Auditory characteristics and balance function of diabetic patients

By

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Abstract

Aims and Objectives. This study aimed to describe auditory characteristics and balance function in patients with diabetes between 18-55 years of age as well as determine the association between patients' auditory and balance function with diabetes characteristics (type, duration and control).

Background. Diabetes is one of the most prevalent non-communicable diseases worldwide with approximately 422 million people diagnosed globally. This number is projected to rise to 642 million by 2040 if no appropriate interventions are implemented to reverse the rise in the number of people with diabetes. South Africa has the second highest diabetes prevalence in Africa (after Nigeria) with 2.6 million cases.

A rise in diabetes prevalence should be a concern for audiologists with increasing literature linking diabetes with the risk of acquiring hearing and balance disorders. However, there is currently a lack of research done in South Africa to investigate auditory and balance disorders in patients with diabetes. Therefore, the current study sought to investigate auditory characteristics and balance function in South African patients diagnosed with diabetes. It is anticipated that the study findings will yield evidence that will highlight the role of an audiologist in the clinical management of patients with diabetes.

Research Design. The study utilised an observational cross-sectional matched groups design with a cohort (patients with diabetes) and control (volunteers without diabetes) group of participants. Participants were recruited from a Primary Health Care clinic in Polokwane, Limpopo using purposive and convenience sampling for the cohort and control group respectively.

Methodology. Several methods were used to collect data pertinent to this study. These included case history interview and a medical folder review to obtain information related to participants' diabetes status. Furthermore, all participants underwent the following assessments: otoscopy, pure tone audiometry, diagnostic distortion product otoacoustic emissions (DPOAE), vision screening, peripheral neuropathy screening, Dynamic Gait Index test (DGI) and the Modified Clinical Test of Sensory Integration (MCTSIB). Data were analyzed using both descriptive and inferential statistical tests.

Results. A total of 192 participants took part in this study; 110 in the cohort and 82 in the control group. There were similar distributions of gender in both groups with the following age distributions (in years) for each group; cohort; *median* =46, *range* =20-55, control; *median* =43, *range* =21-55. Pure tone audiometry assessments showed a significantly higher prevalence of hearing loss in the cohort (55%) when compared to the control (20%) group ($p <$ .001). Participant age, gender and diabetes duration were associated with the likelihood of having hearing loss (age: odds ratio=2.90, 95% CI: 1.19-7.08, p=0.019; gender (male): odds ratio=.266, 95% CI: .104-.677, p=0.005; diabetes duration: odds ratio=1.12, 95% CI: 1.02-1.22, p=0.013). DPOAE assessments showed significantly higher percentages of abnormalities with signal to noise ratio ($p < 0.01$) and DPOAE level ($p < 0.01$) in the cohort compared to the control group. A significantly higher proportion (38%) of participants in the cohort group reported tinnitus when compared to 15% in the control ($p <$ .001). Balance screening assessments with the DGI and the MCTSIB, showed significantly poorer performance in the cohort group than the control (DGI:, $p <$ .001; MCTSIB: $p <$ *.001*).

Conclusion. Overall findings of this study showed that participants who were diagnosed with diabetes had a higher proportion of auditory and balance abnormalities when compared to those in the control group. Older age, male gender and longer duration since diabetes diagnosis were

associated with a higher likelihood of having hearing loss. The findings of this study therefore suggest that auditory and balance dysfunction should be considered as comorbidities associated with diabetes. This study also highlighted the role of an audiologist in the managment of patients with diabetes with respect to early identification and management of auditory and balance dysfunctions amongst these patients.

Keywords: balance, diabetes, hearing loss, prevalence, tinnitus.

Key Abbreviations:

cPTA- Conventional Pure Tone Average

CI: Confidence Interval.

dB HL- Decibel Hearing Loss

dB SPL- Decibel Sound Pressure Level

DGI- Dynamic Gait Index

DPOAE- Distortion Product Otoacoustic Emissions

DNS- Diabetic Neuropathy Score

DoH- Department of Health

HF-PTA- High frequency Pure Tone Average

IDF- International Diabetes Federation

MCTSIB- Modified Clinical Test of Sensory Integration and Balance

NCD- Non-communicable Diseases

OR- Odds ratio

PTA- Pure tone average

SNR- Signal to Noise Ratio

WHO- World Health Organization

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Chapter 1: Introduction

Introduction: This chapter will provide the study background by presenting global and local prevalence reports of non-communicable diseases, with emphasis on the prevalence of diabetes in Africa and South Africa. Associations between diabetes, hearing loss and balance dysfunction will also be introduced to provide the study rationale.

Prevalence of non-communicable diseases

The prevalence of non-communicable diseases (NCDs) such as diabetes, is expected to surpass that of the current predominant communicable (infectious) diseases in the next 20 years (World Health Organization [WHO], 2012; Mendis & Chestnov, 2013). NCDs are recognised as a significant burden on the health systems and economies globally, particularly in developing nations (Boutayeb & Boutayeb, 2005). Collectively, NCDs are responsible for an estimated 38 million deaths per year globally and almost three quarters of the deaths occur in low and middle income countries (Mendis & Chestnov, 2013; WHO, 2015). African countries are expected to have the world's largest increase in NCDs morbidity and mortality over the next decade (Naik & Kaneda, 2015). In South Africa, the burden of NCDs currently accounts for up to 700 in every 100 000 deaths (Chopra et al., 2009; Distiller, 2004; Mathee, 2011; Mayosi et al., 2009, 2012).

Diabetes, which was the focus of this study, is one of the most prevalent non-communicable diseases and has become a worldwide epidemic (Frisina, Mapes, Kim & Frisina, 2006; Rheeder, 2006). It is a metabolic disorder characterized by chronic hyperglycaemia resulting from defects in insulin secretion, insulin action, or both (International Diabetes Federation, [IDF] 2015). There are three types of diabetes; Type 1 (insulin dependent), Type 2 (non-insulin dependent), and gestational diabetes which occurs during pregnancy (Tuomi, 2005; Drouin et al., 2009). Current estimates show that as of 2014, 422 million people above

18 years of age, have diabetes and this number is projected to reach 642 million by 2040 (WHO, 2016). It is also estimated that up to 192 million people worldwide are living with undiagnosed diabetes (IDF, 2015). Global mortality rates show that 5 million people between 20 and 79 years of age died from diabetes and diabetes related complications, compared to only 3.6 million that died from Human Immunodeficiency Virus (HIV), Tuberculosis (TB) and malaria combined in 2015 (IDF, 2015).

The African continent has up to 25 million people living with diabetes along with the highest proportion of undiagnosed adults under 60 years of age (WHO, 2016). The existence of diabetes in Africa was once a rare occurrence, however the prevalence is rapidly rising with numbers estimated to continue to increase by 110% in the region (Peer, Kengne, Motala & Mbanya, 2013). South Africa has one of the highest and fastest growing diabetes prevalence numbers in Africa with more than 2 million people living with diabetes (Peer et al., 2013).

Factors contributing to the increasing prevalence of diabetes in Africa include growing urbanization, increases in economic development, life expectancy and the worldwide rise in obesity (Levitt 2008; Peer et al., 2013). There is evidence that urbanization and economic development have been linked to the increase in diabetes prevalence owing to the change in lifestyle (more sedentary) and diet (more processed foods), hence diabetes was termed "the disease of opulence" (Sherif & Sampio, 2015; Azevedo & Alla, 2008). Africa is already burdened with communicable diseases, for example, HIV, Acquired Immunodeficiency Syndrome (AIDS) and high rates of TB (Lam & LeRoith, 2012; Levitt, 2008; Peer et al., 2013). Therefore, the rise of NCDs in developing regions add a significant burden to already under-resourced public health budgets (Mayosi et al., 2009).

Diabetes, hearing loss and balance dysfunction

The projected epidemiological trends of diabetes suggest that it is likely to be a significant contributor to the burden of disease globally, especially in developing countries. This is a major concern for hearing health care professionals because there is an emerging body of research evidence that associates diabetes with the risk of developing auditory and balance dysfunctions (Kakarlapudi, Sawyer, & Staecker, 2003; Panchu, 2008; Pemmaiah & Srinivas, 2011; Thimmasettaiah & Shankar, 2012). Thus an increase in the prevalence of diabetes may potentially lead to an increase in the burden of auditory and balance dysfunctions (Pemmaiah & Srinivas, 2011).

At present, research evidence linking diabetes with auditory and balance dysfunctions is not extensive, however the reported association has moved from uncertain to plausible (Jáuregui-Renaud, Sánchez, Olmos, & González-Barcena, 2009; Panchu, 2008; Pemmaiah & Srinivas, 2011; Thimmasettaiah & Shankar, 2012). This plausibility was based on pathological anatomical changes observed in post-mortem investigations of patients with diabetes revealing damage to the vasculature and neural system of the inner ear (Bainbridge, Hoffman, & Cowie, 2008; Botelho, Carvalho, & Silva, 2014; Frisina et al., 2006; Lisowska, Namysłowski, Morawski & Strojek, 2001). Abnormalities observed include thickening of capillaries in the stria vascularis, atrophy of the spiral ganglion, narrowing of the internal auditory artery and/or demyelination of the eighth cranial nerve (Bainbridge et al., 2008; Frisina et al., 2006; Lisowska et al., 2001). The inner ear and its associated neural systems have complex components and arrangement that requires glucose and high-energy for the intricate functioning involved in hearing and balance functioning (Frisina et al., 2006). Therefore, complications of hyperglycaemia can result in physiological disturbances that affect auditory and balance functions in patients with diabetes (Botelho et al., 2014; Drouin et al., 2009).

Hearing loss reported amongst patients with diabetes include sensorineural, conductive and mixed hearing losses (Pemmaiah & Srinivas, 2011). Several plausible explanations for the presence of sensorineural hearing loss in patients with diabetes as discussed by Akbar (2016) include: microangiopathy, neuropathy, and genetic mutation in mitochondrial DNA. Presence of mixed and conductive hearing losses in patients with diabetes may be explained by the increased susceptibility to middle and outer ear pathologies due to their compromised immune systems, especially in those with comorbidities (Thimmasettaiah & Shankar, 2012).

Hearing loss is already a major public health issue globally with adult-onset hearing loss ranked second highest contributor to years lost to disease (Olege & Okorot, 2005; Bagli, 2012). Hearing loss (regardless of the aetiology), can have a negative impact on an individual's physical, cognitive, behavioural, and social functions, as well as general health-related quality of life (Bagli, 2012; Mozaffari, Tajik, Ariaei, Ali-Ehyaii& Behnam, 2010; Danermark et al., 2010). For example, hearing loss has been associated with dementia as well as difficulties in employment acquisition and retention with up to 11% of adults changing their job due to their hearing loss (Lin et al., 2011; Shield, 2005). Therefore, the potential increase in hearing loss prevalence among patients with diabetes is a concern for hearing health professionals, the public health system as well as the economy (Shield, 2005).

Diabetes has also been associated with deterioration in balance function. The most common balance disorders reported in patients with diabetes include unsteady gait and increased risk for falls (Agrawal, Carey, Schubert & Minor, 2009). D'Silva, Lin, Staecker, Whitney and Kluding (2016) suggested that balance deficits are due to multi-organ structural, and functional changes due to diabetes related microvascular complications such as lower limb peripheral neuropathy and retinopathy.

Balance dysfunction can also have a negative impact on an individual because of its effect on quality of life. Activity restrictions, decreased social participation, and an increased need for sick leave may occur in up to 80% of affected patients visiting the doctor's office due to balance disorders (Agrawal et al., 2013; Sturnieks, St George, & Lord, 2008). In addition, balance dysfunctions can have social impacts which include disruption of social life, family difficulties, and challenges with travel (Agrawal et al., 2013). A study by Formiga et al. (2015) further demonstrates that balance dysfunction can result in falls and accidental injuries. According to the WHO (2012) factsheet, falls and unstable gait are the second leading cause of unintentional injuries worldwide.

Therefore, an increase in the burden of diabetes should be a concern for audiologists and it is against this backdrop that the current study was conducted to document auditory characteristics and balance function in patients with diabetes in South Africa as a country with one of the highest diabetes prevalence findings in Africa (Peer et al., 2013).

Chapter 2: Literature Review

Introduction: In this chapter, literature linking diabetes with hearing and balance dysfunction will be critically reviewed. Existing gaps in literature specific to diabetes related dysfunctions in hearing and balance will be highlighted and justification regarding the need for this study will also be presented.

Hearing loss and diabetes

There is some research evidence supporting the association of hearing loss in patients with diabetes (Ramma & Sebothoma, 2016; Thimmasettaiah & Shankar, 2012; Pemmaiah & Srinivas, 2011; Ologe & Okoro, 2005; Lisowska et al., 2001). In Poland, Lisowska, et al. (2001), in a cross-sectional study involving patients with Type 1 diabetes (n=42) reported peripheral and central disturbances of the auditory pathway which lead to subsequent sensorineural hearing loss. A similar study by Pemmaiah and Srinivas (2011) (n=110), conducted in India, reported a statistically significant correlation between hearing loss and diabetes. In Africa, Ologe and Okoro (2005) in their matched cross-sectional study (n=105) reported that middle-aged adults in Nigeria with Type 2 diabetes are more likely to have hearing loss than their nondiabetic compatriots of a similar age. In South Africa, a cross-sectional survey by Ramma and Sebothoma (2016) (n=2494) reported diabetes as one of the factors associated with hearing loss.

However, there are considerable regional differences in prevalence reports of hearing loss amongst patients with diabetes, with prevalence ranging between 13-78% (Kakarlapudi et al., 2003; Mozaffari et al., 2010; Bhaskar, Chalihadan, Vaswani & Rehaman, 2014). In the United States of America, Kakarlapudi et al. (2003) (n=12575) reported 13.1% hearing loss prevalence; in contrast, Mozaffari et al. (2010) (n=160) in Iran, reported a higher prevalence of 45%. Most recent, Srinivas, Shyamala and Shiva Kumar (2016) documented a 66%

prevalence of sensorineural hearing loss in their study (n=50). The highest prevalence was reported in India by Bhaskar et al., (2014) (n=107) with 78.2% prevalence of sensorineural hearing loss in their study. There are several factors that may help explain this variation in the prevalence of hearing loss reported in previous studies. These include differences in study designs, sample sizes, and hearing loss assessment methods carried out to determine prevalence.

In terms of study design, Kakarlapudi et al. (2003) utilised a retrospective medical folder review design and their low prevalence finding (13.1%) could have been due to common drawbacks associated with their study design, e.g. missing information in folders. In terms of sample size, it was noted that a study by Bhaskar et al. (2014) which had the smallest sample of participants with diabetes (n=57) of the studies reviewed for this study, reported the highest hearing loss prevalence (78.2%). With hearing loss assessments administered in previous studies, there were key factors identified that impacted prevalence reports. These included the classification of hearing loss in terms of hearing level norms (in dB HL), pure tone average (PTA) calculation, and the type of assessments used.

First, the classification of hearing loss in terms of the cut-off threshold used to distinguish between presence or absence of hearing loss may have influenced prevalence reports. Presence of hearing loss is determined using pure tone hearing thresholds (measured in decibels, dB HL) with 25 dB HL as the typical cut-off used to differentiate between presence or absence of hearing loss (in adults) (WHO, 2015). However, there are other cut-off thresholds that can be used to classify presence and degree of hearing loss, e.g. Clark's (1981) cut-off of 15 dB HL. The prevalence of hearing loss reported will therefore vary depending on which one of these two cut-offs is used. For instance, hearing loss prevalence of 70% was reported by

Agarwal et al., (2013) using a 15 dB HL as a cut-off whereas, Thimmasettaiah and Shankar, (2012), reported a lower hearing loss prevalence of 42% using 25 dB HL as a cut-off.

Second, the frequencies used to determine the PTA can also influence the prevalence of hearing loss reported. In most clinical settings, a PTA is derived using three frequencies that cover the low to mid ranges (0.5, 1 and 2 kHz), however diabetes related hearing loss first affects the high frequencies between 2 and 8 kHz, (Mozaffari et al., 2010; Pemmaiah & Srinivas, 2011). Thus, variable prevalence reporting may also be accounted for depending on the PTA calculation researchers utilise to classify hearing loss in patients with diabetes. In order to observe possible diabetes related hearing loss with PTA calculations that are inclusive of higher frequencies, some studies have added modified PTA calculations. For instance, Mitchell, Gopinath, McMahon, Wang, and Leeder (2009) and Mozaffari et al. (2010) used a PTA with frequencies (0.5, 1, 2 & 4 kHz) and Helzner et al. (2011) used a specific high frequency PTA (HF-PTA) (2, 4, & 8 kHz). The impact of the different PTA calculations on hearing loss prevalence is demonstrated by Samelli et al. (2017) in their study with their findings showing a higher prevalence of hearing loss within the higher frequencies than the lower frequencies.

Third, the type of assessments used to establish diabetes related auditory dysfunction can also impact on the prevalence findings reported. Most studies that have investigated the presence of auditory abnormalities in diabetes patients used pure tone audiometry assessment in the standard frequency range (250-8000 Hz) (Panchu, 2008; Pemmaiah & Srinivas, 2011;). Pure tone audiometry may not be sufficiently sensitive to detect diabetes related damage therefore, the addition of otoacoustic emissions (OAEs) as part of the test battery was recommended to cross check of findings with an objective and sensitive assessment of the diabetes related damage to the auditory pathway (Botelho et al., 2014). OAEs assess cochlear

function, specifically the outer hair cells, with objective monitoring of dynamic changes in cochlea responsiveness before functional and significant hearing loss occur (Hamed & El-attar, 2010). While OAEs do not test hearing acuity as such, the assessments give valuable information about the site of lesion by differentiating between sensory abnormalities, that may be due to diabetic microvascular damage to the cochlea (Sanju & Kumar, 2015), and a neural abnormality. Therefore, considering the variations in the current literature as identified above, the current study design was selected to avoid the methodological shortfalls of previous studies.

Tinnitus and diabetes

Tinnitus refers to a perception or awareness of sound in the ears in the presence or absence of an external source (Negrila-Mezei, Enache & Sarafoleanu, 2011). McCombe and colleagues (2001) reported that up to a third of the normal adult population experience tinnitus in their lifetime. However, only one in ten of those affected by tinnitus will report an impact to their quality of life and negatively impact psychosocial well-being (Kenny, 2014; Negrila-Mezei et al., 2011).

There is currently no known single cause for tinnitus, however many possible aetiologies have been suggested including but not limited to: hearing loss, metabolic diseases, inner ear hair cell loss, stress, head injury, and ototoxic medication (Negrila-Mezei et al., 2011; McCombe et al., 2001, Gopinath et al., 2009). Akkuzu, Yilmaz, Cakmak and Ozluoglu (2004) describe that tinnitus incidence rises with age. With tinnitus prevalence, adults 30 years and above show a 7% prevalence whilst those 80 years and above showing up to 21% prevalence (Akkuzu et al., 2004). Although tinnitus affects many secondarily, it can be a clinical problem on its own for some.

Gibrin, Melo and Marchior (2012) reported an increased risk of tinnitus occurrence in patients with diabetes. Prevalence of tinnitus in patients with diabetes in their study was found

to be 43% (n= 519) (Gibrin et al., 2012). Furthermore, findings from their study showed a twofold increased risk of tinnitus in patients with both diabetes and hypertension (Gibrin et al., 2012). Akkuzu et al. (2004) explained the presence of tinnitus in patients with diabetes could be due to the observed macro-vascular damage in the inner ear of these patients as well as medication used to treat diabetes. Lacking in literature reviewed, are studies investigating the presence of tinnitus along with hearing loss in the same sample of patients with diabetes.

Balance dysfunction and diabetes

Balance is the perception of orientation and postural stability that depends on the integration of visual, somatosensory and vestibular information, with motor responses (Salsabili, Bahrpeyma, Forogh, & Rajabali, 2011). Yim-Chiplis and Talbot (2000) stated that the ability to maintain balance is the foundation for mobility and overall functional independence throughout the lifespan. A balance dysfunction is a disturbance with the integration of visual, somatosensory, and vestibular information that causes an individual to feel unsteady, having a sensation of movement, spinning, or floating (Walley, Anderson, Pippen & Maitland, 2014). Balance dysfunction can be debilitating and may lead to catastrophic outcomes such as falls (Agrawal et al., 2009). Fall risk is the probability and or potential threat for an individual to have a fall influenced by certain intrinsic and extrinsic factors (Cheng & Luo, 2015).

Balance dysfunctions resulting in falls are the third leading cause of unintentional deaths in homes and communities, and the leading cause of unintentional injuries (Maurer, Burcham & Cheng, 2005). An individual's chance of falling is described as fall risk, which is derived from a combination of extrinsic and intrinsic factors (Cheng & Luo, 2015). The more intrinsic factors someone has, and these include poor balance, diabetes, neuropathies, and arthritis, the greater the risk of falling (Salsabili et al., 2011; Walley et al., 2014). Maurer and

colleagues (2005) indicated that there are major health and economic burdens that come with balance dysfunction resulting in falls and suggest prevention and early diagnosis can relieve both the affected patient population and the public health system.

A systematic review by D'Silva et al. (2016) reported on numerous studies that present evidence of the link between diabetes and balance dysfunction (Gawron et al., 2002; Agrawal et al., 2010; Salsabili et al., 2011; Yoda et al., 2011). Agrawal et al. (2010) reported balance dysfunction to be 70% higher in people with diabetes than those without. Similar findings were reported by Juregui-Renaud and colleagues (2009) in their cross-sectional matched groups survey (n=202) in which they established that patients with diabetes showed a higher frequency of dizziness (49%); instability when changing posture (43%), and instability when walking on uneven surfaces (38%). Maurer, Burcham and Cheng (2005), using a prospective cohort of patients with diabetes (n=139) found that 78% of their study participants had balance disorders which resulted in falls.

Although there is evidence in literature for balance dysfunction leading to fall risk in patients with diabetes, there were several shortcomings identified in a review of the literature. Some of the previous studies had several methodological limitations that make it difficult to associate the balance dysfunction identified in these patients to diabetes. Some of the noteworthy methodological limitations include use of elderly participants; use of subjective/self-rating questionnaires, use of inappropriate assessment procedures as well as lack of interrogation of how multiple sensory deficits that are highly prevalent in these patients impact their balance function and susceptibility to falls.

First, in terms of the age group of participants in previous studies, most studies investigating balance dysfunction in patients with diabetes focused on the elderly population which is a limitation as this population may already be predisposed to fall risk because of age

related deterioration (Maurer et al., 2005; Walley et al., 2014; Formiga et al., 2015; Wilson, Garner & Loprinzi, 2016; Wrisley & Kumar, 2016).

The second and third drawbacks in previous balance studies with patients diagnosed with diabetes are in relation to the assessments that investigators used. In a systematic review by D'Silva et al. (2016), there were studies that utilized subjective patient questionnaires as assessments to determine balance dysfunction. This is a limitation as subjective assessments are open to be influenced by the patient's understanding, interpretation and weighting of their symptoms which may have been avoided by using objective clinician assessments. Also, other studies like that of Agrawal and colleagues (2010) with the National Health and Nutrition Examination Survey in America, used the modified Romberg test to assume vestibular function and fall risk in patients with diabetes. This is a limitation because according to Jacobson et al. (2011) the Romberg test has poor sensitivity and specificity to determine vestibular dysfunction.

Finally, Wilson et al. (2016) and Walley et al. (2014), noted the lack of research evidence in terms of how multiple sensory impairments affect balance and fall risk especially in patients with diabetes. This is important as hearing and vision deficits influence balance and increase fall risk (Walley et al., 2014). Therefore, research focusing on screening and assessment of balance in terms of predicting fall risk among patients with diabetes is needed to bridge the gap in literature (D'Silva et al., 2016; Ozel, Ozkiris, Gencer, & Saydam, 2014).

Diabetes related versus comorbidity-related dysfunctions

The challenge in establishing an association between diabetes with auditory and balance dysfunction has been that most of diabetes comorbidities are also risk factors for both hearing loss and balance dysfunction on their own (Chang et al., 2011; Chao, 2004). For instance, hypertension, peripheral neuropathy, retinopathy, and age related deterioration which are

common diabetes co-morbidities are also reported in literature as risk factors for acquiring hearing loss and balance dysfunction (Bainbridge et al, 2008; Chang et al., 2011).

Specific to hypertension, adverse synergistic effects were observed with microvascular damage in the inner ear that is similar to diabetes related damage (Chang et al., 2011; Chao, 2004; Kakarlapudi et al, 2003). This is important to note because the prevalence of hypertension in patients with diabetes varies between 10% and 80%, (Kakarlapudi et al., 2003). Unfortunately, most of the previous studies did not investigate whether the presence of hypertension increased the risk for auditory and balance dysfunction in patients with diabetes.

Specific to peripheral neuropathy and retinopathy, both increase a patient's susceptibility to balance dysfunction (Rubenstein, 2006, D'Silva et al., 2016). Agrawal, Ward and Minor (2013) elaborate that balance dysfunctions in patients with peripheral neuropathy and/or retinopathy include postural instability, gait disturbances, syncope, and dizziness. Existing literature also indicates that peripheral neuropathy and retinopathy impact the sensory inputs from vision and gravity from lower limbs, which are both necessary for postural stability and balance (D'Silva et al., 2016; Agrawal et al., 2010). Therefore, balance assessments in patients with both diabetes and retinopathy or peripheral neuropathy, should consider the added impact of the comorbidities to the patient's balance function. Rubenstein (2006) recommended that vision and neuropathy screening be added with balance assessments in at risk populations such as patients with diabetes. However, most studies that investigated balance dysfunction in patients with diabetes did not screen for retinopathy and peripheral neuropathy to document the assumed increase in risk.

Other factors (besides diabetes) have also been identified in previous studies to explain the presence and or exacerbation of auditory and balance dysfunction in people with diabetes. These include family history of hearing loss, smoking, exposure to ototoxic drugs, cancers,

other cardiovascular diseases, occupational noise exposure, head injuries as well as alcohol, and age related deterioration (Pemmaiah & Srinivas, 2011). However, these factors are not specific to diabetes and can affect even those without diabetes. For example, there is a consensus regarding the negative impact of increasing age to hearing and balance function, independent of diabetes presence (Kakarlapudi et al., 2003; Pemmaiah & Srinivas, 2011; Thimmasettaiah & Shankar, 2012; Sturnieks et al., 2008).

Study rationale

There are several studies that investigated the impact of the communicable diseases such as HIV/AIDS and TB on audiological and balance functions in developing countries like South Africa (Flower, 1991; Harris et al., 2012; Khoza & Ross, 2002; Khoza-Shangase, 2010a, 2010b). However, not much research has focused on NCDs and their impact on audiological and balance functioning. Diabetes is one of the most prevalent NCDs, and projections show that its prevalence is expected to increase. South Africa has the second highest diabetes prevalence in the continent with over 2 million people diagnosed with diabetes (WHO, 2016). What is of concern to audiologists is the emerging body of research that associates diabetes with auditory and balance dysfunctions. However, as discussed in the literature review above, there is currently lack of conclusive research literature evidence that confirms a clear association between diabetes, auditory and balance dysfunctions. There is also limited research from developing countries such as South Africa investigating this association between diabetes and dysfunctions in auditory and balance systems, hence this study.

It is anticipated that outcomes of the study will be used to obtain information to answer some of the unanswered questions as well as inform health promotion with respect to the need for auditory and balance screening in patients with diabetes and highlight the role of audiologists in diabetes care.

Chapter 3: Methodology

Introduction: This chapter will outline the aims, objectives, methodological aspects as well as ethical considerations for the study. Last, the chapter will outline how the data obtained in the study was analysed.

Aims and objectives

The aim of this study was to describe the audiological characteristics and balance function in patients with diabetes between 18-55 years of age and compare findings with a group of individuals without a diabetes diagnosis (control group). The objectives of the study were to:

1. Determine the proportion of patients diagnosed with diabetes who:
    a. Present with abnormal audiometric findings: as determined through hearing levels using pure tone audiometry and outer hair cell function using distortion product otoacoustic emissions (DPOAE)
    b. Reported tinnitus: as determined through participant self-report during case history. The presence or absence of tinnitus was based on participants' subjective reports of any ringing, whooshing, thumping sound in the ear without the presence of an external sound source at any time (Negrila-Mezei et al., 2011).
    c. Present with abnormalities in balance function: as determined by screening for fall risk through
        i. Screening static balance: postural stability screened with the Modified Clinical Test of Sensory Integrationof Balance (MCTSIB).
        ii. Screening dynamic balance: fall risk screened with the Dynamic Gait Index (DGI).

2. Describe the characteristics of hearing loss, tinnitus and balance function in patients with diabetes
3. Determine the associations between the hearing loss, tinnitus and balance function with the following characteristics of diabetes mellitus:
    a. Type (type I, type II)
    b. Duration of disease (in years)
    c. Glycemic status (last reading in g/mol as determined by the doctor and documented in patient file)
    d. Demographics of age and gender.
    e. Co-morbidities:
        i. Hypertension: presence or absence as reported in patient files
        ii. Peripheral neuropathy: determined through screening with the diabetic neuropathy symptoms (DNS) score.
        iii. Retinopathy: determined through screening with a visual screening chart.

Research design

This study employed an observational cross-sectional matched groups design. The study design was an observational cross-sectional design as the variables of interest were measured at one point in time and the researcher had no influence and/or intevention to the study variables (Hartung & Touchette, 2009; Morrow, 2010). Observational cross-sectional designs are best suited to determine prevalence of a variable of interest, which in this study were hearing loss and balance function (Hartung & Touchette, 2009; Mann, 2003; Morrow, 2010). The drawback of a cross-sectional study design include the inability to determine cause and effect, however, with a cross-sectional design, relationships between variables can be determined using this type of design. (Hartung & Touchette, 2009). Matched group designs are used in research to ensure comparability as well as reducing variability and systematic

differences due confounding variables (Song & Chung, 2010). The two groups used in this study comprised participants diagnosed with diabetes (Cohort) and another group consisting of participants without a diagnosis of diabetes (Control). Participants in both groups were matched for age and gender to allow for comparison between the two groups. Advantages of a matched group design include eliminating the influence of age and gender which are often the strong confounding variables (Song & Chung, 2010).

Sampling method

Participants in the cohort group were purposively sampled to ensure that only those who meet the eligibility criteria participate. A convenience sampling strategy was used to select participants for the control group as they readily made themselves available to the researcher (Mann, 2003). The non-probability sampling frames that were used for both participant groups are advantageous in that less time constraints, and overall fewer costs are implied (Palys, 2008). A major disadvantage of non-probability sampling is the inability to generalize findings compared to probability sampling (Kar & Ramalingam, 2013).

Sample Size

The sample size required for this study was determined using a G-Power analysis calculator (Faul, Erdfelder, Buchner & Lang, 2009). With a power of 0.95 and an error probability of 0.05, the sample size required for this study was 222 individuals; 111 participants per group (Faul et al, 2009). (see Table 1).

Previous studies had sample sizes ranging between 80 and 220 participants and were determined to have sufficient power (Mozaffari et al., 2010; Pemmaiah & Srinivas, 2011). Therefore, the targeted sample size for the study was 222 participants.

Table 1

Sample size calculation.

Analysis	Required sample size	
Input	Tails	One
	Error probability	0.05
	Power	0.95
Output	Non-centrality parameter	4.6857
	Critical t	2.3434
	Df	220
	Total Sample size	222
	Actual Power	0.9901086

All participants (cohort and control) were selected to participate in this study based on the following inclusion and exclusion criteria:

Inclusion criteria:

- Clinically confirmed diagnosis of diabetes of either type (only for cohort group)
- Above the age of 18 and below 55 years of age. The upper limit of 55 years was selected in order to avoid impact of age related deterioration (> 55 years) to both the auditory and balance functions (Bagli, 2012). The lower limit of 18 years was selected in order to target only adults to participate in the study and avoid special consent and assent which is required for individuals < 18 years old. A similar age range was used in a study by Panchu (2008) for the same rationale.

Exclusion criteria (established through case history):

- No exposure to loud recreational or occupational noise (24 hours prior testing) to avoid a temporary threshold shift (Franz & Phillips, 2001).

- No prior use of ototoxic drugs to avoid ototoxicity and vestibulotoxicity that might result in either hearing or balance dysfunction (Akinpelu, Ibrahim, Waissbluth & Daniel, 2014). History of all medication taken was documented in the patient files.
- No history of head injury, radiotherapy to the head or ear surgery as either may affect hearing or balance functions (Low, Toh, Wee, Fook-Chongand & Wang, 2006).
- No clinical diagnoses or reports of neurological impairments that can affect balance such as multiple sclerosis, cerebrovascular accidents (ischemic and hemorrhagic strokes), Parkinson's disease and ataxia (Neuhauser et al, 2005).

Recruitment of participants

Cohort Group:

Patients attending a Primary Health Care Clinic at Rethabile Health Centre in Polokwane were invited to participate in this study by the researcher using various methods. Posters and notices with information about the study were placed on notice boards at strategic points in the facility e.g. patient waiting rooms, to invite participants. The notices and posters were written in English and were translated into Northern Sotho (a common language in the study area) in order for the posters to be linguistically accessible to a broad range of people (See Appendix A, Appendix B and Appendix C). Clinical staff seeing chronic patients at the chronic illnesses section at the facility also assisted in identifying potential participants based on eligibility criteria of the study.

Control Group:

Volunteers from staff of the primary health care centre and nearby provincial hospital as well as members of the general public were invited to participate in the study through an advertisement in the staff newsletter and notice boards (See Appendix A, Appendix B and Appendix C). Notices of the study (in English and Sesotho) were also placed in the local free magazine to attract the general public that may not be in or around the clinic.

Participants

Participants in the cohort group were patients attending a Primary Health Care clinic in Polokwane, Limpopo. The participants for the control group were volunteers working or residing in the area around the Primary Health Care clinic in Capricon health district, Polokwane. There were 192 participants in this study; 110 in the cohort and 82 in the control group. There were 40 (13 for the cohort and 27 for the control) potential participants who were excluded due to various reasons e.g. age, prior exposure to occupational noise and history of head injuries. For some of the audiolgical assessment reporting, individual ears were used as sample size and this was done to ensure accurate reporting as some findings were in one and not both ears.

Study context

The current study was conducted in Polokwane, the provincial capital of Limpopo province. This province has the highest poverty in comparison to other South African provinces, with 78.9% of the population living below the national poverty line (Statistics South Africa, 2013). In terms of language, Sesotho is spoken by most of Limpopo's population. Most access health care at public health facilities similar to the data collection site which is located centrally in Polokwane, the province's capital. The data collection site, Rethabile Health Centre was ideal for accessing partipants as it is one of the biggest primary health care clinics that serves residents of the Capricon health district. Also, the facility was selected as it has a large chronic disease clinic managing patients with various diseases with diabetes as one of them. Limpopo province accounts for 2.8% of the national prevalence numbers in of people aged 25 years and older, after Gauteng and North West in ranking (Statistics South Africa, 2011). Furthermore, the incidence of diabetes in Limpop province is reported at 2.5 cases per 1000 population (Massyn et al., 2016).

Data Collection

Data collection tools:

a) Data abstraction sheet- The data abstraction sheet was developed by the researcher specifically for this study based on information that was needed. Information captured in the abstraction sheet included participant age & gender, diabetes characteristics (cohort only) and other relevant medical information. (See Appendix D).

b) Audiological assessment tools- See Appendix E with all the audiological tests administered. Audiological testing was administered in a soundproof booth with the following equipment:

    a. *Welch Allyn Otoscope:* to examine the ear canal and the tympanic membrane

    b. *GSI 61 clinical audiometer:* used to determine participants' pure tone hearing thresholds with pure tone audiometry assessments.

    c. *GSI Audera version 2.7:* used to administer diagnostic otoacoustic emissions assessments.

c) Charted audiogram- Audiological information of the patients was recorded onto a charted audiogram (See Appendix F).

d) Balance assessment tools- Balance function information was obtained from two main assessments, the Modified Clinical Test of Sensory Integration of Balance (MCTSIB) and the Dynamic Gait Index (DGI) (Shumway-Cook & Horak, 1986; Shumway-Cook & Woollacott, 1995). Tools for the MCTSIB were as follows; *a Temper® foam* (also called T-foam 4 inches thick, medium density T41 firmness rating) and *a stopwatch*. Tools for the DGI were as follows; *a shoe box, measuring tape, gait belt, cones* (traffic safety cones) and a 6 meter distance measured on the floor with tape.

e) Balance assessment score sheets- Scoring for both balance tests was recorded on the respective scoring sheets. (See Appendix G and Appendix H).

f) Diabetic neuropathy symptoms score (DNS)- Screening for peripheral neuropathy specifically of the lower limbs was carried out using this tool (Meijer et al., 2003). (See Appendix I).

g) Visual screening chart- Screening for visual acuity was carried out using this tool (Pandit, 1994). (See Appendix J).

Data Collection Procedure

1. Ethics approval was first sought and obtained from the Faculty of Health Sciences Human Research Ethics Committee, University of Cape Town (HREC/Ref:134/2015) (See Appendix K).
2. Thereafter permission to conduct the study was sought and obtained from the Limpopo Department of Health (See Appendix L and Appendix M).
3. Recruitment of participants followed after ethical clearance and permission from relevant authorities was granted. Recruitment of participants was done mainly via notices that were placed at the clinic notice boards. Patients in the waiting room were also approached in person, informed about the study and given the written study information and then invited to participate in this study. (See Appendix A and Appendix B).
4. Pilot study: a pilot trial was conducted on the first 10 participants with the aim of clarifying the study process, resource needs and data management for the main study (Kar & Ramalingam, 2013). The outcome of the pilot study did not indicate a need to modify data collection protocol for the main study. Data collected from the participants in the pilot study were included in the main study data analysis. Data collection for the main study commenced shortly after the completion of the pilot study.
5. On the day of data collection, participants who accepted the invitation to participate in this study were:

a. Given the study information sheet (See Appendix O).

b. Given consent form to sign as an indication of their willingness to participate in this study. (See Appendix P).

c. Participants were then assigned into the cohort and or cohort group and assigned study numbers.

6. Thereafter participants were taken into the audiology room for the case history interview.

    a. Case history interview with participants of both groups included questions to ascertain participant medical and social information as needed for the study (See Appendix D).

    b. Recording of medical details on data abstraction sheet was done. For participants in the cohort group, information on the diabetes characteristics (type, duration and glycemic status) was recorded from their medical folders. All the diabetes characteristics information was pre-recorded into the medical folders by the nurses that conduct the monthly chronic clinic to monitor the patients.

7. After case history, the participants underwent audiological and balance assessments. See Appendix E with all the information about data collection tests, test instructions and norms thereof. Testing protocol was as follows:

    a. Audiological assessments:

        i. Otoscopy

        ii. Pure Tone Audiometry. The Modified Hughson-Westlake procedure (Carhart & Jerger, 1959) was used to establish the pure tone thresholds. The hearing threshold for any given frequency was defined as the lowest

intensity level in dB HL where a participant hears a sound 50% of the time (Carhart & Jerger, 1959).

iii. Diagnostic Otoacoustic emissions

b. Prior to the balance assessment, visual acuity and lower-limb neuropathy screening assessments were carried out. See Appendix I and Appendix J.

c. Balance assessment proceeded as follows:

i. Modified Clinical Test Of Sensory Integration

ii. Dynamic Gait Index

8. After all testing, the researcher reviewed the results and counselled participants on findings. In instances where abnormalities were detected, the researcher made the appropriate referrals for the participants at their local/closest healthcare facility.

Data collection personnel

Data collection was conducted and managed by the researcher who is a qualified audiologist. The researcher administered the audiological and balance assessments for all the participants in both groups. The visual acuity and lower-limb neuropathy screening assessments were administered by the researcher as they are screening tests. The researcher has consulted both the optometrist and internal medicine doctors for training in the short assessment methods. All the data collected was collated by the researcher into an Excel sheet.

Reliability and Validity

Reliability refers to the consistency of measurements and can be assumed when the same result can be obtained should the same methodology be utilized (Odom & Morrow, 2006). Validity refers to the extent to which an empirical measure adequately reflects the meaning of the concept under investigation (Odom & Morrow, 2006). Validity is achieved when a study measures that which it intended to measure. (Odom & Morrow, 2006). In this study there were a variety of instruments used to quantify the variables of interest and their validity and

reliability is discussed in Table 2. In capturing of all information, intra-rater reliability was calculated in 10% of the sample. Intra-rater reliability calculation was carried out by re-entering data in and recorded onto a separate spreadsheet to compare. The process of re-entering of data was carried out in a blinded manner (no participant names) by using participant's research numbers. A comparison of the two separate records was undertaken with expectation to attain > 90% reliability using the following formula: (Agreement)/ (Agreement + Disagreement) x 100 (de Vet, Terwee, Knol, & Bouter, 2006). A 94% reliability outcome was attained.

Table 2

Reliability and Validity

Test	Reliability & Validity
Pure tone audiometry	All assessments administered by the researcher in this study were routine clinical tests with established reliability and validity in clinical practice. All testing equipment complied with the South African National Standard (10154-1/2 10182) and were calibrated for the years 2014-2015 to ensure valid results. The researcher also carried out daily biologic checks of the equipment to ensure consistent function and instrument validity before assessing study participants. To ensure reliable auditory thresholds were recorded from participants, researcher retested threshold at 1 kHz in the best ear and reliable auditory thresholds were assumed when the retested threshold was within 5-10 dB of the previously obtained threshold. If reliable auditory thresholds were not obtained, the participant would be retested in both ears. For participants that presented with wax prior pure tone audiometry, wax was removed in order to avoid impact of wax on hearing level findings.
DPOAE	DPOAE assessments have been documented by Hall and Swanepoel (2010) as a sensitive and site specific measure of cochlear function. OAE assessments are also considered reliable as they are an objective measure and have minimised subjective feedback with automated computer systems (Hall & Swanepoel, 2010). To ensure reliability, the researcher administered OAEs in a quiet sound proof room to avoid interference from external noise. OAEs measurements were repeated twice; [first test was done, ear probe was taken out and replaced back in the canal, then a retest was done] to take the best response as the participant's OAE.

DGI &MCTSIB	According to Wrisley and Kumar (2010) the DGI as an assessment tool can predict dynamic balance disorders with a good inter-rater reliability. Furthermore, Wrisley and Kumar (2010) reported the DGI as a tool to have adequate discriminative ability with 0.84, Sensitivity and 0.89, Specificity to identify dynamic balance and gait impairments as well as quantify fall risk. The MCTSIB according to Yim-Chiplis and Tablot, (2000) is a reliable tool to assess balance function in terms of sensory integration and dynamic balance. Cohen et al., (2014) in their study established the efficacy of the MCTSIB as a screening assessment for balance function. The researcher administered both the DGI and MCTSIB according to the tool instructions to ensure instrument validity. To ensure test-retest reliability, a subset (10%) of participants were tested twice and a correlation coefficient (r) > 0.7 was accepted for a good repeatability of the instrument.
DNS	The Diabetic Neuropathy Symptom Score has been evaluated in 73 diabetic studies, it was found to have a reliability of 0.64, a sensitivity of 79% and a specificity of 78% in screening for the presence of lower limb neuropathy in a diabetic population (Dias, Nienov, Parisi, & Schmid, 2015). To ensure appropriate screening was administered with the DNS, the researcher was trained by the internal medicine doctor at the facility to carry out the screening assessment.
Snellen E chart	The Snellen E chart has been used as a vision screener in various studies and was found to be a reliable and most common measure for visual acuity screening (Pandit, 1994). The researcher consulted with an optometrist on how to administer the visual screening chart to ensure the appropriate protocol is followed for valid results. The Snellen E chart is a good measure for illiterate persons as well, as it can be administered similar to the tumbling E chart where the participant only indicates the direction of the 'E'.

Ethical considerations

This study adhered to the ethical principles outlined in the Declaration of Helsinki, (2013) throughout its completion to ensure transparency, integrity of data and respect for participant dignity as well as their physical well-being (Krleža-Jerić & Lemmens, 2009; World Medical Association, 2013). Furthermore the Belmont principles (1979) were used in the study to ensure adherence to ethical guidelines regarding human research to ensure respect for persons, beneficence and justice (Irving, 2013).

Autonomy: Informed Consent

Autonomy of the participants was ensured through informed consent. The participants were given adequate information (in the language that they understand through bilingual [English & Sotho] oral presentations in the waiting area) to enable them to make an informed decision to participate voluntarily in the study. Consent forms for the participants included a separate information sheet about the details of the study (See Appendix N) and participants were asked to sign the informed consent form prior to commencing with the study to indicate their willingness to volunteer to participate in the study which was in line with the Declaration of Helsinki, (2013) (See Appendix O and Appendix P) (Irving, 2013; World Medical Association, 2013). For those that could not read, the consent and information sheet was read to them by the researcher and they made an X to sign the consent slip. Participants were made aware that they have the right to withdraw from the study at any time (without negative consequences to them).

Beneficence

The principle of beneficence entails that researchers should act in the best interest of the participants at all times (Irving, 2013; World Medical Organization, 1996). There were no direct benefits for the participants in this study; however when any abnormalities were detected, participants were counselled and referred to the provincial hospital nearby with all necessary resources for further management. In the interest of not unduly burdening the audiological services

in the Capricon district health, referrals were made to all districts in the province within access and choice of the participants to equally disperse potential patient load.

Nonmaleficence

The principle of nonmaleficence (absence of harm to the research participant) in line with the Belmont beneficence principle was used in this study mainly to protect patients by minimising risks in the study (Irving, 2013; Rhodes, 2010; World Medical Organization, 1996). There were no significant direct risks identified for the participants in this study. In terms of assessment for balance, risk of falls was mitigated by using a gait belt throughout assessment.

Justice

Justice is the act of distributing the burdens or benefits of a society fairly amongst the people involved (Irving, 2013; Rhodes, 2010). All the patients that consented to the study and met the inclusion criteria were part in the study. The sampling method allowed for all the available participants to join fairly and equally in line with the Belmont principle of justice (Irving, 2013; Rhodes, 2010). Furthermore, according to distributive justice principles, the possible identified risks and gains identified applied equally to participants and the benefits/gains of the study were used to enhance service delivery in the same community (Irving, 2013).

Anonymity

In order to ensure participant's information was available only to the researcher and when participants signed informed consent to join the study, thereafter all medical information was recorded along the participants' assigned study number. Furthermore, all data collected was kept in a excel spreadsheet on the data collection computer that was always password protected and only accessible to the researcher. Last, in terms of publication of results, no patient names or identifying data will be included, only assessment findings which patients consented to on signed consent forms.

Data Analysis

In this study, data analysis was done using both descriptive and inferential statistics (Coolican, 2004). (See Table 3).

Table 3

Methods for descriptive statistical analysis

Variables		Statistical Tests for Analysis
Hearing Loss:	Prevalence & type Severity (Using cPTA & HF-PTA calculations)	Proportions (%), Frequency tables
Tinnitus:	Prevalence & type	Proportions (%), Frequency tables
OAE:	Normal or not. Norms: A DPOAE was regarded as present with a signal to noise ratio > 6 dB as well as absolute DPOAE level > 0 dB (Botelho et al., 2014).	Proportions (%), Frequency tables
Balance:	DGI MCTSIB	Proportions (%), Frequency tables
Diabetes:	Type, Duration, Control	Proportions (%), Frequency table Median, Range Mean, Standard Deviation
Patient Factors:	Age, Gender	Proportions (%), Frequency tables
Co-morbidities:	Prevalence	Proportions (%), Frequency tables

Inferential Statistics:

- The Pearson's correlation coefficient was used to determine the strength of associations between the presence of hearing loss, tinnitus and balance dysfunction with characteristics of diabetes (type, control and duration), patient specific factors (age, gender) and presence of comorbidities (hypertension, etc). Pearson's correlation coefficient were interpreted as follows:
    - A value of 1 indicated a total positive linear correlation, 0 showed no linear correlation, and −1 indicated a negative linear correlation.
- The logistic regression model was used to determine odds ratios. Odds ratios obtained showed the relative risks of hearing loss, tinnitus and balance disorders with diabetic patients. Interpretation of odds ratio findings were as follows:
    - An odds ratio of exactly 1 indicated that exposure to diabetes does not affect the odds of hearing loss, for example.
    - An odds ratio of more than 1 means that there is a higher odds of hearing loss happening with exposure to diabetes.
    - An odds ratio is less than 1 is associated with lower odds.
- Independent T-tests were also used to determine significance of differences in prevalences between the cohort and control group data. In this study, the significance level (alpha) was taken at 0.05 (Coolican, 2004).

Chapter 4: Results

Introduction: This chapter will present the findings according to the study objectives. The chapter starts with presentation of demographic data; sample size, gender and age distribution as well as diabetes and other comorbidities (cohort group only). Thereafter, the results regarding auditory and balance characteristics of the participants will be presented

Participant description

A total of 232 individuals consented to participate in this study; 123 in the cohort and 109 in the control group. A total of 40 of the potential participants; 13 in the cohort group and 27 in the control group, could not be included in this study because they did not meet the inclusion criteria for the study. Most of the exclusions were either due age or prior exposure to occupational noise. The resultant study sample was a total of 192 participants; 110 in the cohort and 82 in the control arms of the study respectively. There were similar proportions of males and females in each arm of the study and majority of the participants were ≤ 49 years old with a range of 20 to 55 years; (cohort; M =46, SD =8.24, control; M =43, SD =9.94). (see Table 4). The difference in distribution of the ages between the cohort and control groups was not statistically significant across all age bands.

Table 4

Participant demographics.

Description	**Control (n =110) [n, (%)]**	**Cohort (n = 82) [n(%)]**	**Statistical Significance (α = 0.05)**
Gender (%)			
Males	53(48%)	41(50%)	$t(175) = -0.58$, $p = .56$
Females	57(52%)	41(50%)	
Age (years)			
20-30 years	13(12%)	4(5%)	$t(6) = -0.75$, $p = .48$
31-40 years	25(23%)	13(16%)	$t(34) = 1.51$, $p = .14$
41-49 years	27(24%)	25(30%)	$t(37) = -0.80$, $p = .42$
>49 years	45(41%)	40(49%)	$t(60) = 1.37$, $p = .17$

Cohort description: Diabetes & Comorbidities

The cohort group was the group of participants with the main variable of interest for the study, diabetes. Majority (92%) of the participants presented with type II diabetes and most had an uncontrolled glycemic status (see Figure 1 and 2). The duration of disease ranged from a month post diagnosis to 33 years and most were living with diabetes for less than 5 years.

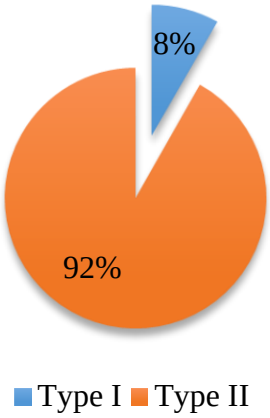

Figure 1: Diabetes Type Distribution.

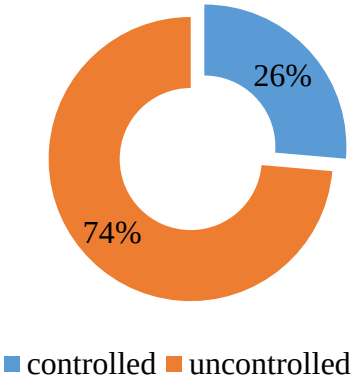

Figure 2: Diabetes Control: Glycemic Status

In terms of co-morbidities, more than half of the participants in the cohort group had a comorbidity with their diabetes (see Table 5). The comorbidity with the highest prevalence was hypertension.

Table 5

Co-morbidities.

Comorbidity	Number of participants (n)	Percentage (%)
Hypertension	62	56%
Positive for Diabetic Neuropathy	56	51%
Failed the vision screener	62	56%

*Co-morbidities only investigated in the cohort (diabetic) group.

Auditory Status:

The hearing status findings were recorded per ear to enable accurate recording of asymmetrical unilateral findings. Most participants had symmetrical hearing in both groups, regardless of hearing loss presence, cohort (80%) and control (71%) .

Hearing loss: prevalence

The prevalence of hearing loss was higher in the cohort than the control group with both cPTA and HF-PTA (see Table 6). The difference in the hearing loss prevalence between the groups was found to be statistically significant with both cPTA, $t(376) = -3.06$, $p = .002$ and HF-PTA $t(377) = -7.47$, $p < .001$.

Table 6

Prevalence of hearing loss.

Description	**Cohort (n)**	**Control (n)**
Total sample size	110	82
Total number of ears in sample	220	164
Number of ears with normal hearing	**[n(%)]**	**[n(%)]**
cPTA (Conventional)	138(63%)	124(76%)
HF-PTA (high frequency)	98(45%)	132(80%)
Number of ears with hearing loss	**[n(%)]**	**[n(%)]**
cPTA (Conventional)	82(37%)	40(24%)
HF-PTA (high frequency)	122(55%)	32(20%)

For the purposes of describing more information on hearing loss findings, the HF-PTA will be used to define hearing loss presence in the remainder of this report.

In terms of co-morbidities and hearing loss, it was found that in those with diabetes and hypertension, there was more than double the amount of ears with sensorineural hearing loss when compared to those without hypertension (54% and 25% respectively). In those with diabetes and possible diabetic peripheral neuropathy, there were more ears with sensorineural hearing loss compared to those without neuropathy (see figure 3).

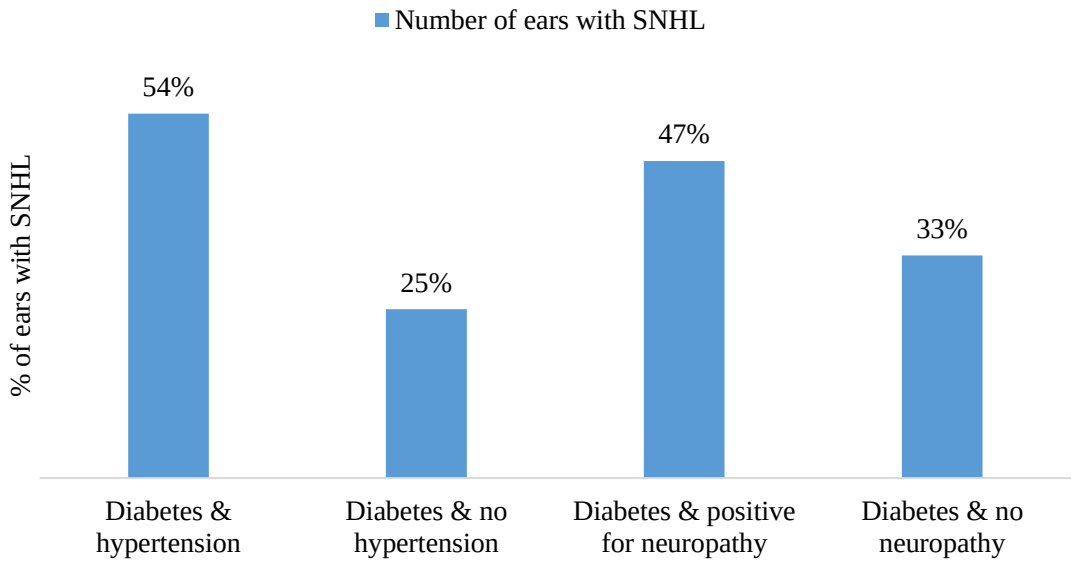

Figure 3: Hearing loss and comorbidities.

A logistic regression analysis was done to investigate the odds of hearing loss presence with the following (independent) variables; gender, age, diabetes characteristics (duration and control) and the presence of hypertension (see Table 7, next page).

The outcome of the regression analysis indicated that an increase in diabetes duration was associated with an increase in the odds of hearing loss presence (OR=1.12, 95% CI: 1.02 -1.23, p =0.01). A similar pattern was observed in the case of age where an increase by a year also showed higher odds of hearing loss presence (OR=2.9, 95%CI: 1.19-7.07, p =0.01). Furthermore, with gender, in comparison to female participants, males had significantly higher odds of hearing loss presence (OR=.266, 95%CI: .10-.67, p <0.01).

Table 7

Logistic Regression Model Results.

Predictor Variables	Odds Ratio	P Value (α= 0.05)	95% Confidence Interval	
			Lower	Upper
Diabetes duration (years)	1.120859	**0.013**	1.024482	1.226303
Diabetes control (g.mol)	.9920032	0.786	.9362205	1.05111
Age (years)	2.904431	**0.019**	1.191974	7.0771
Gender[¥]	.2661657	**0.005**	.1045702	.6774794
Presence of hypertension	1.847933	0.215	.7005446	4.874572

* Regression calculated with n = 110, R^2 = .181 and Log likelihood = -62.149578. [¥] reference variable = female

Hearing loss: Type & Severity

Sensorineural hearing loss was the most prevalent type of hearing loss observed in both groups (see Table 8, next page). Sensorineural hearing loss was present in a higher proportion of ears in the cohort than the control. Majority of the hearing losses observed in both groups) were of a slight degree (16-25 dB HL). There were relatively more ears (up to 3 times more) with disabling hearing loss (> 41 dB HL) in the cohort (48) than the control (10) group.

Otoacoustic Emissions:

In addition to pure tone audiometry, diagnostic distortion product otoacoustic emissions (DPOAE) were administered and recorded per ear and categorised into low (< 2.5 kHz) and high (>2.5 kHz) frequencies. DPOAE findings were consistent with pure tone audiometry results in that there was a higher proportion of ears with abnormal findings in the cohort than control group. (see Table 9, next page). The difference in DPOAE findings between the participant groups were found to be statistically significant in the higher frequencies with both signal to noise ratio ($t(381) = -6.65, p < 0.01$) and DPOAE level findings ($t(323) = -3.99, p < 0.01$).

Table 8

Type and severity of hearing loss

Description	**Cohort** number of ears (%)	**Control** number of ears (%)
Number of ears with hearing loss	122	32
Total number of ears in sample	220	164
Type of Hearing loss		
Conductive	7(6%)	4(12%)
Sensorineural	91(74%)	22(67%)
Mixed	24(20%)	7(21%)
Severity of Hearing loss		
Slight (16-25 dB HL)	42(35%)	14(44%)
Mild (26-40 dB HL)	32(26%)	8(25%)
Moderate (41-70 dB HL)	39(32%)	7(22%)
Severe (71-90 dB HL)	9(7%)	3(9%)
Profound (> 90 dB HL)	0(0%)	0(0%)

*Hearing loss severity classification according to Harrell (2002).

Table 9

Abnormal diagnostic DPOAE Findings

	Low Frequencies	**High Frequencies**
	Signal to Noise Ratio (dB) (n [%])	
Cohort (n=220)	112(51%)	186(85%)
Control (n=164)	39(24%)	107(65%)
Significance of differences	$t(290) = -1.24$, $p = .21$	$t(381) = -6.65$, $p < 0.01$
	DPOAE level (dB SPL) (n [%])	
Cohort (n=220)	89(40%)	213(97%)
Control (n=164)	65(40%)	139(85%)
Significance of differences	$t(358) = -8.06$, $p < 0.01$	$t(323) = -3.99$, $p < 0.01$

*n= number of ears. Norms used for DPOAE: signal to noise ratio > 6 dB, DPOAE level > 0 dB (Botelho et al., 2014).

Tinnitus:

The presence or absence of tinnitus was based on participants' subjective reports during case history interview. A higher tinnitus prevalence was found in the cohort (44%) compared to the control group (15%).

The difference in tinnitus prevalence between the groups was found to be statistically significant ($t(190) = -4.41$, $p < .001$). Specific to the cohort group, the correlation between tinnitus reports and diabetes duration (years post diagnosis) and control (glycemic status) was investigated using the pearson correlation coefficient. A weak inverse relationship ($r = -.02$) was found between diabetes duration and tinnitus presence and no relationship ($r = .00$) was found between diabetes control and the presence of tinnitus.

Balance Functions:

DGI findings:

The DGI consisted of 8 tasks with varying demands, with each item was scored on a 4-level ordinal scale with a maximum possible scoreof 24. A score of 19 or less indicated an increased risk of falling (Leddy et al., 2011; Wrisley et al., 2003). Findings show that twenty-two percent of participants in the cohort group failed dynamic balance screening assessment (i.e. DGI scores ≤ 19) and therefore were at risk of falls when compared to one percent in the control group. The difference in the number of participants that failed the dynamic balance screening with the DGI between the groups was statistically significant ($t(166) = -6.14$, $p < .001$). The distribution of the DGI scores of the cohort and control is illustrated in Figure 4.

The correlation between DGI scores and participants' age was also analysed using the Pearson correlation coefficient. The results indicated weak inverse correlations between DGI scores and age with $r = -.29$ and $r = -.37$, for the cohort and control groups respectively. Specific to the cohort group, the correlation of DGI score with diabetes duration (years post diagnosis) and

control (glycemic status) was also investigated using the Pearson correlation coefficient. The findings also showed a weak inverse correlations with diabetes duration r= - .13 and diabetes control r= - .23, indicating that a longer diabetes duration in years and a higher glycemic status was correlated with a lower DGI score.

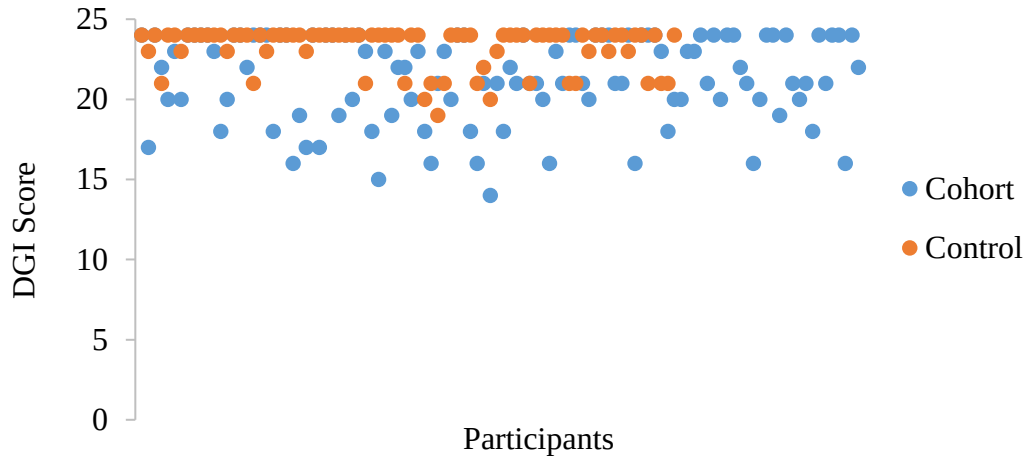

Figure 4. DGI score distribution. *maximum scores at 24

MTCSIB findings:

The MCTSIB was carried out over four conditions which are eyes open and closed with foam and firm surface. Participants were timed in each condition with the standard at 30 seconds and the total score was out of 120 seconds (Leddy et al., 2011). MCTSIB scores show that more than half (56%) of the participants in the cohort group failed the static balance screen (scores <120 seconds) when compared to 21% of the control participants. The difference in the number of participants that failed the static balance screening between both participant groups was statistically significant ($t(149) = -6.13$, $p < .001$).

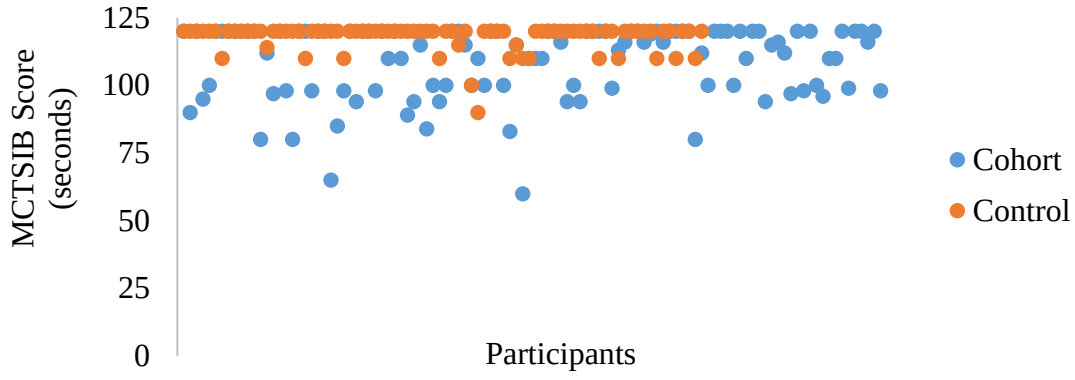

Figure 5. MCTSIB score distribution. *Maximum score at 120 seconds

The distribution of the MCTSIB scores, as indicated in Figure 5 show that the cohort and control groups had minimum scores of 60 and 90 seconds, respectively. Participants with abnormal findings (<120s) in both groups, mostly had difficulties in condition three and four (see Figure 6).

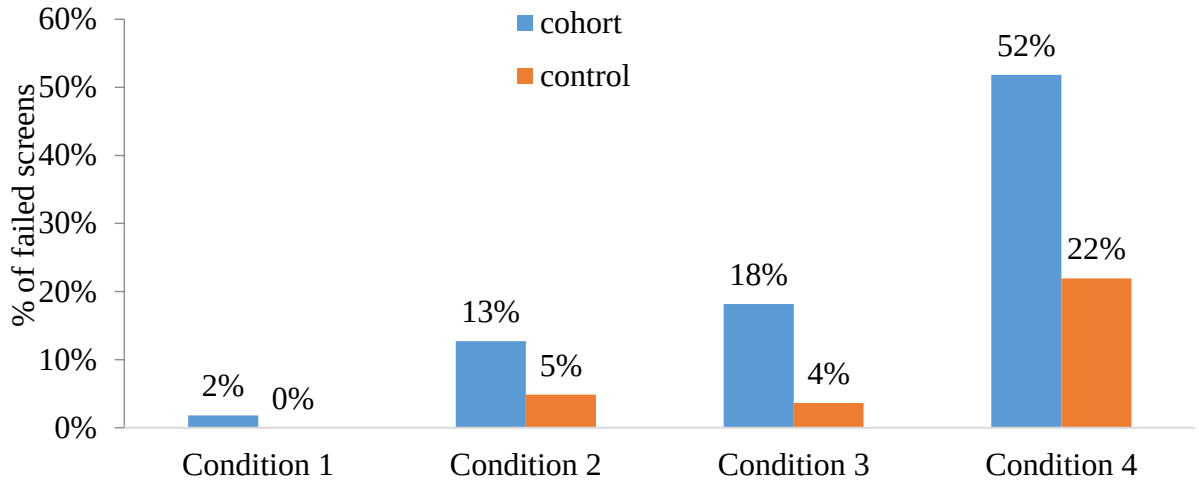

Figure 6. *MCTSIB conditions.*

*Conditions: 1= on firm surface, eyes open, 2= on firm surface, eyes closed, 3= on foam surface, eyes open, 4= on foam surface, eyes closed

Analysis of correlation between MCTSIB scores and participant age using the Pearson correlation coefficient also yielded weak inverse correlations with r= - 0.29 and r= - 0.14 for cohort and control groups respectively thus indicating that increasing age was weakly related to a lower MCTSIB score. Specific to the cohort group, the correlation between MCTSIB score and diabetes duration (years post diagnosis) and control (glycemic status) was also investigated. Pearson correlation coefficient findings showed a weak negative correlation with diabetes duration r= - 0.20 and diabetes control r= - 0.06, indicating that with longer diabetes duration in years and a higher glycemic status, a lower MCTSIB score was obtained.

Diabetes comorbidities and Balance findings:

Further analysis was conducted to determine the likelihood of abnormal balance screening test findings in patients with diabetes and were positive for those with diabetic neuropathy and those who failed the vision screener. The outcome of that analysis showed that those with diabetes

and one or both comorbidities, consistently presented with a higher prevalence of abnormalities compared to those without comorbidities (see Table 10).

Table 10

Diabetes comorbidities and Balance findings

Participants with diabetes	**Number of participants**	**Abnormal DGI [n (%)]**	**Abnormal MCTSIB [n (%)]**
Participants positive for diabetic neuropathy	56	**22(39%)**	**40(71%)**
Participants negative for diabetic neuropathy	54	3(6%)	21(39%)
Participants that failed vision screening	62	**15 (24%)**	**50(81%)**
Participants that passed vision screening	48	9(19%)	25(52%)
Participants positive for diabetic neuropathy and failed the vision screener	31	**11(35%)**	**27(87%)**

Results summary:

Overall, participants with diabetes presented with a statistically significant higher prevalence of abnormalities for both auditory characteristics and balance function than those without diabetes. A higher prevalence of hearing loss and abnormal cochlear function was found in those with comorbidities (hypertension and neuropathy) and the likelihood of hearing loss presence was associated with diabetes duration and participant factors (age & gender). A similar pattern was found with balance function where a higher prevalence of abnormalities was found with those with comorbidities (possible neuropathy and visual difficulties) and uncontrolled diabetes, longer diabetes duration and participant age was correlated with with abnormal balance findings.

Chapter 5: Discussion and Conclusion

Introduction: This chapter will discuss the study findings in relation to existing literature. In addition, the chapter will present the researcher's commentary on the findings and their relation to clinical practice. Strengths and weaknesses of the current study will also be discussed and finally, clinical implications, recommendations for future research and conclusions based on the study findings will be presented.

The current study sought to describe the auditory characteristics and balance function in a group of South African patients with diabetes (cohort group) and compare that to a group of volunteer participants without diabetes (control group). Overall findings of this study showed a higher proportion of auditory abnormalities and balance dysfunctions in participants with diabetes than the control group.

The prevalence of hearing loss amongst patients diagnosed with diabetes in this study was found to be 55%. This is a slightly higher prevalence finding than previous study reports of 13.1% (Kakarlapudi et al., 2003), 43.6% (Pemmaiah & Srinivas, 2011) and 45% (Mozaffari et al., 2010). Several factors may be plausible explanations for the variation in prevalence percentages of hearing loss reported in different studies, such as the use of different classifications of hearing loss in terms of the normative cut-off (in dB HL); and PTA calculations.

To classify hearing loss, a low cut off hearing level norm (15 dB HL) was used in this study to acknowledge a slight hearing loss (16-25 dB HL), which is not typically acknowledged by many researchers in their findings (Timmer, 2014; Kaderavek & Pakulski, 2002) even though it is known to impact speech discrimination and comprehension even in adults (Arlinger, 2003). Also, the current study made use of a HF-PTA in line with literature evidence indicating that diabetes related hearing loss mainly affects the high frequency hearing thresholds (2-8 kHz) which may be missed by the conventional PTA calculation (0.5-2 kHz) (Pemmaiah & Srinivas, 2011;

Mozaffari et al,2010). With the use of a HF-PTA and a low cut-off norm to classify presence of hearing loss in the current study, there was an additional 42 ears (35%) with slight high frequency hearing loss identified, which may have otherwise been missed. It can be argued that identifying more individuals with slight hearing loss, can increase the caseload of individuals with hearing loss, which may potentially create an additional burden to the health care system. However, in a resource constrained environment such as South Africa, early identification of hearing loss (no matter how slight), in a population at risk for hearing loss such as patients with diabetes can prompt early patient education on how to cope with hearing loss (Arlinger, 2003).

In terms of type of hearing loss, most studies investigating hearing loss in patients with diabetes did not report on all types of hearing loss (Botelho et al., 2014; Panchu, 2008; Pemmaiah & Srinivas, 2011; Mozaffari et al., 2010). Although sensorineural hearing loss may be the most prevalent type of hearing loss in patients with diabetes, other hearing loss types are are worth noting and discussing. In this study, conductive and mixed hearing losses, were found in 15% and 26% respectively among patients with diabetes. Similar findings were reported by Thimmasettaiah and Shankar (2012) with mixed hearing loss in 16% of their participants with diabetes. Hearing losses attributed to outer and middle ear pathologies such as otitis externa and otitis media should not be overlooked in patients with diabetes because their ability to heal and recover from wounds and infections may be compromised. Furthermore, unlike sensorineural hearing loss, losses attributed to outer and middle ear pathologies can be treated and reversed if detected early.

With respect to severity of hearing loss, moderate or worse hearing loss (i.e. thresholds > 40 dB HL) was established in a higher proportion in the cohort group (82%) than the control (18%). Moderate or worse hearing loss can be disabling as it can negatively impact audibility, discrimination and comprehension of sound and speech to the listener (Timmer, 2014) and often requires intervention in the form hearing amplification. Reports of a high proportion of ears

diagnosed with disabling hearing loss in patients with diabetes is not unique to this study, previous studies like that of Pemmaiah and Srinivas (2011) also reported more than 20% of their participants had moderate to severe hearing loss. However, despite this strong evidence of a high proportion of disabling hearing loss in patients with diabetes reported in literature, it is a concern that disabling hearing loss is still not recognized as a comorbidity of diabetes.

The presence and severity of hearing loss in patients with diabetes in previous studies has been associated with diabetes characteristics such as type, control and duration (Mitchell et al., 2009; Sunkum & Pingile, 2013). However, the current study did not find any such association. The difference in findings between the current study and previous studies may be due to differences in the participants' characteristics of the diabetic group and or study design. For instance, Mitchell et al. (2009) study involved a much larger sample size (n=3654) than the current study (n=192) and their study used a longitudinal design compared to a cross-sectional design in the current study. Also, Sunkum and Pingile (2013) recorded control of diabetes from fasting blood glucose measurements unlike the current study that used glycohemoglobin blood test results which are the ideal measurement to monitor diabetes control over a 3 month period in patients (American Diabetes Association, 2012).

Diabetes related hearing loss has also been associated with diabetes duration (Frisina et al. 2006). The current study also found that each year increase in diabetes duration was associated with about 12% (OR: 1.12) increase in odds of hearing loss. Similar findings were also reported by Mitchell et al. (2009) and Akinpelu et al. (2014) who reported that a longer duration of hyperglycaemia was associated with a higher risk of pathological outcomes in the inner ear. These findings are in line with the hypothesis that an increased diabetes duration implies increased patient age, which is, apart from diabetes presence, a risk factor for hearing loss (Frisina et al., 2006). Moreover, the current study also found that an increase by one year in participant's age

was associated with increased odds of hearing loss presence (OR: 2.9, p = 0.01). In agreement, Frisina et al. (2006) and Kakarlapudi et al. (2003) found that diabetic changes appear to accelerate or act in synergy with age related deterioration in the ear. The current study findings also highlighted that, in adults younger than 49 years, age was a predictor variable for hearing loss although this age group may not be identified to be at risk for age related impact to their hearing (Blevins, 2015). This is important to note as it indicates that even in a younger population, diabetes may contribute to hearing deterioration (Sparring et al., 2013).

In terms of comorbidities, previous studies have associated hearing loss in patients with diabetes with hypertension (Bainbridge, Yiling & Cowie, 2010; Bos & Agyemang, 2013). Among participants with diabetes, the current study found that in comparison to participants without hypertension, those with hypertension had a 84% higher risk of hearing loss. Similar findings were also reported by Li, Gong, Yang and Yu (2003) who stated that hypertension is a key risk factor associated with deterioration of the cochlea. Furthermore, it has long been established that hypertension and diabetes work synergistically against hearing acuity, even in age controlled studies (Duck, Prazma, Bennett, & Pillsbury1995). Physiologically, the combination of hypertension and diabetes is thought to have a multisystem vascular and end-organ damage in the cochlea that in turn is associated with high-frequency sensorineural hearing loss (Duck et al., 1995). Whilst, the current study did not aim to attribute the cause of hearing loss in those with both diabetes and hypertension, findings showed 54% of those with hypertension had sensorineural hearing loss compared to 25% in those without hypertension. These findings are in agreement with Duck et al. (1995) in their association of hypertension and hearing loss. This is important to note as findings can be used to identify those with both diabetes and hypertension as an at risk population should universal hearing screening in all patients with diabetes not be feasible in a resource constraint context like South Africa.

This study also found a significantly higher prevalence of tinnitus in patients with diabetes (43%) when compared to the control group (15%) ($p < .001$). Gribin, Melo and Marchiori (2013) in their study (n=498) also reported a high prevalence of tinnitus (42%) amongst patients with diabetes and further associated tinnitus with diabetes and hypertension. Tinnitus has been reported as a pre-clinical indicator of hearing loss as well as a co-morbidity in those with hearing loss, diabetes, hypertension and other age related disorders (Gribin et al., 2013). Physiologically, the correlation between tinnitus and diabetes is understood to result from inner ear modifications caused by hyper-viscosity or micro-angiopathy resulting from diabetes or hypertension (Gribin et al., 2013). Clinically significant tinnitus is important to detect and manage as it has been proven as a significant negative impact to mental and emotional wellness of those affected (Rent, Bhojwani, Bhat & Unnikrishnan, 2013). However, it is important to note that the current study did not investigate whether the participants were bothered by their tinnitus or not, to make it a clinically relevant symptom.

With respect to participant characteristics, males with diabetes had significantly higher odds of hearing loss presence (OR: 0.74, $p < 0.01$), in comparison to females with diabetes. Several studies have reported that hearing loss is generally more common in men than women (Sharashenidze, Schacht & Kevanishvili, 2007). The difference in risk to acquire hearing loss between men and women has been attributed to occupational differences, reaction time to symptoms and or frequency of doctor's visits (Sharashenidze et al., 2007). Also, women have been shown to take better care in issues of health than men (Sharashenidze et al., 2007). Therefore, findings in the current study on gender as a predictor variable for hearing loss are in line with literature independent of the presence of diabetes. These findings can be utilized to emphasise efforts for hearing loss prevention and early detection through screening especially in males with diabetes.

Diabetes and balance

Twenty-two percent (22%) of the participants with diabetes in this study were at risk for falling based on their DGI score when compared to only 1% in the control group. Low DGI scores are indicative of increased fall risk in participants with diabetes. Similar findings were reported by Juregui-Renaud et al. (2009) who also found that 38% of their participants with diabetes experienced instability when walking. Other authors explain that fall risk in patients with diabetes may be due to decreased sensorimotor function, musculoskeletal deficits, foot and body pain as well as pharmacological complications and peripheral neuropathy (Salsabili et al., 2011; Ahn & Song, 2012; D'Silva et al., 2016; Sturnieks et al., 2008; Walley et al., 2014). In agreement the current study also established that in participants with diabetes that screened positive for diabetic peripheral neuropathy (n=56), there was more than six times higher prevalence of fall risk at 39% compared to those that screened negative (n=54) at 6%.

Risk of falls in patients with diabetes, especially those with comorbidities like peripheral neuropathy, is essential to note. Falls are ranked among the 20 most expensive conditions to treat considering hospitalization, possible need for surgery and thereafter implications for rehabilitation (Carroll, Slattum & Cox, 2005). Moreover, in a low socioeconomic context such as the data collection site of this study, prevention of falls through health education and balance screening in patients with diabetes, may be a feasible strategy to minimise furher strain onto the healthcare system.

It was also found in this study that more than half (56%) of the participants with diabetes could not maintain postural stability especially in condition four (eyes closed on foam) of the static balance screening with the MCTSIB. According to Rubenstein (2006) postural instability is expected in patients with diabetes because most of the affected areas of the body including the eyes, ears and the legs, are integral in maintaining proprioception and avoiding falls. In agreement

the current study found that in participants with diabetes that screened positive for diabetic neuropathy and failed the vision screener (n=31), 87% could not maintain postural stability. Postural instability in patients with diabetes with sensory impairments like peripheral neuropathy is attributed to the lack of precise proprioceptive response (sensory ataxia) from the lower limbs (Walley et al., 2014). Furthermore, Wilson, Garner and Loprinzi (2016) in their study (n=1662) reported that visual impairment can impact the vestibulo-ocular reflex, an important system that maintains balance and prevents falls. Consequently, there is a crucial need to investigate postural instability in order to prevent fall-related injuries especially in patients with diabetes and multiple sensory impairments (Wilson et al., 2016).

Balance dysfunction findings in the current study, along with possible vision loss and lower limb neuropathy are imperative to note in relation to the age group affected in the study. Majority of participants in this study were middle aged (range: 20-55years), potentially economically active adults, thus highlighting that a younger population may be at risk for balance dysfunction with multiple sensory impairments including, vision and hearing (Lin et al., 2004). Multiple sensory impairments especially in an economically active age range can result in significant negative impact to occupational productivity as well as cognitive and functional decline (Lin et al., 2004; Wilson et al., 2016). Therefore, the current study findings highlight the need to screen for balance function in patients with diabetes at a primary level of care to enable early identification and appropriate management to prevent possible impact to quality of life such as activity restrictions, decreased social participation and increased need for a doctor's visit (Agrawal et al., 2013). The findings of this study also highlight the need for a multidisciplinary team approach inclusive of medical doctors, physiotherapists, optometrists, dieticians and all other relevant health professionals in order to provide holistic management of patients with diabetes (Van Leeuwen & Bruintjes, 2014).

Strengths and Limitations of the Study

This study comprehensively investigated both the auditory characteristics and balance function in patients with diabetes. Previous studies focused on either auditory or balance function, seldom was the complete audiological spectrum investigated. Also, the current study design which included a matched control group ensured that the influence of confounding variables was minimized. This is in contrast to most of the previous studies that employed mostly retrospective reviews of records without control groups. Moreover, the current study used a test battery approach in the assessments of participants' auditory status, including both audiometry and DPOAE assessments allowing for cross checking of findings. Lastly, participants were carefully selected to ensure that only individuals <55 years old were selected to minimize the impact of age-related hearing loss and balance dysfunctions which could be confounding variables in this study.

The current study also had some limitations: first, it was a descriptive cross-sectional study with observation/assessments carried out at one time point thus only associations and correlations can be inferred. Participants were sampled using non-probability sampling which can introduce researcher and selection bias because it is not randomized. Also, there was an unequal number of participants between the cohort (n=110) and control (82) groups therefore findings between sample groups to be compared with caution. Last, this study investigated mainly prevalence and did not include a quality of life aspect that may have added more context with respect to the impact of diabetes related hearing loss and balance abnormalities. However, despite these limitations, the findings of the current study provide a comprehensive description of auditory and balance characteristics in patients with diabetes.

Clinical Implications

The clinical implication emerging from the current study is that, in patients with diabetes, hearing and balance dysfunctions should be addressed. The findings of the current study also indicated that healthcare providers should include, as part of their management, a referral for hearing and balance screening for early detection of hearing loss and balance dysfunction. Therefore, the current study highlighted the need for an audiologist within the multidiscipliary team involved in diabetes patient care. Audiologists need to be more involved in diabetes education in health screening and awareness campaigns, especially in the younger economically active adults that may also be at risk. Furthermore, audiologists need to start administering hearing, tinnitus and balance screening in patients with diabetes, if not universally, should be mandatory for those identified to be at a higher risk like, males and those with hypertension.

Specific to audiological testing protocols, clinical implications of the current study include the use of the high frequency pure tone calculation (PTA: 2, 4 & 8 kHz), more stringent hearing loss classification norms (>15 dB HL), inclusion of DPOAE assessments in combination with pure tone audiometry, tinnitus screening questionnaires as well as balance screening with readily available resources for low-resourced primary levels of care.

Overall, the findings of the current study suggest that auditory and balance dysfunction should be recognized as a comorbidity of/with diabetes. Recognition in instruments such as the annual diabetes fact sheets of key organizations like the IDF and WHO will increase awareness of the prevalence of auditory and balance dysfunction in patients with diabetes. Also, other official documents such as the WHO guidelines for primary healthcare in low-resource settings should advocate for diabetes patient education inclusive of hearing and balance matters. At present both the WHO and IDF fact sheets have information on diabetes related comorbidities which focuses primarily on neuropathies specific to vision and limbs and not on other sensory impairments. This

is despite numerous studies documenting the relationship between diabetes, auditory and balance dysfunctions(Kakarlapudi et al., 2003). These organizations (IDF, WHO) are significant in diabetes education, research and information dissemination thus their recognition will catalyse promoting hearing health care amongst patients with diabetes.

Recommendations for Future Research

Future research can add to the knowledge base with studies focusing on the following:

- Incidence of hearing loss and balance dysfunctions in patients with diabetes through longitudinal prospective research.
- Effective methods of hearing and balance dysfunction prevention, management approaches and monitoring methods in patients with diabetes.
- Investigations on the impact of diabetes related hearing loss and balance abnormalities on quality of life.
- Collaborative research with multiple disciplines such as dieticians/nutritionists, occupational therapists or physiotherapists, focusing on prevention and management of diabetes related sensory impairments.

Conclusion

In conclusion, the current study has provided a broad description of auditory characteristics and balance function in patients with diabetes in a South African population. Overall, the findings of this study showed that participants diagnosed with diabetes had a higher proportion of auditory and balance abnormalities when compared to those in the control group. With hearing loss, a higher prevalence was established in those with comorbidities (hypertension and neuropathy) and the likelihood of hearing loss presence was associated with diabetes duration and participant factors (age & gender). A similar pattern was established with balance function where a higher prevalence of abnormalities was found with those with comorbidities (neuropathy and possible visual difficulties) and there was a correlation between uncontrolled diabetes, longer diabetes duration and participant age with abnormal balance findings.

The findings of this study therefore suggest that auditory and balance dysfunctions should be considered as comorbidities associated with diabetes. The findings of this study also indicate the audiologist's role for screening, early identification and management of auditory and balance dysfunctions within the multidisciplinary framework in the care of patients with diabetes.

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Appendices

Appendix A: ***Advertisement for recruitment of control group participants (English)***

WOULD YOU LIKE A FREE HEARING AND BALANCE ASSESSMENT?

ARE YOU INTERESTED IN PARTICIPATING IN A RESEARCH?

My name is Vera-Genevey Hlayisi and I am a student from the University of Cape Town. I am doing a study to know about diabetes, hearing loss and balance.

I would like to invite you to be part of this study as part of the group of people that do not have Diabetes. This clinical study protocol has been granted ethical approval by the University of Cape Town, Human Research Ethics Committee (HREC)

In summary, if you agree take part in the study, please be aware of the following:

You will also be asked to give permission to have audiological and balance assessments done. The assessments will take 40 minutes to an hour.You will also be asked to give permission to have your information be used for research purposes.There will be no costs to you related to participating in this research study. You will not be paid or compensated for taking part in this study. All information collected about you during the course of this study will be kept without any identifiers.

Taking part in this study is voluntary. If you are interested, come to XXXXX clinic and get more information on how to be involved or contact;

Vera-Genevey Hlayisi (Researcher) 0718376207 blyver002@uct.ac.za

Appendix B: ***Advert for recruitment of cohort group participants (English)***

WOULD YOU LIKE A FREE HEARING AND BALANCE ASSESSMENT?

ARE YOU INTERESTED IN PARTICIPATING IN A RESEARCH?

My name is Vera-Genevey Hlayisi and I am a student from the University of Cape Town. I am doing a study to know about diabetes, hearing loss and balance. I would like to invite you to be part of this study.

This clinical study protocol has been granted ethical approval by the University of Cape Town, Human Research Ethics Committee (HREC). In summary, if you agree take part in the study, please be aware of the following:

You will also be asked to give permission to have audiological and balance assessments done. The assessments will take 40 minutes to an hour. You will also be asked to give permission to have your information be used for research purposes. Your hospital file will also be used to obtain more information about your medical history pertaining diabetes.

There will be no costs to you related to participating in this research study. You will not be paid or compensated for taking part in this study. All information collected about you during the course of this study will be kept without any identifiers.

Taking part in this study is voluntary. If you are interested, come to XXXXX clinic and get more information on how to be involved or contact;

Vera-Genevey Hlayisi (Researcher) 0718376207 blyver002@uct.ac.za

Appendix C: ***Advert for recruitment of both cohort & control group participants (Sotho)***

Naa O nyaka go hlahlofiwa mahala?

Leina laka ke Vera-Genevey Hlayisi, ke moithuti wa Univesiti ya Cape Town. Ke e thuta go tseba ka bolwetshi ba swekere, bothatha ba go otlwa le balance. Ke rata gole mema.

Research ena e na e humane tumelelo ho Human Research Ethics Committee ya Univesiti ya Cape Town. Ge o tseya karolo ya thoto ye o swanetse go dira tse latelago;

Re tho hlahlofa ditsebe le balance ya hago. Hlahlofo e tlo go tsea metsotso e masometharo go fihla go ye masometshela

Retlo kgopela go bona file ya gago

Ga yona le patella ke mahala. Le mohlahlubi ga a le patele

O tlo fiwa nomoro ga go nyakege leina la gagwe

Ge o na le khahlego o tla bona XXXXXX kapa o fonela V. HLAYISI mo go 0718376207

Appendix D: ***Data abstraction sheet (demographic and medical information)***

Name	Study No.	Gender	Age	Diabetes Characteristics (cohort group only).	Co-morbidities and patient specific factors	Tinnitus (type, laterality, pitch)	Other medication

Appendix E: ***Data collection tests, participant instructions and norms***

Test	**Definition and Norms**	**Participant instruction**
Otoscopy	Otoscopy was done to assess outer ear structures. Normal otoscopy was considered as visualization of the tympanic membrane with a light reflex (Roeser, Clark, & Mendrygal, 2011; Sautter & Hirose, 2007). Patients with wax impaction, perforations as well as discharging ears were referred for audiological and medical treatment within the facility before diagnostic audiometry is administered.	Participants were not expected to give any subjective feedback and were asked to allow audiologist to look into the ears
Pure tone audiometry	Audiometry was performed to assess the lowest audible threshold across 8 frequencies (0.25 to 8 kHz) with normal hearing classified as thresholds at or below 15 dB HL with both air and bone conduction assessments (Harrell, 2002). The guidelines for manual pure tone audiometry were according to the Handbook of Audiology by Katz, (2002) using a 10dB decrease and 5dB increase method to search for the absolute threshold (Soer, n.d.) The absolute hearing threshold for that specific frequency was defined as the lowest intensity level	Participants were instructed to press a response button when they hear the pure tone sounds presented to them. Participants were instructed to press the button when they hear even the softest sounds.

	in dB where a person hears a sound 50% of the time. When participants had normal air conduction thresholds (< 15 dB HL), no bone conduction was done. Severity and Type of hearing loss: Classification norms for hearing loss severity and type of loss used were according to Stach, (2008) (see Table1 and Table2). Severity of loss was determined with two averages of the pure tone thresholds (PTA). The first average was the low to mid frequency average (0.5, 1 & 2 kHz) and the second a high frequency average (2, 4 & 8 kHz).	
Otoacoustic emissions (OAE)	Otoacoustic emission (OAE) testing was done to assess cochlear function with objective monitoring of the dynamic changes in cochlea responsiveness before functional and significant hearing loss occur (Botelho et al., 2014; Hamed & El-attar, 2010). Distortion Product OAEs were assessed and recorded using DPgram charts. DPOAE's were elicited at 2f1-f2 between frequencies from 1 kHz to 8 kHz. (Botelho et al., 2014; Hall & Swanepoel, 2010). The intensities of F1 and F2 will be at 65 dB SPL (L1) and 55 dB SPL (L2), and a f2/f1 ratio of 1.22 were used. A DPOAE was regarded as present with a signal to noise ratio > 6 dB as well as absolute DPOAE level > 0 dB (Botelho et al., 2014).	Distortion Product OAE assessment was conducted and researcher will place in the participant's ear and participants were asked to remain quiet and calm as this test is objective and requires no responses from the participant. Participants were instructed not chew, swallow or speak during this test.

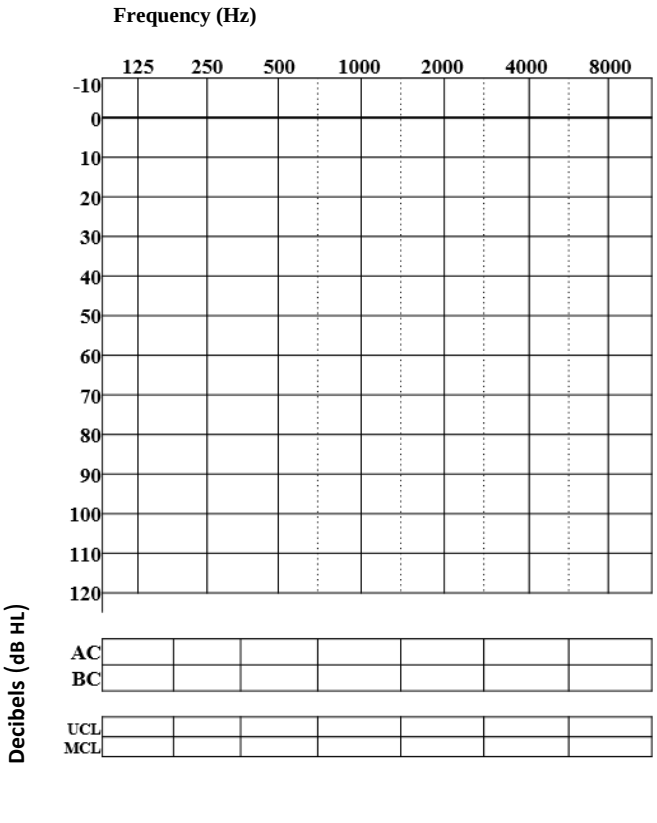
Balance	The MCTSIB is a static balance assessment that gave information about the sensory integration of three main components of balance including somatosensory, visual and vestibular (Leddy, Crowner, & EArhart, 2011; Salsabili et al., 2011; Yim-Chiplis & Talbot, 2000). The MCTSIB was carried out over four conditions which are eyes open and closed with foam and firm surface. Participants were timed on how long they maintain balance in each condition with the standard at 30 seconds (Leddy et al., 2011). The total score was out of 120 seconds for all four conditions and recorded on the relevant score sheet. Timing stopped when the patient opened their eyes and or moved their foot. The DGI is a dynamic balance assessment that provided information about dynamic postural stability and quantified fall risk (Wrisley et al., 2003). This DGI consisted of 8 tasks with varying demands, such as walking at different speeds, ascending and descending stairs, and making quick turns. Each item was scored on a 4-level ordinal scale with a maximum possible score, on the entire DGI, of 24. A score of 19 or less indicated an increased risk of falling (Fujisawa et al., 2007; Leddy et al., 2011; Wrisley et al., 2003).	Participants were asked to take off their shoes and stand upright with eyes open and closed on a firm surface and on foam. Researcher then recorded the time with a timer in each condition (eyes open and closed as well as firm surface and foam). Participant's time scores were recorded in the relevant form. Guarding from falls was done with a gait belt that was placed around the participant's waist. Participants were also asked to walk straight on a level surface with various conditions including, head turns, going up steps and head turns (vertically and horizontally).

Appendix F: *Audiogram Chart*

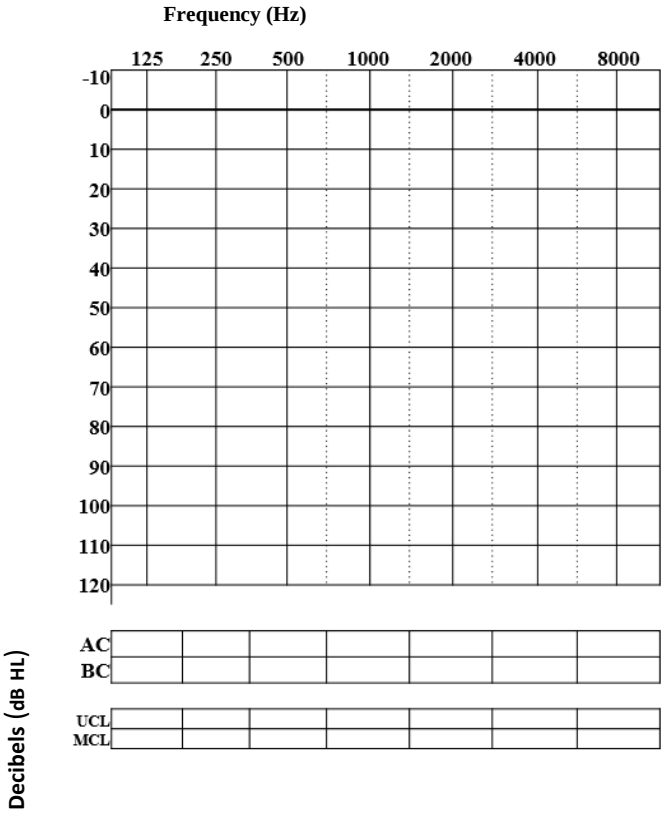
Name: .....Study No..... Age: ..... Gender:.....

Audiologist:: ..... Date:.....

Right ear



Left ear



OAE ASSESSMENTS

Right	
Left	

Norms and classifications of hearing loss:

Table 1.

Classification of hearing loss Severity for adults (Harrell, 2002)

Severity classification	Decibels (dB HL)
Slight hearing loss	16-25 dB HL
mild hearing loss	26-40 dB HL
moderate hearing loss	41-70 dB HL
severe hearing loss	71-90 dB HL
profound hearing loss	90+ dB HL

Table 2.

Type of hearing loss and audiological presentation (Katz, 2002)

Type of Hearing loss	Audiological Presentation
conductive hearing loss	bone conduction levels < 15 dB HL air conduction > 15 dB HL
sensorineural hearing loss	both bone and air conduction levels > 15 dB HL with < 10 dB difference between the levels
mixed loss hearing loss	both bone and air conduction levels > 15 dB HL with > 10 dB difference between the levels when masking is applied

Appendix G: ***Modified Clinical Test of Sensory Interaction in Balance Scoring Sheet***

Subject Name:

Date:

Participants will be asked to stand with their hands at their sides, feet together and perform the following conditions:

- Stand on firm surface, eyes open
- Stand on firm surface, eyes closed
- Stand on foam surface, eyes open
- Stand on foam surface, eyes closed

The participant's performance is timed for 30 seconds. Test is terminated when arms or feet change position as well as when eyes opened in an eyes closed condition.

Total score (Modified CTSIB) =

- Average Time Cond 1 (if > 1 trial required) +
- Average Time Cond 2 (if > 1 trial required) +
- Average Time Cond 3 (if > 1 trial required) +
- Average Time Cond 4 (if > 1 trial required)

TOTAL SCORE: ___/120 sec

Appendix H: ***Dynamic Gait Index Score Sheet***

The test can be performed with or without an assistive device. The highest possible score is 24 points. Tasks involved include: steady state walking, walking with changing speeds, walking with head turns both horizontally and vertically, walking while stepping over and around obstacles, pivoting while walking as well as stair climbing. Scores are based on a 4-point scale:

3 = No gait dysfunction, 2 = Minimal impairment, 1 = Moderate impairment, 0 = Severe impairment

1. Gait Level Surface. Score:

(3) Normal: Walks 6.1 meters; no assistive devices, good speed, no evidence for imbalance, normal gait pattern.

(2) Mild Impairment: Walks 6 meters; uses assistive device, slower speed, mild gait deviations.

(1) Moderate Impairment: Walks 6 meters; slow speed, abnormal gait pattern, evidence for imbalance.

(0) Severe Impairment: Cannot walk 6 meters without assistance, severe gait deviations or imbalance.

2. Change in Gait Speed. Score:

(3) Normal: Able to smoothly change walking speed without loss of balance or gait deviation. Shows a significant difference in walking speeds between normal, fast, and slow speeds.

(2) Mild Impairment: Is able to change speed but demonstrates mild gait deviations or no gait deviations, but unable to achieve a significant change in velocity, or uses an assistive device.

(1) Moderate Impairment: Makes only minor adjustments to walking speed, or accomplishes a change in speed with significant gait deviations or changes speed but loses balance but is able to recover and continue walking.

(0) Severe Impairment: Cannot change speeds, or loses balance and has to reach for wall or be caught.

3. Gait with Horizontal Head Turns. Score:

(3) Normal: Performs head turns smoothly with no change in gait.

(2) Mild Impairment: Performs head turns smoothly with slight change in gait velocity, i.e., minor disruption to smooth gait path or uses walking aid.

(1) Moderate Impairment: Performs head turns with moderate change in gait velocity, slows down, staggers but recovers, can continue to walk.

(0) Severe Impairment: Performs task with severe disruption of gait, i.e., staggers outside 15" path, loses balance, stops, and reaches for wall.

4. Gait with Vertical Head Turns. Score:

(3) Normal: Performs head turns with no change in gait.

(2) Mild Impairment: Performs task with slight change in gait velocity, i.e., minor disruption to smooth gait path or uses walking aid.

(1) Moderate Impairment: Performs task with moderate change in gait velocity, slows down, staggers but recovers, can continue to walk.

(0) Severe Impairment: Performs task with severe disruption of gait, i.e., staggers outside 15" path, loses balance, stops, and reaches for wall.

5. Gait and Pivot Turn Score:

(3) Normal: Pivot turns safely within 3 seconds and stops quickly with no loss of balance.

(2) Mild Impairment: Pivot turns safely in _3 seconds and stops with no loss of balance.

(1) Moderate Impairment: Turns slowly, requires verbal cueing, requires several small steps to catch balance following turn and stop.

(0) Severe Impairment: Cannot turn safely, requires assistance to turn and stop.

6. Step over Obstacle. Score:

(3) Normal: Is able to step over box without changing gait speed; no evidence for imbalance.

(2) Mild Impairment: Is able to step over box, but must slow down and adjust steps to clear box safely.

(1) Moderate Impairment: Is able to step over box but must stop, then step over. May require verbal cueing.

(0) Severe Impairment: Cannot perform without assistance.

7. Step Around Obstacles. Score:

(3) Normal: Is able to walk around cones safely without changing gait speed; no evidence of imbalance.

(2) Mild Impairment: Is able to step around both cones, but must slow down and adjust steps to clear cones.

(1) Moderate Impairment: Is able to clear cones but must significantly slow speed to accomplish task or requires verbal cueing.

(0) Severe Impairment: Unable to clear cones, walks into one or both cones, or requires physical assistance.

8. Steps Score:

(3) Normal: Alternating feet, no rail.

(2) Mild Impairment: Alternating feet, must use rail.

(1) Moderate Impairment: Two feet to a stair; must use rail.

(0) Severe Impairment: Cannot do safely.

Total Score (Score _19/24 indicates increased risk of fall).

Appendix I: ***Diabetic Neuropathy Symptoms- DNS score***

1. Are you suffering of unsteadiness in walking?

Need for visual control, increase in the dark, walk like a drunk man, lack of contact with floor

Remark: it is assumed that the patient has no limiting visual, hearing or central neurological deficits.

2. Do you have a burning, aching pain or tenderness at your legs or feet?

3. Do you have prickling sensations at your legs and feet?

Occurring at rest or at night, distal>proximal, stocking glove distribution

4. Do you have places of numbness on your legs or feet?

Distal>proximal, stocking glove distribution

The questions should be answered "yes" (positive: 1 point) if a symptom occurred more times a week during the last 2 weeks or "no" (negative: no point) if it did not.

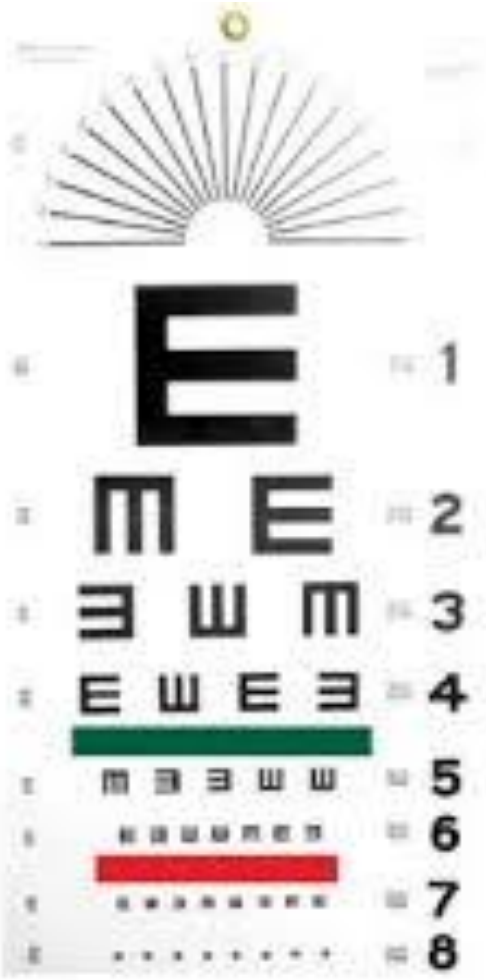
Max. score: 4 points

0 points: PNP absent

1-4 points: PNP present

Meijer et al (2003).

Appendix J: ***Visual Screening Chart***



Participants were asked to stand 6 meters away from the chart and the smallest line they can see without corrected vision will be recorded. A pass was when a participant could identify 6/6 on the chart. This chart was utilised to allow those that cannot read to participate.

Appendix K: Ethics Approval, UCT HREC

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room ES2-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492 • **Facsimile** [021] 406 6411
Email: Sumayah.arieffdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

04 March 2015

REC/REF: 134/2015

Dr L Ramma
Communication Sciences & Disorders
F-45
OMB

Dear Dr Ramma

Project Title: AUDITORY CHARACTERISTICS AND BALANCE FUNCTIONS OF DIABETIC PATIENTS-(MSc-candidate-Vera-Hlayisi)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for approval.

It is a pleasure to inform you that the HREC has **formally approved** the above mentioned study.

Approval is granted for one year until the 28 March 2016.

Please submit a progress form, using the standardised Annual Report Form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

We acknowledge that the following student:- Vera-Genevey-Hlayisi is also involved in this project.

Please note that the on-going ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC REF in all your correspondence.

Yours sincerely

Signed

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

Hrec/ref:134/2015

Appendix L: Permission Request Letter to Limpopo Department of Health

Division of Communication Science and Disorders
Department of Health and Rehabilitation Sciences
Faculty of Health Sciences, F45 Old Main Building
Groote Schuur Hospital
Telephone: (021) 406 – 6401, Fax: (021) 406 – 6323
Email: vera.hlayisi@gmail.com

Dear Sir or Madam

Re: A study on auditory characteristics and balance functions of diabetic patients

My name is Vera-Genevey Hlayisi, a student currently conducting a research study as part of my MSc Audiology project, investigating the effect of diabetes on hearing and balance. As diabetes, hearing loss and balance disorders are public health challenges in South Africa, it is hoped that the results of this study will be significant and ultimately provide information that could guide the management of diabetic patients. I therefore request permission access patients and their medical folders to conduct this research at your clinic.

The study is aimed at determining the proportion of diabetes patients that present with a hearing loss as well as with balance disorders. I plan to assess diabetic patients and review their medical folders to ascertain the information I need. There are no risks identified for patients or the hospital, as data collection will not hinder their continuation with medical management and monitoring of their conditions. I will also be using the audiology consultation room within the facility and need no extra space or resources. Furthermore, throughout the data collection I will be doing the testing and recording myself therefore no extra duties implied for the staff onsite.

I therefore request permission to access patients undergoing diabetes treatment in your clinic as well as their medical records to invite them to be part of this study.

Please find the study proposal attached. For your convenience the consent form is attached. You are free to withdraw your consent at any time during the study. If you need any further information, or have any concerns, please do not hesitate to contact the investigator. If you have any queries or concerns regarding this study, please feel free to contact myself or my supervisors at the numbers provided below:

Yours faithfully

Student Researcher- Hlayisi Vera-Genevey:(0718376207)

Supervisor- Lebogang Ramma - (021) 406-6954 and 073 153 3803.

Faculty of Health Sciences Human Research Ethics Committee (to be contacted if there are any ethical concerns regarding the study) Prof. Marc Blockman:(021)-406-6626 (Phone) or Email: Marc.Blockman@uct.ac.za.

Consent Slip:

This is to certify that I _____ hereby agree to for V. HLAYISI to conduct research as part of her Master's degree with diabetic patients in our facility.

All the documentation from the University of Cape Town faculty of Health Sciences Human Research Ethics Committee regarding ethical clearance for the study has been provided. The study and the clinic's participation in it have been clearly explained in full to me by the researcher and I understand all the explanations given to me. I understand all the proceedings and requirements for the study from our institution and thereby give my support throughout the research time frame. The questions that I asked were answered to my satisfaction. I have contacts for the University and the supervisor's of the researcher should I need to contact them at any time.

Name: Date:

Signature:

Appendix M: DoH Limpopo Approval Letter

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

Enquiries: Latif Shamila

Ref:4/2/2

Hlayisi Vera- Genevey
University of Cape Town
Department of Health and Rehabilitation Sciences
Division of Communication Sciences and Disorders

Greetings,

RE: Auditory characteristics and balance functions of diabetic patients

The above matter refers.

1. Permission to conduct the above mentioned study is hereby granted.
2. Kindly be informed that:-
    - Research must be loaded on the NHRD site (http://nhrd.hst.org.za) by the researcher.
    - Further arrangement should be made with the targeted institutions.
    - In the course of your study there should be no action that disrupts the services.
    - After completion of the study, a copy should be submitted to the Department to serve as a resource.
    - The researcher should be prepared to assist in the interpretation and implementation of the study recommendation where possible.
    - The above approval is valid for a 3 year period.
    - If the proposal has been amended, a new approval should be sought from the Department of Health.

Your cooperation will be highly appreciated.

Head of Department

30/04/2015
Date

18 College Street, Polokwane, 0700, Private Bag x9302, POLOLKWANE, 0700
Tel: (015) 293 6000, Fax: (015) 293 6211/20 Website: http/www.limpopo.gov.za

The heartland of Southern Africa – *development is about people*

Appendix N: ***Information letter***

Division of Communication Science and Disorders
Department of Health and Rehabilitation Sciences
Faculty of Health Sciences
F45 Old Main Building
Groote Schuur Hospital
Telephone: (021) 406 – 6401
Fax: (021) 406 – 6323
Email: vera.hlayisi@gmail.com

Hello, my name is Vera-Genevey Hlayisi and I am a student from the University of Cape Town. I am doing research as part of my Masters degree on Diabetes and how it affects hearing and balance functions. The study seeks to add to the current understanding of hearing loss and balance dysfunctions in their association with diabetes and in a South African population. It is expected that results of the study will be used to inform clinical practice and management practices that could be used to improve the quality of services provided to patients with diabetes in South Africa.

I would like to ask you to be part of this study.

Before agreeing to join the study, you need to read the following which tells you about why the study is important, how the study will work, what you have to do, as well as your rights. These include your right to change your mind at any time about being in the study. This information is to help you to choose if you would like to join the study.

As I student I have to make sure your rights are protected and the study is safe. This study has been approved by the Human Research Ethics Committee of the University of Cape Town whose job it is to make sure everything is correct.

What is the study about?

I am trying to find out the number of Diabetes patients who have hearing loss and balance disorders or both. If you decide to join, you will be tested for your hearing and balance functions.

What will happen to me if I agree to be in the study?

You will have to sign a form to say you agree to be in the study. You can talk about this with your friends and family if you want to and can come back another day to have the tests.

I will look in your folder to find out about your medical problems

You will have hearing and balance tests done. The tests will take 40 minutes to an hour. In the hearing tests you will be asked to listen to sounds over earphones and tell me if you hear them. There are two more tests where the machine does all the work – I will put a probe in your ear and take some measurements. You can relax during this time. In the balance tests, you will be asked to walk a little, sometimes moving your head, sometime stepping over a box or around cones. Then you will stand for a short time with your eyes open and closed. I will time to see how long you can hold the positions, but it is very quick. I will make a note on all your results. I will tell you what all the tests show and what to do if I pick up any problems.

What do I get out of agreeing?

There is no payment if you join the study. We hope that by understanding how Diabetes can change hearing and balance we might be able to offer help to patients with these problems

Is there anything I should be worried about if I agree?

Both the balance and hearing tests have no indicated risks to them and will be carried out by a qualified professional. Should any abnormalities be detected with the balance and hearing assessments or any other medical concerns that may be discovered you will be referred for further management with the relevant medical professional. You can decide if you want to attend or not.

Do I have to pay for the tests?

You do not have to pay for the tests in this study. You will not be paid for doing the tests, you are a volunteer.

Who will know if I join or not?

All information collected about you during the study will be kept by the researcher and your name will be hidden and a number will be used in place of your name. No marks will be put in your folder and you will not lose your place in the queue if you agree, you will go back to your place when I am finished.

Do I have to join? What if I change my mind?

You can choose not to take part in this study, or if you decide to take part, you can change your mind later and that will not be a problem. Taking part or taking part and changing your mind will not change how the doctors and nurses at the clinic treat you.

Questions:

For the time of the study you are still under the care of your doctor whom you should contact them at any time should you have any concerns. For questions about the study you can contact

Dr Lebogang Ramma at any time on the following contact details (021) 406-6954 and 073 153 380.

This study was reviewed by the University of Cape Town, Faculty of Health Sciences Human Research Ethics Committee. If you have any questions about your rights as a person taking part, or if you wish to make a complaint about the study, you may contact Prof. Marc Blockman, Chairperson of the Faculty of Health Sciences Human Research Ethics Committee at: (021)-406-6626 (Phone) or Email: Marc.Blockman@uct.ac.za

All other questions related to this study can be forwarded to the following individuals:

Vera-Genevey Hlayisi (Researcher) 0718376207 blyver002@uct.ac.za

Dr. Lebogang Ramma (Supervisor) 021-406-6954 Lebogang.Ramma@uct.ac.za

Appendix O: ***Consent Slip (cohort group)***

Division of Communication Science and Disorders
Department of Health and Rehabilitation Sciences
Faculty of Health Sciences, F45 Old Main Building
Groote Schuur Hospital
Telephone: (021) 406 – 6401, Fax: (021) 406 – 6323
Email: vera.hlayisi@gmail.com

Study Title: A study on auditory characteristics and balance functions of diabetic patients

Consent Slip:

This is to confirm that I _____ agree to volunteer to be part of this study and give go-ahead for my patient folder to be reviewed. The study and my joining in it have been clearly explained to me in full to me by the researcher, Vera-Genevey Hlayisi and I understand all the explanations given to me. The questions that I asked were answered to my liking, and I understand that I can stop and not take part in the study at any time if I wish to do so.

Participant: Witness:

I the undersigned have defined and fully explained the study to the above participant. I have also answered all questions raised by the participant.

_____

Researcher

Appendix P: ***Consent Slip (control group)***

Division of Communication Science and Disorders
Department of Health and Rehabilitation Sciences
Faculty of Health Sciences, F45 Old Main Building
Groote Schuur Hospital
Telephone: (021) 406 – 6401, Fax: (021) 406 – 6323
Email: vera.hlayisi@gmail.com

Study Title: A study on auditory characteristics and balance functions of diabetic patients

Consent Slip:

This is to confirm that I _____ agree to volunteer to be part of this study as part of the control group. The study and my joining in it have been clearly explained to me in full to me by the researcher, Vera-Genevey Hlayisi and I understand all the explanations given to me. The questions that I asked were answered to my liking, and I understand that I can stop and not take part in the study at any time if I wish to do so.

Participant Witness

I the undersigned have defined and fully explained the study to the above participant. I have also answered all questions raised by the participant.

_____

Researcher