motive of the study is mainly for research purposes. The residents' participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention.

Should you require further information, you can contact me via mobile on 99401719 or via email on annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Muscat

PPROVED

1-11-21

Appendix 13: Approval from the Data Protection Officer of the residence to access data on consenting residents

6th October, 2021

Annalise Muscat

Australia, Flat 1

Triq Hal Ghaxaq,

Gudja GDJ 2031

Dear Ms. Briffa,

I am a state registered podiatrist, currently reading for an M.Sc. (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

I am aware that I will have to strictly adhere to all ethical issues especially relating to confidentiality and informed consent. I will also consult my research supervisor Dr. Stephen Mizzi throughout the research process. Moreover, I will also be seeking approval from the Faculty of Health Sciences and the University of Malta Research Ethics Committee.

My study will be held at St. Vincent de Paul Long Term Care Facility. I would be grateful if you would allow me to access and retrieve data from the participants' medical file such as; medical conditions and current medications, mobility status and Barthel Index, in order to carry out the study. Data collection will start on March 2022 till March 2023. Recruited participants are going to be ambulatory and not suffering from any cognitive difficulties which prevent them from understanding their participation in the study. This study will be divided into three phases. Phase 1 will be a scoping study where around 200 consenting participants will have their footwear assessed for appropriateness, namely fit and style. Phase 2 will be held over a period of 9 months where the Senior Nursing Managers will inform the researcher of any falls happening over that time, at all wards, excluding dementia wards. The nature of the falls will be recorded, and the footwear worn by the residents during the time of fall, will be assessed and recorded. Medical parameters will be retrieved from the patients' files following a fall. Around 50% of consenting participants recruited during phase 2 will be invited to participate in phase 3 of this study. During this phase, participant's balance and stability will be assessed using the Functional Reach Test and the Touch Up and Go Test. All precautions will be taken to ensure the residents' health and safety.

The motive of the study is mainly for research purposes. The residents' participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention.

Should you require further information, you can contact me via mobile on 99401719 or annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on email stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Muscat

approved 1/11/2021

Appendix 14: Approval from the Residence Wards Consultants to recruit participants for the study

L-Università ta' Malta

Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Masters Study Permission

Annalise Muscat <annalise.vassallo.10@um.edu.mt> — 28 October 2021 at 11:33
To: carmelo.spiteri@gov.mt
Cc: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>

Dear Dr. Spiteri,

I am a state registered podiatrist, currently reading for an M.Sc. (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

I am aware that I will have to strictly adhere to all ethical issues, especially relating to confidentiality and informed consent. I will also consult my research supervisor Dr. Stephen Mizzi throughout the research process. Moreover, I will also be seeking approval from the Faculty of Health Sciences and the University of Malta Research Ethics Committee.

This study is going to be held at St. Vincent de Paul long term facility care. I would be grateful if you would allow me to recruit residents from your respective wards, to carry out this study. Data collection will start in March 2022 till March 2023. Recruited participants are going to be ambulatory and not suffering from any cognitive difficulties which prevent them from understanding their participation in the study. This study will be divided into three phases. Phase 1 will be a scoping study where around 200 consenting participants will have their footwear assessed for appropriateness, namely fit and style. Phase 2 will be held over a period of 9 months where the Senior Nursing Managers will inform the researcher of any falls happening over that time, at all wards, excluding dementia wards. The nature of the falls will be recorded, and the footwear worn by the residents during the time of fall, will be assessed and recorded. Around 50% of participants recruited during phase 2 and who consent will be invited to participate in phase 3 of this study. During this phase, participant's balance and stability will be assessed using the Functional Reach Test and the Touch Up and Go Test. All precautions will be taken to ensure the residents' health and safety.

The motive of the study is mainly for research purposes. The residents' participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention.

Should you require further information, you can contact me via mobile on 99401719 or via email on annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Spiteri Carmelo at Health <carmelo.spiteri@gov.mt> — 28 Oct 2021, 20:39
to me

Dear Ms Muscat

You have my permission to recruit residents from my wards, to carry out your study. Should you need any assistance, do not hesitate to contact me.

Thanks and regards

Charles Spiteri

Dr Carmelo Spiteri
Consultant Geriatrician
m 79292988 e carmelo.spiteri@gov.mt

L-Università ta' Malta

Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Masters Thesis Permission

2 messages

Annalise Vassallo <annalise.vassallo.10@um.edu.mt> 27 October 2021 at 14:07

To: george.bugeja@gov.mt

Dear Dr. Bugeja,

I am a state registered podiatrist, currently reading for an M.Sc. (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

I am aware that I will have to strictly adhere to all ethical issues, especially relating to confidentiality and informed consent. I will also consult my research supervisor Dr. Stephen Mizzi throughout the research process. Moreover, I will also be seeking approval from the Faculty of Health Sciences and the University of Malta Research Ethics Committee.

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Should you require further information, you can contact me via mobile on 99401719 or via email on annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Bugeja George at Rehabilitation Services-Health <george.bugeja@gov.mt> 27 October 2021 at 21:12

To: Annalise Vassallo <annalise.vassallo.10@um.edu.mt>

OK Annalise. I agree to the attached. You have permission to conduct the study on my patients at SVPR.

Regards

G Bugeja

2112

L-Università ta' Malta

Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Masters Study Permission

2 messages

Annalise Muscat <annalise.vassallo.10@um.edu.mt> 28 October 2021 at 11:31
To: antoine.b.vella@gov.mt
Cc: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>

Dear Dr. Vella,

I am a state registered podiatrist, currently reading for an M.Sc. (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

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Should you require further information, you can contact me via mobile on 99401719 or via email on annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

/ella Antoine at Rehabilitation Services-Health <antoine.b.vella@gov.mt> 28 October 2021 at 16:5(
'o: Annalise Muscat <annalise.vassallo.10@um.edu.mt>
:c: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>

Dear Annalise,

you have my full support to carry ot the mentioned study.

Kind regards

Antoine

Antoine Vella MD, FRCP(Glasg) FRCP(Edin) FRCP(Lond) MBA(Henley)

Consultant Physician/Geriatrician
Foundation Training Programme Director
Senior Visiting Lecturer, University of Malta

Hon Consultant MCCF, Malta

L-Università ta' Malta

Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Masters Study Permission

2 messages

Annalise Muscat <annalise.vassallo.10@um.edu.mt> 3 November 2021 at 11:37
To: maria-aloysia.abela@gov.mt
Cc: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>

Dear Dr. Abela

I am a state registered podiatrist, currently reading for an M.Sc. (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

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The motive of the study is mainly for research purposes. The residents' participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention.

Should you require further information, you can contact me via mobile on 99401719 or via email on annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Abela Maria Aloysia at MSCA-SVP <maria-aloysia.abela@gov.mt> 3 November 2021 at 16:13
To: Annalise Muscat <annalise.vassallo.10@um.edu.mt>
Cc: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>

Dear Ms Muscat

You have my permission to recruit any of my patients in SVP Long Term Care Facility whom you deem suitable for your research.

Wishing you all the best in your studies.

Kind regards

Dr Marisa Abela

Reg. No. 2233

Consultant Geriatrician

Appendix 15: Permission and consent from Chief Nursing Managers to act as intermediaries

L-Università ta' Malta

Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Masters Study Permission

7 messages

Annalise Muscat <annalise.vassallo.10@um.edu.mt> — 28 October 2021 at 11:04
To: christopher.a.borg@gov.mt
Cc: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>

Dear Mr. Borg,

I am a state registered podiatrist, currently reading for an M.Sc (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

I am aware that I will have to strictly adhere to all ethical issues, especially relating to confidentiality and informed consent. Under no instances will the residents' name and their respective ward be named or published. I will also consult my research supervisor Dr. Stephen Mizzi throughout the research process. Moreover, I will also be seeking approval from the Faculty of Health Sciences and the University of Malta Research Ethics Committee.

The study is going to be held at St. Vincent de Paul Long Term Care Facility. I would be grateful if you would allow me to recruit patients from your respective wards to carry out this study. I would also appreciate it if you would act as an intermediary and alert me of any falls happening to the residents sustained whilst walking, during the study. Data collection will start in March 2022 till March 2023. Recruited participants will be ambulatory and not suffering from any cognitive difficulties which prevent them from understanding their participation in the study. This study will be divided into three phases. Phase 1 will be a scoping study where around 200 consenting participants will have their footwear assessed for appropriateness, namely fit and style. Phase 2 will be held over a period of 9 months where any falls happening over that time, at all wards, excluding dementia wards, will be documented. The nature of the falls will be recorded, and the footwear worn by the residents during the time of fall, will be assessed. Around 50% of participants recruited during phase 2 and who consent will be invited to participate in phase 3 of this study. During this phase, participant's balance and stability will be assessed using the Functional Reach Test and the Touch Up and Go Test. All precautions will be taken to ensure the residents' health and safety.

The motive of the study is mainly for research purposes. The residents' participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention.

Should you require further information, you can contact me via mobile on 99401719 or via email on annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Borg Christopher A at MSCA-SVP <christopher.a.borg@gov.mt> — 28 October 2021 at 12:11
To: Annalise Muscat <annalise.vassallo.10@um.edu.mt>
Cc: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>, Dalli Mary Grace at MSCA-SVP <mary-grace.a.dalli@gov.mt>, Fiorentino Ronald at MSCA-SVP <ronald.fiorentino@gov.mt>

Dear Ms. Muscat,

Good afternoon,

Thank you for informing us. I find no objection to recruiting residents from my respective wards however please note I am copying my immediate superior, Ms. Dalli, and our data protection officer Dr. Firentino for their notification as well prior consent.

Please also note that should your population of residents include ones from the new block I suggest you contact their management as well.

Regards

Chris Borg

SNM

SVPR

Dalli Mary Grace at MSCA-SVP <mary-grace.a.dalli@gov.mt> — 2 November 2021 at 07:48
To: Fiorentino Ronald at MSCA-SVP <ronald.fiorentino@gov.mt>, Borg Christopher A at MSCA-SVP <christopher.a.borg@gov.mt>, Annalise Muscat <annalise.vassallo.10@um.edu.mt>
Cc: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>

No objection from my end.

Mary Grace Dalli
Chief Nursing Manager
Nursing Administration Unit
St Vincent de Paul Long Term Care Facility

t +356 22912212 e mary-grace.a.dalli@gov.mt
www.family.gov.mt | www.publicservice.gov.mt | fb.com/servizzpubbliku

MINISTRY FOR THE FAMILY, CHILDREN'S RIGHTS AND SOCIAL SOLIDARITY

ST VINCENT DE PAUL LONG TERM CARE FACILITY, FLORENCE NIGHTINGALE ROAD, LUQA, MALTA

Kindly consider your environmental responsibility before printing this e-mail

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Appendix 16: Permission and consent from Senior Nursing Managers to act as intermediaries

L-Università ta' Malta

Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Masters Thesis Permission

3 messages

Annalise Vassallo <annalise.vassallo.10@um.edu.mt>
To: bernard.piscopo@gov.mt

27 October 2021 at 11:10

Dear Mr. Piscopo,

I am a state registered podiatrist, currently reading for an M.Sc (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

I am aware that I will have to strictly adhere to all ethical issues, especially relating to confidentiality and informed consent. Under no instances will the residents' name and their respective ward be named or published. I will also consult my research supervisor Dr. Stephen Mizzi throughout the research process. Moreover, I will also be seeking approval from the Faculty of Health Sciences and the University of Malta Research Ethics Committee.

The study is going to be held at St. Vincent de Paul Long Term Care Facility. I would be grateful if you would allow me to recruit patients from your respective wards to carry out this study. I would also appreciate it if you would act as an intermediatory and alert me of any falls happening to the residents sustained whilst walking, during the study. Data collection will start on March 2022 till March 2023. Recruited participants will be ambulatory and not suffering from any cognitive difficulties which prevent them from understanding their participation in the study. This study will be divided into three phases. Phase 1 will be a scoping study where around 200 consenting participants will have their footwear assessed for appropriateness, namely fit and style. Phase 2 will be held over a period of 9 months where any falls happening over that time, at all wards, excluding dementia wards, will be documented. The nature of the falls will be recorded, and the footwear worn by the residents during the time of fall, will be assessed. Around 50% of participants recruited during phase 2 and who consent will be invited to participate in phase 3 of this study. During this phase, participant's balance and stability will be assessed using the Functional Reach Test and the Touch Up and Go Test. All precautions will be taken to ensure the residents' health and safety.
The motive of the study is mainly for research purposes. The residents' participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention.

Should you require further information, you can contact me via mobile on 99401719 or via email on annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Piscopo Bernard at MSCA-SVP <bernard.piscopo@gov.mt>
To: Annalise Vassallo <annalise.vassallo.10@um.edu.mt>

27 October 2021 at 11:18

I found no objection at all. I will also inform the entity managers about this study so MHCS wards will be covered as well.

Bernard

Bernard Piscopo
Senior Nursing Manager
Nursing Administration Unit
St Vincent De Paule' - Long Term Care Facility

t: +356 22912466 **m:** +356 79076280 **e:** bernard.piscopo@gov.mt
[www.family.gov.mt]www.family.gov.mt | [www.publicservice.gov.mt]www.publicservice.gov.mt

MINISTRY FOR THE FAMILY, CHILDREN'S RIGHTS AND SOCIAL SOLIDARITY

Kindly consider your environmental responsibility before printing this e-mail

From: Annalise Vassallo <annalise.vassallo.10@um.edu.mt>

L-Università ta' Malta

Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Permission for Masters Study
5 messages

Annalise Muscat <annalise.vassallo.10@um.edu.mt> 28 October 2021 at 11:02
To: anthony.b.galea@gov.mt
Cc: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>

Dear Mr. Galea,

I am a state registered podiatrist, currently reading for an M.Sc (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

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Should you require further information, you can contact me via mobile on 99401719 or via email on annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Galea Anthony at MSCA-SVP <anthony.b.galea@gov.mt> 28 October 2021 at 12:26
To: Annalise Muscat <annalise.vassallo.10@um.edu.mt>
Cc: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>

Dear colleague

If you need my assistance in any way feel free to contact me .

Noted with thanks

Anthony Galea
Senior Nursing Manager
Administration
St Vincent de Paul Long Term Care Facility

t +356 22912276 e anthony.b.galea@gov.mt
[www.family.gov.mt]www.family.gov.mt | [www.publicservice.gov.mt]www.publicservice.gov.mt

MINISTRY FOR THE FAMILY, CHILDREN'S RIGHTS AND SOCIAL SOLIDARITY

ST VINCENT DE PAUL LONG TERM CARE FACILITY, TRIQ L- INGIERED
LUQA, MALTA

Kindly consider your environmental responsibility before printing this e-mail

---

Annalise Muscat <annalise.vassallo.10@um.edu.mt> 28 October 2021 at 12:29
To: Galea Anthony at MSCA-SVP <anthony.b.galea@gov.mt>
Cc: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>

Thank you so much.
Just to clarify, do I have your approval?

Regards,
Annalise Muscat
[Quoted text hidden]

Galea Anthony at MSCA-SVP <anthony.b.galea@gov.mt> 28 October 2021 at 13:08
To: Annalise Muscat <annalise.vassallo.10@um.edu.mt>
Cc: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>

YES

Anthony Galea
Senior Nursing Manager
Administration
St Vincent de Paul Long Term Care Facility

t +356 22912276 e anthony.b.galea@gov.mt
[www.family.gov.mt]www.family.gov.mt | [www.publicservice.gov.mt]www.publicservice.gov.mt

MINISTRY FOR THE FAMILY, CHILDREN'S RIGHTS AND SOCIAL SOLIDARITY

ST VINCENT DE PAUL LONG TERM CARE FACILITY, TRIQ L- INGIERED
LUQA, MALTA

Kindly consider your environmental responsibility before printing this e-mail

L-Università ta' Malta

Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Masters Study Permission

3 messages

Annalise Muscat <annalise.vassallo.10@um.edu.mt> 1 November 2021 at 12:50
To: robert.a.camilleri@gov.mt
Cc: STEPHEN MIZZI <stephen.mizzi@um.edu.mt>

Dear Mr. Camilleri

I am a state registered podiatrist, currently reading for an M.Sc (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

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The study is going to be held at St. Vincent de Paul Long Term Care Facility. I would be grateful if you would allow me to recruit patients from your respective wards to carry out this study. I would also appreciate it if you would act as an intermediary and alert me of any falls happening to the residents sustained whilst walking, during the study. Data collection will start on March 2022 till March 2023. Recruited participants will be ambulatory and not suffering from any cognitive difficulties which prevent them from understanding their participation in the study. This study will be divided into three phases. Phase 1 will be a scoping study where around 200 consenting participants will have their footwear assessed for appropriateness, namely fit and style. Phase 2 will be held over a period of 9 months where any falls happening over that time, at all wards, excluding dementia wards, will be documented. The nature of the falls will be recorded, and the footwear worn by the residents during the time of fall, will be assessed. Around 50% of participants recruited during phase 2 and who consent will be invited to participate in phase 3 of this study. During this phase, participant's balance and stability will be assessed using Functional Reach Test and the Touch Up and Go Test. All precautions will be taken to ensure the residents' health and safety.

The motive of the study is mainly for research purposes. The residents' participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention.

Should you require further information, you can contact me via mobile on 99401719 or via email on annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Camilleri Robert at MSCA-SVP <robert.a.camilleri@gov.mt> 3 November 2021 at 10:55
To: Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Dear Ms. Muscat,

Please be informed that obviously I have no objection in granting you permission.

Do not hesitate to contact the undersigned should you require any further assistance.

Best of luck for your studies.

Regards.

Robert Camilleri
Senior Nursing Manager
Nursing Administration Unit
St Vincent de Paul Long Term Care Facility

t +356 22912461 e robert.a.camilleri@gov.mt
www.family.gov.mt | www.publicservice.gov.mt | fb.com/servizzpubbliku

MINISTRY FOR THE FAMILY, CHILDREN'S RIGHTS AND SOCIAL SOLIDARITY

ST VINCENT DE PAUL LONG TERM CARE FACILITY

Appendix 17: Consent from the Podiatry Department Manager of the residence to utilize their premises for data collection

L-Università ta' Malta

Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Consent for Masters Study

2 messages

Annalise Vassallo <annalise.vassallo.10@um.edu.mt> 26 October 2021 at 11:17

To: anne-marie.cutajar.2@gov.mt

Dear Ms. Cutajar,

I am a state registered podiatrist, currently reading for an M.Sc (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

I am aware that I will have to strictly adhere to all ethical issues especially relating to confidentiality and informed consent. I will also consult my research supervisor Dr. Stephen Mizzi throughout the research process. Moreover, I will also be seeking approval from the Faculty of Health Sciences and the University of Malta Research Ethics Committee.

The study is going to be held at St. Vincent the Paul Long Term Care Facility. I would be grateful if you, as a podiatry coordinator at SVP, would allow me to use the Podiatry Clinic, in order to carry out data collection. Data collection will start on March 2022 till March 2023. Recruited participants will be ambulatory and not suffering from any cognitive difficulties which prevent them from understanding their participation in the study. This study will be divided into three phases. Phase 1 will be a scoping study where around 200 consenting participants will have their footwear assessed for appropriateness, namely fit and style. Phase 2 will be held over a period of 9 months where the Senior Nursing Managers will inform the researcher of any falls happening over that time, at all wards, excluding dementia wards. The nature of the falls will be recorded, and the footwear worn by the residents during the time of fall, will be assessed and recorded. Around 50% of participants recruited during phase 2 and who consent will be invited to participate in phase 3 of this study. During this phase, participant's balance and stability will be assessed using Functional Reach Test and the Touch Up and Go Test. All precautions will be taken to ensure the residents' health and safety.

The motive of the study is mainly for research purposes. The residents' participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention.

Should you require further information, you can contact me via mobile on 99401719 or via email on annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Cutajar Anne Marie 2 at MSCA-SVP <anne-marie.cutajar.2@gov.mt> 26 October 2021 at 16:43

To: Annalise Vassallo <annalise.vassallo.10@um.edu.mt>

Dear Ms Muscat,

No objection from my end.

Regards,

Anne Marie Cutajar Bsc(Hons) Podiatry, MSc Skin Integrity Skills & Treatment (Herts)

Allied Health Practitioner

Podiatry Department

St Vincent de Paul Long Term Care Facility

Appendix 18: Approval from an experienced podiatrist who assisted the researcher during data collection

L-Università ta' Malta

Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Consent for Masters Studies

2 messages

Annalise Vassallo <annalise.vassallo.10@um.edu.mt> 26 October 2021 at 11:15
To: charlene-joan.sant@gov.mt

Dear Mrs. Sant,

I am a state registered podiatrist, currently reading for an M.Sc (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

I am aware that I will have to strictly adhere to all ethical issues, especially relating to confidentiality and informed consent. I will also consult my research supervisor Dr. Stephen Mizzi throughout the research process. Moreover, I will also be seeking approval from the Faculty of Health Sciences and the University of Malta Research Ethics Committee.

The study is going to be held at St. Vincent the Paul Long Term Care Facility. Data collection will start in March 2022 till March 2023. Recruited participants will be ambulatory and not suffering from any cognitive difficulties which prevent them from understanding their participation in the study. This study will be divided into three phases. Phase 1 will be a scoping study where around 200 consenting participants will have their footwear assessed for appropriateness, namely fit and style. Phase 2 will be held over a period of 9 months where the Senior Nursing Managers will inform the researcher of any falls happening over that time, at all wards, excluding dementia wards. The nature of the falls will be recorded, and the footwear worn by the residents during the time of fall, will be assessed and recorded. Around 50% of participants recruited during phase 2 and who consent will be invited to participate in phase 3 of this study. During this phase, participant's balance and stability will be assessed using the Functional Reach Test and the Touch Up and Go Test. These tests will be held at the Podiatry Clinic. I would be grateful if you would assist me during phase 3 of the study, where you would help me in ensuring the patients' safety by guarding them during the FRT and TUG tests.

The motive of the study is mainly for research purposes. The residents' participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention.

Should you require further information, you can contact me via mobile on 99401719 or via email on annalise.vassallo.10@um.edu.mt . You can also contact my supervisor Dr. Stephen Mizzi on stephen.mizzi@um.edu.mt

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Sant Charlene Joan at MSCA-SVP <charlene-joan.sant@gov.mt> 26 October 2021 at 12:04
To: Annalise Vassallo <annalise.vassallo.10@um.edu.mt>

Dear Ms Muscat,

No objection from my end.

Kind regards,

Charlene Joan Sant

Appendix 19: Permission from the Podiatry Lead to conduct the research

SKMBT_28316122709540.pdf
file:///C:/Users/vassa066/Desktop/SKMBT_28316122709540.pdf
ta' Malta

Annalise Muscat <annalise.vassallo.10@um.edu.mt>

Podiatry Masters Thesis Permission
3 messages

Annalise Vassallo <annalise.vassallo.10@um.edu.mt> 27 October 2021 at 10:53
To: andrew.scicluna@gov.mt

Dear Mr. Scicluna,

I am a state registered podiatrist, currently reading for an M.Sc (Hons) in Podiatry within the Faculty of Health Science. I will be conducting a research project as part of my dissertation entitled: 'The evaluation of footwear worn at a time of fall at a Maltese long term elderly residence'.

The aim of this study is to investigate the relationship between footwear fit and style and the risk of falls in a geriatric population at a long-term residence facility. It is estimated that one in three people aged 65 years and over fall each year. This increases to one in two for those aged 80 years and over. Falls are a common reason for hospitalization in the older population and fear of falling can lead to loss of mobility and reduction in quality of life. A number of risk factors have been attributed to falls, with footwear being linked to falls by many researchers.

I am aware that I will have to strictly adhere to all ethical issues, especially relating to confidentiality and informed consent. I will also consult my research supervisor Dr. Stephen Mizzi throughout the research process. Moreover, I will also be seeking approval from the Faculty of Health Sciences and the University of Malta Research Ethics Committee.

I would be grateful, that as a Podiatry lead, you would allow me to carry out this study. The study will take place at St. Vincent de Paul Long Term Facility Care. Data collection will start in March 2022 till March 2023. Recruited participants will be ambulatory and not suffering from any cognitive difficulties which prevent them from understanding their participation in the study. This study will be divided into three phases. Phase 1 will be a scoping study where around 200 consenting participants will have their footwear assessed for appropriateness, namely fit and style. Phase 2 will be held over a period of 9 months where the Senior Nursing Managers will inform the researcher of any falls happening over that time, at all wards, excluding dementia wards. The nature of the falls will be recorded, and the footwear worn by the residents during the time of fall, will be assessed and recorded. Around 50% of participants recruited during phase 2 and who consent will be invited to participate in phase 3 of this study. During this phase, participant's balance and stability will be assessed using the Functional Reach Test and the Touch Up and Go Test. All precautions will be taken to ensure the residents' health and safety.

The motive of the study is mainly for research purposes. The residents' participation in this study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention.

The motive of the study is mainly for research purposes. This study would help us gain a better understanding on footwear characteristics and fit amongst a sample of elderly Maltese population, and its relation, if any, with falls. This will eventually benefit the older population in the management of fall prevention.

Your support for this project would be greatly appreciated.

Sincerely,

Annalise Muscat

Scicluna Andrew at Health-Primary Health Care <andrew.scicluna@gov.mt> 4 November 2021 at 10:18
To: Annalise Vassallo <annalise.vassallo.10@um.edu.mt>

No obiection

Good luck with your studies

Andrew Scicluna
Professional Lead Podiatry

Appendix 20: Phase 1- Correlation between difference in foot-shoe length (top table) and width (bottom table) and gender

			Gender		
			Female	Male	Total
Difference in foot-to-shoe **length**	Too Short	Count	34	14	48
		Percentage	39.5%	28.6%	35.6%
	Good Fit	Count	33	19	52
		Percentage	38.4%	38.8%	38.5%
	Too Long	Count	19	16	35
		Percentage	22.1%	32.7%	25.9%
Total		Count	86	49	135
		Percentage	100.0%	100.0%	100.0%

X2(2) = 2.399 p = 0.301

Difference in foot to shoe **width**	Too narrow	Count	28	9	37
		Percentage	32.6%	18.4%	27.4%
	Good fit	Count	55	34	89
		Percentage	64.0%	69.4%	65.9%
	Too wide	Count	3	6	9
		Percentage	3.5%	12.2%	6.7%
Total		Count	86	49	135
		Percentage	100.0%	100.0%	100.0%

X2(2) = 6.024 p = 0.049

Appendix 21: Phase1- Correlation between gender and shoe style in the study population

			ShoeStyle								
			Athletic Shoe	Backless Slipper	Courtshoe	Flip-flop	Oxford Shoe	Sandal	Slipper	Walking Shoe	Total
Gender	Female	Count	4	17	1	1	0	24	30	9	86
		% within ShoeStyle	33.3%	68.0%	100.0%	25.0%	0.0%	66.7%	75.0%	60.0%	63.7%
	Male	Count	8	8	0	3	2	12	10	6	49
		% within ShoeStyle	66.7%	32.0%	0.0%	75.0%	100.0%	33.3%	25.0%	40.0%	36.3%
Total		Count	12	25	1	4	2	36	40	15	135
		% within ShoeStyle	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

X2 (2)= 14.091 p= 0.050

Appendix 22: Phase 2- Correlation between type of fall and injuries sustained

Injury		Type of Fall: Slipped	Tripped	Loss of Balance	Legs Gave Way	Unknown
Skin Cuts/ Lacerations	Count	3	7	7	2	1
	Percentage	3.9%	9.2%	9.2%	2.6%	1.3%
Bruises	Count	4	10	9	3	1
	Percentage	5.3%	13.2%	11.8%	3.9%	1.3%
Head Injury	Count	2	1	2	1	0
	Percentage	2.6%	1.3%	2.6%	1.3%	0.0%
Fractures/ Dislocations	Count	1	7	8	0	1
	Percentage	1.3%	9.2%	10.5%	0.0%	1.3%
No Injuries	Count	4	6	7	3	0
	Percentage	5.3%	7.9%	9.2%	3.9%	0.0%
Sprains	Count	2	2	1	1	0
	Percentage	2.6%	2.6%	1.3%	1.3%	0.0%

$X^2(20) = 9.952$, $p = 0.969$