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THE USE OF MHEALTH TOOLS IN THE EVALUATION OF HEARING AND VISION IN ADULTS WITH DIABETES

By

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- “Whoever dwells in the shelter of the Most High will rest in the shadow of the Almighty. I will say of the Lord that He is my refuge and my fortress, my God, in whom I trust”. Your grace and Your mercy over my life have been the wind beneath my wings, and I know I could not have done this without You. My faith has been the source of strength and comfort throughout my academic journey, and I will be forever grateful to God for His blessings and faithfulness.

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LIST OF ABBREVIATONS

dB	Decibels
DIN	Digits-in-noise
DME	Diabetic macular edema
EHF	Extended high frequency
EHF-PTA	Extended high frequency pure tone average
PTA	Pure tone average
HF-PTA	High frequency pure tone average
Hz	Hertz
IDF	International Diabetic Federation
kHz	Kilohertz
mHealth	Mobile Health
PTA	Pure tone average
SNHL	Sensorineural hearing loss
SNR	Speech-to-noise Ratio
VI	Visual impairment
WHO	World Health Organization

FORMATTING

This research dissertation used APA 7th edition referencing style.

The formatting style of chapter 3 differs from the rest of the dissertation as the article followed the format of the journal of submission.

ABSTRACT

Possible links between diabetes-associated hearing loss (HL) and visual impairment (VI) have been identified in literature. Adults with diabetes are twice as likely to acquire HL and/or VI, compared to adults without diabetes. However, in developing countries, access to hearing and vision services are limited, and usually costly. Additionally, to the researcher's knowledge, there are no published studies on the evaluation of hearing and vision in adults with diabetes using mHealth technology. This study aimed to describe the use of mHealth tools in the evaluation of both hearing and vision in adults with diabetes living in developing countries.

This study utilized a cross-sectional, observational study design, which involved the inclusion of 33 adults between the ages of 21 and 60, who have been diagnosed with diabetes. Participants were recruited from two public institutions in Pretoria, South Africa. Participants were excluded if they self-reported any comorbidities of HL and/or VI, such as history of occupational noise exposure, any neurological impairments, ototoxic exposure, history of traumatic brain injury, history of ear and/or eye infections and surgeries, family history of HL, and currently or previously pregnant in the last 3 months. Validated mHealth applications were used to assess hearing and screen vision, namely the HearTest™, the South African English Digits-in-Noise (DIN), and the PeekAcuity™ using one smartphone device.

The smartphone-based pure tone audiometry revealed the presence of HL in more than one-third (37.8%) of the ears examined, along with majority (86.4%) presenting with elevated extended high frequency thresholds (thresholds above 25 dB HL). Significant correlations were found between increasing age and elevated extended high frequency thresholds bilaterally (r_s= 0.43; p = 0.012), and between the presence of hypertension and all pure tone averages (0.5 – 16 kHz) (r_{pb} range from 0.35 to 0.57; p = <0.001 to 0.043) . No significant association was found for duration of diabetes and presence of HL (p > 0.005). Additionally, more than half (63.6%) of the participants failed the DIN test. Almost one-third (27.3%) of the participants failed the smartphone-based vision screening. Additionally, approximately one-fifth of the participants (21.2%) presented with co-occurrence of HL and VI. Signficant correlations were found between VI and high frequency, and extended high frequency HL (r_{pb} range 0.25 to

0.29; p = 0.017 to 0.046). No significant associations were found for the co-occurrence of HL and VI, and participant variables (age, duration of diabetes, and presence/absence of comorbidities).

A single smartphone utilized different applications to evaluate both hearing and vision in adults with diabetes. Significant correlations were found between HL and VI in this population suggesting a possible link between diabetes and hearing and visual impairments. These findings support previous literature demonstrating link between diabetes-associated VI and HL. These findings further emphasize the importance of regular hearing and vision screening in adults with diabetes. This study suggests that mHealth tools can be an accessible alternative to promote early detection and awareness of hearing and vision services in developing countries.

Keywords: Diabetes; hearing loss; visual impairment; mHealth technology; mobile hearing assessments; mobile vision screening

CHAPTER ONE: INTRODUCTION

1.1 Types and prevalence of diabetes mellitus

Diabetes is a widespread health crisis and is recognized as one of the four most prevalent non-communicable diseases worldwide (World Health Organization [WHO], 2016). Diabetes is a chronic metabolic disease caused by a deficiency of insulin production or the ineffectiveness of the insulin produced (WHO, 2016). There are two main types of diabetes, namely type 1 and type 2. Type 1, which affects 5% of people with diabetes, is caused by insufficient insulin production and requires daily insulin use. The causes and prevention thereof are unknown (WHO, 2016). Type 2, affecting 90% of people with diabetes, is caused by pancreatic cell dysfunction and insulin resistance (Jáuregui-Renaud, 2016; WHO, 2016). Many factors contribute to type 2 diabetes, including family history, gestational diabetes, age, obsesity, physical inactivity, and poor diet and lifestyle (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2022; Oputa & Chinenye, 2012; WHO, 2016).

The International Diabetes Federation (IDF) reported that there are approximately 537 million people living with diabetes globally, with 75% of these cases occurring in developing countries (IDF, 2021). In Africa, there were 24 million reported cases of diabetes which has a predicted increase of 129% (55 million) of cases by 2045. In South Africa, there are approximately 4.2 million adults living with diabetes and diabetes was found to be the second leading cause of death in the country between 2015 and 2017 (IDF, 2020; Statistics South Africa, 2017). Diabetes can lead to several health complications, including cardiovascular disease, stroke, kidney failure, limb amputation, and neuropathy, which significantly increases the risk of premature death (Harding et al., 2019; WHO, 2016).

1.2 Health implications of diabetes mellitus

Adults with diabetes have a deficiency of insulin which causes increased concentration of sugar in the blood, known as hyperglycaemia (Jáuregui-Renaud, 2016). Hyperglycaemia is one of the main causes of the development of microvascular complications (Donnelly, et al., 2000; IDF, 2021; Jáuregui-Renaud, 2016). Abnormal glucose (sugar) metabolism, including extremely low sugar levels, affects the small

blood vessels in the body, leading to damage and failure of various organs and tissues of the body. The tissues and organs include the heart, kidneys, nerves, blood vessels, the eyes, and the inner ear structures (Dahl-Jørgensen, 2007; Goyal & Jialal, 2021; Hall, 2021; Rigon et al., 2007, Rossi, & Cóser, 2007). Strict sugar level control is reported to significantly reduce the risk of damage to these organs (Donnelly, et al., 2000; Konrad-Martin, et al., 2015).

The development of microvascular complications is found to also be dependent on duration of diabetes, with evidence showing the longer the duration, the greater the risk of microvascular disease. The presence of hypertension and a history of smoking were also found to have a negative impact on microvascular function (Donnelly, et al., 2000; Verhulst, et al., 2019). Additionally, concomitant hypertension in adults with diabetes is one of the major risk factors in the incidence and progression of sensory impairments such as hearing loss (HL) and visual impairment (VI) (Bener, et al., 2017; Duck, et al., 1997; Verhulst, et al., 2019).

1.3 Diabetes and hearing loss

In adults with diabetes, HL is attributed to vascular dysfunction in the cochlea, which is caused by the high sugar levels in the blood. The narrowing of capillaries and arterioles induced by hyperglycaemia disrupts the normal functioning of critical hearing structures including the stria vascularis and cochlea (Bener et al., 2017; Hall, 2021; Signia, 2017).

Adults with diabetes are reported to be twice as likely to develop diabetes-associated HL as those without diabetes (Horikawa et al., 2013). Diabetes-associated HL has been widely researched, although a direct causal relationship has not yet been found (Austin et al., 2009; Diniz & Guida, 2009; Hall, 2021; Horikawa et al., 2013; Kim et al., 2017). Literature shows varying prevalence rates of HL in this population, although the general agreement is that adults with diabetes are more susceptible to HL than those without diabetes (Austin et al., 2009; Diniz & Guida, 2009; Hall, 2021; Hlayisi et al., 2019; Horikawa et al., 2013; Kim et al., 2017; Sachdeva et al., 2018; Shin et al., 2021). The wide range of prevalence rates may be attributed to several factors, including but not limited to, coexisting conditions like peripheral neuropathy and cardiovascular disease, which independently increase the risk of HL in the general population, as well as difference in HL classification (Austin et al., 2009; Diniz & Guida, 2009; Hall, 2021;

Hlayisi et al., 2019; Horikawa et al., 2013; Kim et al., 2017; Sachdeva et al., 2018; Shin et al., 2021).

Bilateral sensorineural hearing loss (SNHL) with elevated thresholds at high frequencies was the most common type of HL in adults with diabetes, resembling age-related HL (Diniz & Guida, 2009; Hall, 2021; Hlayisi et al., 2019; Kakarlapudi et al., 2003; Mozaffari et al., 2010; Thomas et al., 2013). Additionally, extended high frequencies (EHF) were also reported to be significantly more elevated in this population than those without diabetes, although EHF audiometry is not readily assessed in clinical practice (Bornman et al., 2019; Das et al., 2018; Vignesh et al., 2015). Several studies found that adults with diabetes commonly struggle with speech discrimination in noise, and this may be attributed to the effect of EHF loss on speech-in-noise comprehension (Axelsson et al., 1968; Bornman et al., 2019; Das et al., 2018; Falahzadeh et al., 2020; Vignesh et al., 2015; Zadeh et al., 2019).

Age, duration of diabetes, and sugar levels were reported to influence the development of HL in adults with diabetes (Konrad-Martin et al., 2015; Mozaffari et al., 2010; Thimmasettaiah et al., 2012; Thomas et al.,2013). Aging and diabetes together accelerate the risk of HL (Kakarlapudi et al., 2003; Konrad-Martin et al., 2015; Mozaffari et al., 2010). Additionally, duration of diabetes has been widely found to increase the risk of HL and severity of HL (Al-Rubeaan et al., 2021; Braffet et al., 2019; Ferrer et al., 1991; Hlayisi et al., 2018; Kim et al., 2017; Malucelli et al., 2012; Mozaffari et al., 2010; Pemmaiah & Srinivas, 2011; Roy et al., 2019). Uncontrolled sugar levels and the presence of hypertension also increase the risk of HL (Braffet et al., 2019; Duck, et al., 1997; Ferrer et al., 1991; Kim et al., 2017; Malucelli et al., 2012; Mozaffari et al., 2010; Roy et al., 2019; Verhulst, et al., 2019).

1.4 Diabetes and visual impairment

Visual impairment (VI) in adults with diabetes is caused by several eye complications including diabetic retinopathy, diabetic macular edema (DME), cataracts, glaucoma and age-related macular degeneration (Jingi et al., 2015; Khan et al., 2016; Zhang et al., 2008). The most common cause of VI in adults with diabetes is due to diabetic retinopathy and DME, which can occur simultaneously (CDC, 2021; Davidson et al., 2017; Jingi et al., 2015; Khan et al., 2016; Lee et al., 2015; Zhang et al., 2008). Diabetic retinopathy is the leading cause of blindness in the working-age population worldwide

(CDC, 2021; Kahloun et al., 2014; Jingi et al., 2015; Lee et al., 2015; Zhang et al., 2008).

Diabetic retinopathy occurs when the glucose in the blood blocks the vessels in the eyes causing microvascular leakage or bleeding, and in compensation, abnormal growth of new blood vessels follows. Signs of diabetic retinopathy usually presents itself with vision problems and/or anatomical abnormalities in the retina (Curtis et al., 2009; Davidson et al., 2007; Donnelly et al., 2000).

Diabetes-associated VI share similar risk factors with diabetes-associated HL such as age, duration of diabetes, uncontrolled sugar levels and high blood pressure (Davidson et al., 2007; Kahloun et al., 2014; Moss et al., 1993; NHS, 2017). The control of glycaemic levels and blood pressure levels were found to significantly reduce the risk of VI (Moss et al., 1993; UK Prospective Diabetes Study, 2004).

1.5 Dual hearing and visual impairment in adults with diabetes

Several studies suggest a link between HL and VI in adults with diabetes, although the exact nature of this relationship is not yet fully understood (Ashkezari et al., 2018; Bener et al., 2016; Goyal & Jialal, 2021; Harding et al., 2019; Kurt et al., 2002; Ooley et al., 2017; Shin et al., 2021). This link may be due to the similar microvascular damage caused by hyperglycaemia in the blood vessels and nerves in the ears and eyes, and the shared risk factors of diabetes-associated HL and VI (Ashkezari et al., 2018; Bener et al., 2016; Dahl-Jørgensen, 2007; Hall, 2021; Konrad-Martin et al., 2015; Rigon et al., 2007; Ooley et al., 2017).

There are few studies focused on the presence of both sensory impairments as most studies focused on individual sensory impairment associated with diabetes. Only two studies reported associations between the severity of diabetes-associated VI and degree of HL (Ooley et al., 2017; Shin et al., 2021). Additionally, literature also reported that adults with diabetes-associated VI were more likely to acquire HL than those without diabetes-associated VI (Kurt et al., 2002; Ooley et al., 2017; Shin et al., 2021). Several studies indicated that diabetes-associated HL and VI pose a significant burden on adults with diabetes, as the co-occurrence of these sensory impairments can significantly impact a person's quality of life and ability to perform daily tasks including effective communication, mobility, retain employment and effectively manage diabetes

(Ashkezari et al., 2018; Shin et al., 2021; WHO, 2019; WHO, 2019). Therefore, to reduce the impact of diabetes-associated HL and VI, research indicates that detecting and monitoring HL, VI, retinal status, and sugar levels at an early stage can effectively prevent or delay the onset of diabetes-associated HL and VI. Identifying sensory impairment in its early stages can aid in providing prompt and effective treatment and intervention for adults with diabetes (Ellis, et al., 2013; Heydari, et al., 2012; Kader & Mohamed, 2020; Konrad-Martin, et al., 2015; Wang & Lo, 2018). However, people living in developing countries may face several challenges in accessing timely and appropriate care due to lack of access, quality and affordability in these settings (Bastawrous et al., 2015; Eksteen et al., 2019; Potgieter et al., 2018; Rono et al., 2018; Swanepoel et al., 2014).

1.6 The role of mHealth tools in diabetes mellitus

In the Southern Sub-Saharan region, there is approximately 39 audiologists and 53 optometrists per million population (Naidoo et al., 2022; Pillay et al., 2020). Although the availability of these health professionals seem adequate in provision of these services, the poor distribution in public and private sectors as well as rural and urban settings is a great barrier to access of these services. For example, majority of audiologists (78%) provide private healthcare, whereas most of the individuals living in poor communities requiring these services cannot afford healthcare in the private sector (Pillay et al., 2020). Similarly, the need for eye care in rural settings is typically far greater than the need in urban settings, yet very few eye-related professionals choose to work in rural settings (Gilbert & Patel, 2018). Hence, individuals living in the poorer communities of developing countries, do not have sufficient access and affordability to hearing and vision services.

Therefore, the use of novel technology such as mobile health technology (mHealth) may address these challenges faced by individuals requiring hearing and vision services. Research in mHealth technology has grown rapidly in driving the potential of transformation in healthcare systems by significantly improving service delivery, specifically for people living in developing countries (Bastawrous et al., 2015; Eksteen et al., 2019; Oosthuizen et al., 2023; Osei & Mashamba-Thompson, 2021; Swanepoel et al., 2014). Literature has shown that mHealth tools can be effective in various medical conditions including screening of non-communicable diseases such as

hypertension, diabetes, cancer, HL and VI (Bastawrous et al., 2015; Eksteen et al., 2019; Oosthuizen et al., 2023; Osei & Mashamba-Thompson, 2021; Swanepoel et al., 2014). mHealth tools can screen for diseases, surveillance disease, and empower patients and healthcare workers through self-monitoring devices, and online guidelines and referrals services (Oosthuizen et al., 2023; Osei & Mashamba-Thompson, 2021). The use of mHealth technology enables early detection of diseases, improved communication between patients and healthcare workers, improved treatment compliance and assist in retaining patients through cloud-based data management, appointment reminders (via text message), and remote referral system (Eksteen et al., 2017; Hussein et al., 2018; Oosthuizen et al., 2023; Osei & Mashamba-Thompson, 2021; van Olmen et al., 2020).

Several mHealth tools have been validated and have demonstrated prominent success in the provision of hearing and vision screening in developing countries. mHealth tools can be administered by minimally trained community health workers which has the potential to optimize human resources in developing countries, where the unemployment rate is high (Eksteen et al., 2017; Manus et al., 2021; O'Neil, 2023). Several studies have shown the feasibility of community-based dual screenings and showed that the mHealth model offers a way to improve the affordability, quality and access of hearing and vision services, as well improve engagement and awareness of hearing and visual impairment in developing countries (Eksteen et al., 2019; Hussein et al., 2018; Manus et al., 2021).

1.7 Study rationale

This study aims to describe the use of mHealth tools in evaluating both hearing and vision in adults with diabetes. To the best of the researcher's knowledge, no published studies have explored the application of mHealth technology in the evaluation of HL and VI in adults with diabetes. By investigating the use of mHealth tools, this study explores a novel approach to the assessment and management of sensory impairments in this population, and may inform policymakers, healthcare providers and stakeholders on the benefits of integrating mHealth technology in the management of adults with diabetes.

CHAPTER TWO: METHODOLOGY

2.1 Research aim and objectives

The main aim of this study was to describe the use of mHealth tools in the evaluation of both hearing and vision in adults with diabetes mellitus.

Objectives:

1. To describe auditory function using mHealth smartphone-based application in adults with diabetes mellitus

2. To detect visual impairment through screening using an mHeath smartphone-based application in adults with diabetes mellitus

3. To describe the co-occurrence of hearing loss and abnormal vision in adults with diabetes

2.2 Research design

The current study employed a cross-sectional and observationaldesign. Observational studies are conducted in natural settings and reflect real-life situations (Shadish et al., 2002). This means that they have high external validity and makes them better suited for studying phenomena that are difficult to replicate in a laboratory setting, such as social interactions or environmental factors (Shadish et al., 2002).

Adults diagnosed with diabetes attending the diabetic clinics at a district and tertiary hospital were recruited. Adults who consented to participate underwent a brief case history questionnaire, and smartphone-based hearing assessment and vision screening.

2.3 Ethical considerations

Ethical clearance was obtained (Appendix A) from the Research Ethics Committee of the Faculty of Humanities and the Faculty of Health Sciences, University of Pretoria (HUM010/0121). Furthermore, ethical approval was granted by the Gauteng

Department of Health (GP_202202_056) to conduct data collection at two public facilities in the Tshwane region (Appendix B). Odi District Hospital and Steve Biko Academic Hospital provided permission for the research to take place (Appendix C). Ethical approval included permission to approach diabetic patients, access records/files of patients with diabetes mellitus and to conduct a hearing assessment and a visual screening on consenting patients at these institutions. All ethical considerations where human participants are involved, including voluntary and informed consent, protection of harm, and confidentiality were adhered to in this study (Leedy & Omrod, 2015).

Voluntary and Informed consent

Written and/or verbal informed consent forms were obtained from all the research participants (Appendix D). This study complied with the local research and ethical requirements of the Declaration of Helsinki (1964).

Protection of harm

Researchers are obligated to protect participants from any physical or psychological harm (Leedy & Omrod, 2015). During this study, the researcher handled all research participants with respect and dignity and provided ample opportunity for participants to ask questions or raise concerns once all the relevant information had been given to them. Individuals who consented to participate in the study were involved in active research by undergoing hearing assessment and vision screening with the use of mHealth tools. The mHealth tools used in this study were non-invasive. Participants were also assured that they had the right to withdraw from the study at any given time. Prior to the commencement of the testing, each participant underwent a Covid-19 screening (Appendix E) and thereafter, Covid-19 protocols were implemented throughout the procedures. Below is the list of protocols that were followed:

- Both the participant and primary investigator were required to wear a 3-ply face mask correctly throughout interaction and testing. The primary investigator made use of a face shield for further prevention of the spread of Covid-19.
- The primary investigator ensured the physical distance of 2 meters between each participant in the waiting area.

- The primary investigator ensured the waiting area and the area of testing were well-ventilated. The primary investigator also ensured to regularly decontaminate all frequently touched surfaces in the waiting area and the area of testing, and all the equipment used in testing before and after consulting with a participant.
- The primary investigator practised good hand hygiene by hand washing with soap and water for at least 20 seconds and sanitizing of hands with at least 70% alcohol. Hand washing and/or sanitizing were done before touching a participant, before the procedure, after touching the participant, and after touching surroundings and participant's file. The participants' hands were also sanitized before and after testing.

Risks and benefits of the research study

There were no risk of physical, psychological, social/economical and loss of confidentiality involved in participating in this study due to the non-invasive nature of the equipment. Participants were made aware of no risks and Covid-19 protocols were adhered to, to reduce the risk of spreading the virus (Appendix E). The participants did not directly benefit from the study but the results assisted participants in early detection of any possibile hearing and/or vision problems. Early detection of hearing and/or visual problems is important for prevention or delay of total sensory loss (Konrad-Martin, et al., 2015; Ellis, et al., 2013). If hearing and/or visual problems were detected, participants were then referred to the Department of Audiology and/or the Department of Ophthalmology at the relevant institution, where further investigation and management may occur (Appendix F).

Confidentiality

Personal information, hearing assessment and visual screening results from participants were kept strictly confidential in the data analysis and reporting process. To ensure the confidentiality of the participants, a numeric code was allocated to each participant (i.e. T1-T1; T1-T2 for type 1 diabetes participants and T2-T1; T2-T2 for type 2 diabetes participants). The participant's data is currently stored in a password-protected format and information was reported using this numeric code. This code is only known to the primary researcher and academic supervisors.

Data storage and sharing of results

All data obtained from consenting participants were stored in the application's internal storage of the smartphone device and were manually recorded on the data collection sheet (Appendix H). The data was also recorded on an electronic Microsoft Excel spreadsheet that was only accessible to the primary researcher and academic supervisors. All soft copies will be stored on the University of Pretoria's research repository. The data collection sheets and signed informed consent forms will be archived in the Speech-Language Pathology and Audiology building at the University of Pretoria for 15 years. The findings of this study is intended to be used to publish a scientific research article and postgraduate dissertation, of which these findings can be accessed for academic and research use.

2.4 Research participants

Potential participants were identified with the help of the healthcare workers at the respective hospitals and were invited to participate in the study as part of their routine check-up.

Participant selection

The researcher obtained informed consent from the potential participants prior to accessing their files and observing medical history. The participants who consented were taken to a low noise level room on the same floor as the diabetic clinic at the relevant institution to answer a brief case history questionnaire (Appendix G). The case history questionnaire relied on participants' self-reported medical and personal history. Participants with diabetes aged between 18 to 60 years were included in this study. Participants were excluded from this study if they presented with any comorbidities of HL and/or VI including: history of occupational noise exposure; any neurological impairments (i.e. cardiovascular accident); ototoxic exposure; history of traumatic brain injury; history of ear and/or eye infections and surgeries; family history of hearing loss; currently pregnant or pregnant in the last 3 months; abnormal otoscopy (i.e. impacted wax or ear infection); type B and type C tympanograms; Covid-19 symptoms. The exclusion criteria were selected due to each criterion being identified as a comorbidity of HL and/or VI in the general population (Atkins, et al., 2008; Hall, 2021; Palomer, et al., 2001).

2.5 Material and equipment for participant selection

Table 1 indicates the materials and equipment used for participant selection.

Table 1

Materials and equipment used to select participants

Equipment	Rationale	Procedure
Covid-19 screening tool	Checklist for the researcher to screen participants for any signs and symptoms of the Covid-19 virus based on the comprehensive review by Esakandari et al. (2020).	The researcher asked each participant whether they presented with any signs and symptoms of Covid-19 such as flu-like symptoms, lack of taste and smell, and body malaise (Esakandari et al., 2020). This information was recorded on the Covid-19 register (Appendix E). Participants who presented with these symptoms were referred to the doctor at the respective institution for further management.
Case history questionnaire	This tool was used to investigate suitability of the participants for the study based on the inclusion and exclusion criteria.	Participants were interviewed with the questionnaire and information was recorded on the data collection sheet (Appendix F), if any risk factor was identified, participants were excluded from the study.
Welch-Allyn Pocketscope™ (Hillrom, New York, United States)	This otoscope was used to visually inspect the tympanic membrane and external ear canal.	This was done to observe any problems in the external auditory meatus such as inflammation, wax impaction, acute otitis media, perforation of the tympanic membrane, and cholesteatoma (Falkson & Tadi, 2020). This information was recorded on the data collection sheet (Appendix F). Participants who presented with abnormal otoscopic examinations

		were excluded from the study and were referred to the audiologist at the respective institution (Appendix H).
Amplivox Otowave 102 – Middle ear tympanometer screener (Amplivox Ltd, Kent, United Kingdom)	This middle ear tympanometer screener was portable and conducted tympanometry. Tympanometry determined the middle ear functioning of the participants	Tympanometry was used to further investigate and confirm otoscopy that may reveal external ear canal condition or middle ear pathologies (Louis et al., 2012). This information was recorded on the data collection sheet (Appendix F). Participants who were presented with any ear condition or pathology were referred to the audiologist at the relevant institution (Appendix H) and excluded from the study.

2.6 Materials and equipment for data collection

Table 2 indicates the applications used in the data collection procedure with a Samsung A3 smartphone connected to Sennheiser HDA 300 headphones, which were calibrated according to the ISO calibration standards (ISO 389-9).

Table 2

Materials and equipment for data collection

Equipment	Rationale
hearTest™ smartphone application (hearX Group, Pretoria, South Africa) connected to Sennheiser HDA 300 headphones (Sennheiser, Wedemark, Germany)	The application was selected for this study as it is an affordable, and more time efficient tool to use than a conventional audiometer that requires a soundproof booth and compared to other costly equipment that can also be used for screening (Bornman et al., 2019; Swanepoel et al., 2016). This application determined air conduction thresholds at 250, 500, 1000, 2000, 4000 and 8000 Hz. Furthermore, this application tested extended high frequencies (10 kHz to 16 kHz). Extended high frequencies audiometry is reported to be clinically useful in detecting early onset of hearing loss in adults with diabetes as these frequencies are commonly affected first (Das et al., 2018; Vignesh et al., 2015).

South African English Digits-in-Noise test (hearX Group, Pretoria, South Africa)	This speech-in-noise test was selected as it accommodates individuals in multilingual populations such as South Africa, where English digits are familiar to non-native English speakers . Additionally, the inclusion of this DIN test was because literature found that adults with diabetes commonly struggle with speech recognition in noise (Axelsson et al., 1968; Falahzadeh et al., 2020; Prabhu & Shanthala, 2016). Furthermore, individuals who experience hearing loss at extended high frequencies usually find it difficult to hear speech in noise (Bornman et al., 2019; Hunter et al., 2020; Zadeh et al., 2019). Thus, it is important for this test to be used in this study to investigate the real-life hearing abilities of this population (Hall, 2021; Zadeh et al., 2019)
Smartphone with PeekAcuity™ application (Peek Vision, London, United Kingdom)	This screening tool was selected due to its accurate and reliable method of detecting change in vision (Bastawrous, et al., 2015). This software follows the standard of Early Treatment of Diabetic Retinopathy Study (ETDRS) charts with the 5x5 grip optotype of the letter “E” presented in one of the four orientations including 90°, 180°, 270° and 0° (Bastawrous, et al., 2015). The use of the “E” allows for individuals who may be illiterate to also be screened (Bastawrous et al., 2015; Rono et al., 2018). This tool was also selected as it can be administered by a non-eye specialist (Bastawrous et al., 2018; Eksteen et al., 2017).

2.7 Reliability and validity of equipment

Reliability describes the consistency of a measure. It implies that the same result will be obtained when the same method of measure is used at any given time (Heale & Twycross, 2015). Validity describes the extent to which an instrument accurately measures what it is intended to (Heale & Twycross, 2015). In this study, the researcher conducted routine clinical tests on all equipment used and each instrument has established reliability and validity in a clinical setting. Table 3 indicates the reliability and validity of equipment used in data collection.

Table 3

Reliability and validity of equipment

Test	Reliability and Validity
Hearing assessment	The smartphone was connected to Sennheiser HDA300 headphones, which was calibrated according to the ISO calibration standards (ISO 389-9) to ensure valid test results. The researcher conducted daily biological

	checks on the equipment prior to testing participants to ensure reliability of function and instrument validity. The HearTest™ test has been validated by van Tonder et al. (2017) and provides accurate and reliable air conduction thresholds including extended high frequencies (Bornman et al., 2019; Corona et al., 2020; Sandstrom, et al., 2020). The South African English DIN test has been validated and results obtained have agreed well with previously developed smartphone-based DIN tests (Potgieter, et al., 2016; Smits, et al., 2004).
Vision screening	The PeakAcuity™ software provides accurate, reliable and repeatable visual acuity results (Bastawrous et al., 2015; Satgunam et al., 2021; Venecia et al., 2018). They have been verified and validated through the use of 5-letter-per-line retroilluminated logMAR charts (Bastawrous et al., 2015).

DIN – Digits-in-noise

2.8 Data collection procedure

The researcher ensured that each participant understood the purpose of the study and signed the informed consent form. They were then stationed in a separate room with lower noise levels on the same floor as the diabetic clinic at the relevant institution.

Air conduction pure tone audiometry

The primary researcher ensured that consultation room had minimal background noise. Air conduction audiometry was conducted to determine thresholds from 0.5 to 16 kHz. Participants were instructed to listen for the tone through the headphones and if heard, they should raise their hand to indicate the tone was heard. If they did not hear the tone, they should not raise their hand. Participants were reassured that even if the tone heard was very soft, they should still raise their hand indicating the tone was heard. The test commenced by the presentation of a series of tones at different frequencies, from 0.5 to 16 kHz (Swanepoel et al., 2014; van Tonder et al., 2017). At each frequency, the tone was presented at 25 dB HL. If participants raised their hand (confirmed response), the primary researcher pressed the “heard” button on the phone indicating a confirmed response. The tone was automatically decreased by 10 dB on the smartphone. If the participants did not raise their hand (no response), the primary researcher pressed the “not heard” button and the smart phone automatically

presented a tone that was 5 dB higher than the previous tone. Once the participant provided two confirmed responses to the same intensity, this was automatically recorded as the hearing threshold at that frequency. If a participant did not respond to the maximum intensity level, this was recorded as 'no response' at that frequency (Swanepoel et al., 2014; van Tonder, et al., 2017).

Once each test was complete, the researcher recorded the thresholds on the data collection sheet (Appendix G). In epidemiological and population-based studies, the most commonly used definition for pure tone average (PTA) is the four-frequency average of thresholds at low to high frequencies (0.5, 1, 2, and 4 kHz), which was calculated by the researcher (Gates & Hoffman, 2011). Furthermore, the researcher calculated the hearing thresholds at mid to high frequencies (2, 4, and 8 kHz) referred to as the higher frequency PTA (HF-PTA). Additionally, the extended high frequency PTA (EHF-PTA) was also calculated at the extended high frequencies (10, 12.5, and 16 kHz). In this study, normal hearing was considered for PTA thresholds less than 25 dB HL (WHO, 2021).

Digits-in-Noise (DIN) test

The DIN test was completed after pure tone audiometry. The DIN test was used to determine speech recognition in noise (Potgieter et al., 2018; Smits, et al, 2013). The primary researcher instructed the participant to listen to the three digits presented binaurally and to indicate when the volume of the digits was at a comfortable listening level (Potgieter, et al., 2018). The researcher adjusted the volume accordingly. Participants were instructed to repeat the three digits heard and if unsure, they were encouraged to guess the numbers. The primary researcher typed the recalled three digits onto the keypad of the smartphone. When the participant recalled the incorrect three digits, the signal-to-noise ratio (SNR) was automatically increased by 2 dB and when a correct response of three digits was recalled in order, the SNR was decreased by 2 dB. The test was comprised of 24-digit triplets and an average SNR was estimated by the application based on 50% of participant's correctly recalled three digits (Potgieter, et al., 2017). The participant's SNR was recorded on the data collection sheet by the primary researcher (Appendix G). A failed response was considered for SNR values greater than -8.4 dB (Potgieter et al., 2017).

Vision screening

Each participant was instructed to place their head on the wall behind them to ensure there was no head movement. Participants were instructed to cover their non-test eye with the palm of their hand. Participants were instructed to point in the direction of the "arms" of the letter "E" and if they were uncertain, they were encouraged to guess the direction (Bastawrous et al., 2015). Once the primary researcher ensured that the participant understood the instructions, the primary researcher stood 2 metres away from the participant with the smartphone. The primary researcher held the smartphone device at eye level to the participant, and swiped in the direction that participant indicated. If the participant could not see, the tester shook the phone to record inability to see the "E" (Bastawrous et al., 2015). Once the screening had ended, visual acuity scores were given in standard scores of Snellen including metric (6/6), imperial (20/20) and LogMAR (0.0). For the purpose of this study, only the LogMAR score was observed and recorded on the data collection sheet (Appendix G). Participants with a score of 0.3 or more was considered a failed response (Eksteen et al., 2021; Lamoureux, et al., 2008; Manus, et al., 2021).

Means of referral

Participant who obtained normal results for hearing test and/or vision screening were provided with a feedback letter indicating normal hearing and/or normal vision, and were encouraged to annually screen hearing and vision (Appendix H). Participants who obtained PTA thresholds above 25 dB HL were referred to the Audiology department at the respective institution for diagnostic assessment (Appendix F). According to WHO (2019), PTA thresholds above 20 dB HL are considered a HL. Participants who obtained LogMar scores greater than 0.6 were referred to the eye clinic at the respective institution for diagnostic assessment and intervention (Lamoureux, et al., 2008; Manus, et al., 2021) (Appendix F).

2.9 Data processing and analysis

Slight HL was recognized at PTA thresholds between 16 – 25 dB HL, although this was not classified as a signficant HL in this study. HL was classified as mild HL for PTA thresholds between 26 - 40 dB HL. Moderate HL was considered for PTA thresholds between 41 – 55 dB HL, moderately-severe for PTA between 56 – 70 dB HL, and severe for PTA above 71 dB HL (Clark, 1981; WHO, 2019). Additionally, a

difference of 15 dB HL at three adjacent frequencies between both ears was considered a asymmetrical HL (Djalilian, 2015).

All raw data was captured onto a Microsoft Excel spreadsheet in numerical format. All PTAs (PTA, HF-PTA & EHF-PTA) were calculated on the spreadsheet. Any duplicate or incomplete entries were excluded during the data cleaning process. Participants who had no responses for certain frequencies during pure tone audiometry, an additional 10 dB was added to the maximum output level of the audiometric test and that value was included in the analysis. Table 4 shows the number of no responses for every frequency tested.

Table 4

Number of no responses for every frequency tested (n= 92)

Frequency (kHz)	Maximum output level (dB HL)	Number of no responses (*n*)
0.5	90	1
1	90	0
2	90	0
4	90	0
8	75	1
10	65	3
12.5	60	31
16	40	56

kHz = kilohertz; dB HL = decibels in hearing level

All data was captured in a Microsoft Excel spreadsheet for analysis. Hearing thresholds (all PTAs), DIN scores and LogMar scores were used as continuous data and were categorized into pass or fail for statistical purposes. Hearing tests were considered a “pass” for all PTA thresholds below 26 dB HL, and a “fail” for all PTA thresholds above 25 dB HL.

Statistical Package for the Social Sciences (SPSS, v28.0. Chicago, Illinois) was used for statistical analyses using a 5% level of significance. The Shapiro-Wilk test was used to test for normality. For most of the continuous variables in the data set (age, frequency thresholds, PTAs, DIN scores, LogMar scores), the p-value was less than 0.05 and therefore, the data differed from normality, and non-parametric tests were used. Descriptive statistics such as frequency tables, means (M), standard deviations (SD), medians (Mdn) and interquartile ranges (IQR) were calculated.

Mann-Whitney (MW) test was used to test whether there is a significant difference in hearing thresholds (PTAs, HF-PTAs & EHF-PTAs) between two groups of participants with different variables such as participants with type 1 diabetes and type 2 diabetes, and participants with hypertension and those without hypertension.

Kruskal-Wallis (KW) test was used to compare hearing thresholds of participants using different modes of treatment (i.e. insulin injections, oral medication or both). When significant differences were found using the KW test, pairwise comparisons were used to indicate where the significant differences were between the categories of mode of treatment.

Correlations and association coefficients were used to measure a monotonic association and to estimate the strength of association between hearing thresholds and vision screenings (PTA scores and pass/fail LogMar), and participant variables and data (sex, age, duration of diabetes, presence and/or absence of comorbidities, modes of treatment). Spearman's correlation (r_s) was used to investigate the association between PTA thresholds and LogMar scores, and continuous participant variables (age and duration of diabetes). Point-biserial correlation (r_{pb}) was used when correlating a continuous participant variable and a binary variable (e.g., PTA and sex), and Phi coefficient (φ) was used when investigating the association between two binary variables (e.g., male/female and pass/fail).

In the results section of chapter three, the tables presenting correlations and association results include subscripts CV and BV to indicate whether the variables are continuous or binary, respectively. For binary variables, the coding and description of the categories were provided, such as ""Sex_{BV} (0=male,1=female)". This has been done as the interpretation of these variables are influenced by the coding of the categories.

The absolute values of correlations and associations were interpreted as follows:

[0 (none), $0<r<0.3$ (poor), $0.3\leq r<0.6$ (fair), $0.6\leq r<0.8$ (moderate), $0.8\leq r<1$ (very strong correlation), 1 (perfect)] and those of Phi coefficients [0 (none), $0<\varphi \leq 0.05$ (very weak), $0.05<\varphi \leq 0.10$ (weak), $0.10<\varphi \leq 0.15$ (moderate), $0.15<\varphi \leq 0.25$ (strong), $0.25<\varphi \leq 1$ (very strong), 1 (perfect)] (Akoglu, 2018).

CHAPTER THREE: RESEARCH ARTICLE

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TITLE: THE USE OF MHEALTH TOOLS IN THE EVALUATION OF BOTH HEARING AND VISION IN ADULTS WITH DIABETES

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Note: This chapter has been modified to meet the editorial requirements of the journal and may differ from the rest of the document.

3.1 Abstract

Background/Purpose: Literature suggests a link between diabetes-associated hearing loss (HL) and visual impairment (VI). Research recommends regular hearing and vision screening in adults with diabetes. However, in developing countries, hearing and vision services are limited. This study aimed to describe the use of mobile health (mHealth) tools in the evaluation of both HL and VI in adults with diabetes living in developing countries.

Methods: A cross-sectional, observational study design was employed with 33 adults with diabetes between the ages of 21 and 60 years, who were recruited from two institutions in South Africa. Participants were excluded if they presented with any comorbidities of HL and/or VI. Validated mHealth tools, namely HearTest™, South African English Digits-in-Noise (DIN), and the PeekAcuity™ were used to assess hearing and screen vision.

Results: Approximately one-third of the sample (37.8%) presented with HL. Almost two-thirds (63.6%) of the participants struggled with speech recognition-in-noise. Less than one-third (27.3%) failed the smartphone-based vision screening. Co-occurrence of HL and VI was observed in approximately one-fifth of the participants (21.2%).

Conclusion: A single smartphone utilized different applications to evaluate both hearing and vision in adults with diabetes. Significant correlations were found between VI and high frequency HL (4 – 16 kHz). The findings of this study support previous literature demonstrating a link between diabetes and sensory impairments, and further emphasizing the importance of regular hearing and vision screening in this population. This study suggests that mHealth technology can be an accessible alternative to promote earlier detection and awareness of hearing and vision services in developing countries.

Keywords Diabetes • hearing loss • visual impairment • mHealth technology • mobile hearing assessments • mobile vision screening

3.2 Introduction

Diabetes is a chronic metabolic disease characterized by high levels of sugar in the blood, which can lead to a range of complications affecting different parts of the body [1-3]. Among these complications, hearing loss (HL) and visual impairment (VI) are common [1-14]. Adults with diabetes are twice as likely to develop diabetes-associated HL compared to adults without diabetes, although a direct causal relationship has not yet been found [3]. Literature reported diabetes-associated HL commonly presents at high frequencies [2-4]. VI in adults with diabetes is commonly caused by diabetic retinopathy, which is the leading cause of blindness in the working-age population [10-12]. Both diabetes-associated sensory impairments have been related to age, uncontrolled sugar levels, duration of diabetes and hypertension [1-6, 10-14].

Several studies suggest a link between HL and VI, although the exact nature of this relationship is not yet fully understood [17-22]. This link may be due to the similar microvascular damage caused by high levels of sugar in the blood vessels and nerves in the ears and the eyes [2, 17-19]. Literature indicates that diabetes-associated sensory impairments pose a significant burden on adults with diabetes, as the co-occurrence of HL and VI can significantly impact quality of life of this population [19-21]. Therefore, research recommends regular hearing and vision screenings, as early detection and timely treatment may prevent or delay the onset of these diabetes-associated sensory impairments [1-14]. However, individuals living in developing countries may face several challenges in accessing timely and appropriate care in these settings [26-29].

The use of novel and cost-effective mobile health (mHealth) technology may address these challenges [26-29]. mHealth vision screening tools can reliably and accurately detect abnormal vision [26, 29]. The mHealth hearing tests have shown high sensitivity and specificity in diagnostic accuracy of HL [27-29]. The use of mHealth technology offers decentralized service provision, real-time patient monitoring, and distribution of health information. This technology also promotes early detection and intervention, and may reduce the burden on the public health care systems and improve quality of life of adults with diabetes living in developing countries [26-29].

There is, however, limited research on the prevalence of co-occurrence of diabetes-associated HL and VI, despite several studies suggesting that there may be a higher

risk of both sensory impairments in adults with diabetes compared to those without the disease [15-20]. To the best of the researcher's knowledge, there are no published studies on the use of mHealth technology in the evaluation of both hearing and vision in adults with diabetes. Therefore, this study aimed to describe the use of mHealth tools in the evaluation of both HL and VI in adults with diabetes living in developing countries.

3.3 Materials and Methods

Ethical clearance was obtained from the Research Ethics Committees of Faculties of Humanities and Health Sciences, University of Pretoria (HUM010/0121) prior to data collection. This study adhered to the ethical principles outlined by the Declaration of Helsinki (1964).

The current study employed a cross-sectional and observational design. Adults with diabetes attending the diabetic clinic at a district and tertiary hospital in South Africa were recruited. Adults who consented to participate were stationed in a low noise level room. Participants underwent a brief case history questionnaire, otoscopy, tympanometry, and smartphone-based hearing assessments, and smartphone-based vision screening.

Participants

Adults between the age of 18 and 60 years attending their regular check-up at the diabetic clinics were invited to participate in the study. Individuals were excluded from this study if they self-reported comorbidities of HL and/or VI in the general population [2, 9]. These comorbidities included exposure to ototoxic medication, history of occupational noise exposure, history of head trauma, history of neurological impairments, smoking, abnormal otoscopy and tympanometry, older than 60 years of age, and pre-existing HL.

A total of 43 individuals provided consent to participate in this study. Ten individuals were excluded from this study due to occupational noise exposure (n = 4, 40%), ototoxic medication exposure (n = 5, 50%), and age (n = 1; 10%). Therefore, the study sample consisted of 33 participants, with the majority being female (n = 24, 72.7%). The mean age was 49.36 years (SD = 12.66; range 21-60). The majority of the participants (n = 27, 81.8%) presented with type 2 diabetes, with the remaining

participants with type 1 diabetes. More than half (*n* = 17, 51.5%) presented with a duration of diabetes for less than 5 years (*SD* = 7.23; range 0-29). Additionally, approximately sixty percent of the participants (*n* = 20, 60.6%) reported concomitant hypertension, and less than a third (*n* = 10, 30.3%) reported the absence of comorbidities.

Data collection

The first researcher conducted data collection. Participants were interviewed to collect information in terms of type of diabetes and treatment, duration of diabetes, and presence of comorbidities. Thereafter, participants underwent otoscopic examination and tympanometry to ensure the absence of outer and middle ear disease.

mHealth technology

A Samsung Galaxy A3 was used for three applications, namely HearTest™, South African English digits-in-noise (DIN) test and PeekAcuity™. The smartphone was connected to Sennheiser HDA300 headphones, which were calibrated appropriately (ISO 389-9). The validated HearTest™ was selected as it enabled behavioural audiometry at conventional frequencies (0.5 – 8 kHz) and at extended high frequencies (EHF) (10 – 16 kHz) without a sound-proof booth. The inclusion of EHF audiometry was deemed advantageous as studies have shown that adults with diabetes commonly present with HL at frequencies higher than 9 kHz [22-25]. The presence of EHF HL has shown to negatively affect speech discrimination in noise, therefore, the validated South African English DIN test was included in the test battery as a functional test of speech in noise [23-25]. The validated PeekAcuity™ application was selected due to its accurate and reliable method of detecting change in vision and can be administered by a non-eye specialist [26].

Data collection procedure

The researcher conducted behavioural audiometry. Participants were instructed to indicate (by raising their hand) whether they heard the tone, and the lowest intensity that the participant responded twice to was indicated on the smartphone as the hearing threshold at that frequency (0.5 – 16 kHz) [24, 28]. Three averages of behavioural audiometric thresholds were calculated, namely, the pure tone average (PTA) using thresholds at 0.5, 1, 2 and 4 kHz, the high frequency PTA (HF-PTA) at 2, 4, and 8 kHz,

and the EHF-PTA at 10, 12.5 and 16 kHz. A HL was considered for all PTA calculations above 25 dB HL.

After audiometry, the researcher conducted the DIN test. Participants were instructed to listen and repeat three digits presented to both ears simultaneously, in the presence of background noise. If participants were unsure, they were encouraged to guess. The researcher typed the recalled three digits onto the keypad. The adaptive nature of this test estimates the speech perception thresholds, which is the signal-to-noise (SNR) where the participant correctly recall 50% of the digit triplets. A failed response was considered for SNR greater than -8.4 dB [27].

Once the hearing tests were conducted, the researcher conducted the vision screening using the “tumbling E” on the smartphone. Participants were instructed to place their heads against the wall behind them and cover the non-test eye with the palm of their hands. They were instructed to point in the direction of the “arms” of the letter “E” and if they were uncertain, they were encouraged to guess the direction. The researcher stood two metres away from the participant, holding the smartphone at the participant’s eye level and swiped in the direction indicated by the participant. If the participant indicated that they could not see the direction of the “E”, the researcher shook the smartphone to indicate the participant’s inability to see the letter on the screen. Once the screening was complete, a LogMar score was shown on the screen and recorded. A LogMar score greater than 0.2 was considered as abnormal visual acuity [26].

All data was captured in a Microsoft Excel spreadsheet for analysis. Hearing thresholds (all PTAs), DIN scores and LogMar scores were used as continuous data and were categorized into pass or fail for statistical purposes. Participant variables such as age, type of diabetes, duration of diabetes, mode of treatment and other conditions were all self-reported and were not verified.

The Statistical Package for the Social Sciences (SPSS, v28.0. Chicago, Illinois) was used for statistical analyses using a 5% level of significance. The Shapiro-Wilk test was used to test for normality and for most of the continuous variables (age, audiometric frequencies, PTAs, DIN scores, LogMar scores) $p<0.05$; therefore, the data differed from normality, and non-parametric tests were used. Descriptive statistics, namely frequency tables, means (*M*), standard deviations (*SD*), medians

(*Mdn*) and interquartile ranges (*IQR*), were calculated. The Mann-Whitney (Z_{MW}) test was used to test whether there was a significant difference in hearing thresholds of independent groups e.g., type of diabetes (type 1 or type 2), hypertension (absence or presence). The Kruskal-Wallis (KW) test was used to compare hearing thresholds of participants using different modes of treatment (e.g. insulin injections, oral medication or both). When significant differences were found using the KW test, Dunn's (Z_{Dunn}) pairwise comparisons were used to indicate where the significant differences were between modes of treatment.

Correlations and association coefficients were used to measure monotonic association and to estimate the strength of association between hearing thresholds and vision screenings, and participant variables (sex, age, duration of diabetes, presence/absence of comorbidities, and modes of treatment). Spearman's correlations (r_s) were used to investigate the association between PTA thresholds and LogMar scores, and continuous participant variables (age and duration of diabetes). Point-biserial correlations (r_{pb}) were used when correlating a continuous variable and a binary variable (e.g., PTA and sex), and Phi coefficients (φ) were used when investigating the association between two binary variables (e.g., male/female and LogMar pass/fail).

3.4 Results

Table 1 presents the behavioural audiometry findings using different PTAs per ear (*n* = 66). Most of the participants presented with symmetrical, bilateral hearing abilities (*n* = 28, 84.8%), with the remainder presenting with asymmetrical hearing abilities (*n* = 5, 15.2%). More than one-third of the sampled ears (*n* = 25, 37.8%) presented with HL, along with high prevalence (*n* = 57, 86.4%) of EHF HL (see Table 1).

Table 1

Behavioural audiometry findings using different pure tone averages (n = 66)

Classification	PTA [*n*(%)]	HF-PTA [*n*(%)]	EHF-PTA [*n*(%)]
Normal hearing	13 (19.7%)	20 (30.3%)	3 (4.6%)
Slight HL (16-25 dB HL)	28 (42.4%)	23 (34.8%)	6 (9.1%)
Mild HL (26-40 dB HL)	23 (34.8%)	18 (27.3%)	16 (24.2%)
Moderate HL (41-55 dB HL)	0 (0%)	4 (6.1%)	28 (42.4%)

Moderately-severe HL (56-70 dB HL)	1 (1.5%)	0 (0%)	13 (19.7%)
Severe HL (71-90 dB HL)	1 (1.5%)	1 (1.5%)	0 (0%)

kHz – kilohertz; dB HL – decibels in hearing level; PTA –pure tone average (0.5;1, 2 & 4 kHz); HF-PTA – high frequency pure tone average (2, 4 & 8 kHz); EHF-PTA – extended high frequency pure tone average (10, 12.5, 16 kHz). Maximum output levels of EHF audiometry: 10 kHz – 65 dB HL, 12.5 kHz – 60 dB HL, 16 kHz – 40 dB HL. Classifications of HL was based on Clark's (1981) classification.

Participants with type 2 diabetes were more likely to present with elevated PTAs in the right ears (r_{pb} = 0.373; p = 0.032), and elevated HF-PTAs and EHF-PTAs bilaterally (r_{pb} range 0.329 to 0.442; p <0.001 to 0.007). A significant, fair correlation was found between the presence of hypertension and elevated PTAs in the right ears (r_{pb} = 0.354; p = 0.043). Similarly, a significant, fair correlation was also found between hypertension and HF-PTAs bilaterally (r_{pb} = 0.50; p<0.001). Additionally, participants with hypertension presented with significantly (Z_{MW} = -4.04; p<0.001) higher HF-PTA thresholds (*Mdn* = 26.00) than those who did not have hypertension (*Mdn* = 15.00). The presence of hypertension was also found to significantly correlate with EHF-PTAs bilaterally (r_{pb} = 0.57; p<0.001). Conversely, participants without comorbidities typically presented with lower HF-PTAs bilaterally (r_{pb} range from -0.59 to -0.42), and EHF-PTAs bilaterally (r_{pb} range from -0.61 to -0.49). A significant, poor correlation was found between age and HF-PTAs bilaterally (r_s= 0.28; p = 0.026), and a significant, fair correlation between age and EHF-PTAs bilaterally (r_s= 0.434; p = 0.012). Participants who used insulin injections presented with significantly (KW = 7.12; p = 0.028) lower HF-PTAs (n =11, 33.3%; *Mdn* = 15.83) than those who used the other two modes of treatment (n = 22, 66.7%; *Mdn range* 21.67 to 25.83). Significant differences were found between the use of insulin injections and the use of both insulin and oral medication (Z_{Dunn} = -2.61; p = 0.028). Additionally, the use of both insulin injections and oral medications significantly (poorly) correlated with HF-PTAs bilaterally (r_s = 0.252; p = 0.041), and significantly (fairly) correlated with EHF-PTAs bilaterally (r_s = 0.42; p<0.001) (see Table 2).

Almost two-thirds of the participants (n = 21, 63.6%) failed the DIN test, of which DIN test scores had significant, fair correlations with PTAs bilaterally (r_s range 0.38 to 0.42; p =0.014 to 0.030), and with HF-PTAs and EHF-PTAs bilaterally (r_s range 0.35 to 0.39; p =0.001 to 0.004).

Table 2

Correlations between participant variables and air conduction pure tone averages (n = 66)

		PTA_{CV}			$HF\text{-}PTA_{CV}$			$EHF\text{-}PTA_{CV}$		
Variable	**Statistics**	**Left ears**	**Right ears**	**Both ears**	**Left ears**	**Right ears**	**Both ears**	**Left ears**	**Right ears**	**Both ears**
	M (*SD*)	23.45 (9.42)	18.49 (13.14)	23.29 (11.34)	22.83 (11.65)	22.17 (12.59)	22.50 (12.04)	43.69 (14.12)	42.02 (15.27)	42.85 (14.61)
	Mdn (*IQR*)	22.50 (11.25)	20.00 (9.75)	22.50 (10.31)	23.33 (14.17)	21.67 (14.17)	21.67 (13.00)	46.67 (17.50)	45.00 (21.67)	46.67 (20.42)
Sex_{BV}	r_{pb}	0.204	0.223	-0.137	-0.090	-0.029	-0.061	0.079	-0.018	0.014
	p	0.254	0.213	0.273	0.620	0.874	0.627	0.663	0.921	0.909
Age_{CV}	r_s	0.184	0.171	0.182	0.353	0.202	0.275	0.434	0.320	0.387
	p	0.306	0.340	0.144	0.044*	0.259	0.026*	0.012*	0.070	0.001*
Diabetes $type_{BV}$	r_{pb}	0.290	0.373	0.139	0.331	0.327	0.329	0.467	0.413	0.442
	p	0.102	0.032*	0.267	0.060	0.063	0.007*	0.006*	0.017*	<0.001*
Duration of $diabetes_{CV}$	r_s	-0.060	-0.047	0.020	-0.068	-0.126	-0.099	-0.223	-0.144	-0.230
	p	0.741	0.794	0.876	0.709	0.483	0.428	0.212	0.424	0.063
Use of insulin $injection_{BV}$	r_{pb}	-0.240	-0.343	0.049	-0.264	-0.322	-0.292	-0.419	-0.456	-0.448
	p	0.178	0.051	0.696	0.138	0.068	0.018*	0.015*	0.008*	<0.001*
Use of oral diabetic $medication_{BV}$	r_{pb}	0.067	0.170	0.017	-0.077	-0.054	0.069	0.003	0.066	0.081
	p	0.710	0.343	0.893	0.671	0.763	0.583	0.986	0.713	0.519
Use of both insulin and oral $agents_{BV}$	r_{pb}	0.195	0.188	-0.077	0.211	0.304	0.252	0.479	0.445	0.418
	p	0.276	0.295	0.539	0.239	0.085	0.041*	0.005*	0.009*	<0.001*
Absence of $comorbidity_{BV}$	r_{pb}	-0.236	-0.293	-0.102	-0.552	-0.517	-0.526	-0.590	-0.628	-0.607*
	p	0.186	0.099	0.417	0.001*	0.002*	<0.001*	<0.001*	<0.001*	<0.001*
$Hypertension_{BV}$	r_{pb}	0.310	0.354	0.048	0.506	0.516	0.501	0.522	0.620	0.572
	p	0.079	0.043*	0.701	0.003*	0.002*	<0.001*	0.002*	<0.001*	<0.001*

**p<.05 statistically significant; M - mean, SD – standard deviation, Mdn - median, IQR – interquartile range; subscript CV refers to continuous variables and subscript BV refers to binary variable – this was done as type of correlation differs (and the interpretation thereof) by the types of variables being correlated.*

Most of the participants (*n* = 24, 72.7%) passed the vision screening. The majority of participants who failed the vision screening (*n* = 7, 77.8%) presented with hypertension. However, no significant correlation was found between the presence of hypertension and failed vision screenings. Table 3 presents the correlations between the outcome of vision screenings per sampled eye (*n* = 66) and participant variables. A strong association was found between the use of both insulin injections and oral medication, and failed vision screenings in the right eyes only (φ = 0.398; *p* = 0.022) (see Table 3).

Table 3

Correlations between participant variables and outcomes of vision screenings (n=66)

Participant variables	Statistics	Vision screenings$_{BV}$	
		Left eyes (*n*=33)	Right eyes (*n*=33)
Sex$_{BV}$	*φ*	0.256	0.188
	p	0.151	0.296
Age$_{CV}$	r_{pb}	0.090	0.078
	p	0.616	0.665
Diabetes type$_{BV}$	*φ*	0.140	0.083
	p	0.438	0.665
Duration of diabetes$_{CV}$	r_{pb}	0.014	0.000
	p	0.939	1.000
Use of insulin injection$_{BV}$	*φ*	-0.047	-0.100
	p	0.797	0.580
Use of oral diabetic medication$_{BV}$	*φ*	-0.205	-0.232
	p	0.253	0.193
Use of both insulin and oral agents$_{BV}$	*φ*	0.303	0.398
	p	0.086	0.022*
Absence of comorbidity$_{BV}$	*φ*	-0.148	-0.065
	p	0.412	0.718
Hypertension$_{BV}$	*φ*	0.127	0.167
	p	0.482	0.354

**p<.05 statistically significant; subscript CV refers to continuous variables and subscript BV refers to binary variable – this was done as type of correlation differs (and the interpretation thereof) by the types of variables being correlated*

Approximately one-fifth (*n* = 7, 21.2%) of the participants presented with HL and VI. The majority of these participants (*n* = 5, 71.4%) presented with bilateral HL and VI. Table 4 indicates the correlations between the outcome of vision screening and all PTAs. Failed vision screenings were found to have significant, poor correlations with HF-PTAs and EHF-PTAs bilaterally (r_{pb} range 0.25 to 0.29; *p* = 0.017 to 0.046). Additionally, significant, fair correlations were found between PTA and failed vision

screening in left ears and left eyes, and between right ears and right eyes (r_{pb} range 0.36 to 0.39; p = 0.024 to 0.040) (see Table 4).

Table 4

Correlations between outcome of vision screenings and pure tone averages (n=66)

Mean hearing thresholds	Statistics	Vision screenings$_{BV}$		
		Both eyes and ears (*n*=66)	**Left eyes and ears (*n*=33)**	**Right eyes and ears (*n*=33)**
PTA$_{CV}$	r_{pb}	-0.21	0.392	0.358
	p	0.091	0.024*	0.040*
HF-PTA$_{CV}$	r_{pb}	0.293	0.208	0.395
	p	0.017*	0.245	0.023*
EHF-PTA$_{CV}$	r_{pb}	0.247	0.187	0.309
	p	0.046*	0.297	0.081

**p<.05 statistically significant; PTA –pure tone average (0.5;1, 2 & 4 kHz); HF-PTA – high frequency pure tone average (2, 4 & 8 kHz); EHF-PTA – extended high frequency pure tone average (10, 12.5, 16 kHz);* subscript *CV refers to continuous variables and subscript BV refers to binary variable – this was done as type of correlation differs (and the interpretation thereof) by the types of variables being correlated*

3.5 Discussion

The purpose of this study was to describe the use of mHealth tools in the evaluation of hearing and vision in adults with diabetes. The smartphone-based hearing assessment detected the presence of HL in more than one-third (37.8%) of the sampled ears and poor speech recognition-in-noise abilities in more than half of the participants (63.6%). VI was seen in less than one-third of the participants (27.3%). Moreover, approximately one-fifth of the participants (21.2%) presented with co-occurrence of HL and VI.

The prevalence of HL in the current study (37.8%) is similar to studies reporting prevalence rates between 36.4 - 45% [7-9, 19]. In the current study, there was no significant correlation between duration of diabetes and HL, a finding similar to other studies [7-8]. On the contrary, several studies found significant associations for increased duration and HL [4-6]. This discrepancy may be due to the difference in the mean duration of diabetes as the mean duration of the current study (5 years) was less than majority of these studies. EHF HL was prevalent in majority of the participants (86.4%), which was consistent with literature indicating diabetes-associated HL presents at high frequencies [2-4]. Unsurprisingly, older participants in the current study were more likely to present with elevated HF-PTAs and EHF-PTAs bilaterally, consistent with literature [2, 22, 24]. The current study found that

participants who had hypertension were more likely to present with elevated hearing thresholds across frequencies, which is supported by several studies [4, 17]. Additionally, almost two-thirds of the participants in the current study (63.6%) presented with impaired speech recognition-in-noise abilities, with which significant correlations were found between DIN test scores and all PTAs bilaterally. This finding may be attributed to the effect of diabetes on central auditory processing leading to speech recognition-in-noise impairment [21, 25].

Almost one-third of the participants in the current study (27.3%) presented with VI, which was found to be typical of diabetes-associated VI in current population (22.2 - 28.6%) [13, 17-18]. However, Jingi et al. [12] found a higher prevalence (42.1%) than the current study with similar mean duration of diabetes and this discrepancy may be due to their inclusion criteria of blindness. Zhang et al. [10] found a lower prevalence (11%), due perhaps to the difference in access of vision services in developed countries. The current study found significant association between the use of both insulin injections and oral medication, and VI, as did All-Till et al. [11], although they also found significant association for insulin therapy. No other significant associations were found for VI and participant variables, a finding similar to Schellini et al. [14]. On the contrary, several studies reported significant associations for increased age, duration of diabetes and presence of hypertension [10, 12].

Literature indicated varying prevalence rates of co-occurring HL and diabetes-associated VI between 14.6 - 40.6% [18-20]. This wide range may be due to the difference in classification of VI, and inclusion criteria (i.e. comorbidities of HL and/or VI). The current study found co-occurrence in approximately one-fifth of the participants (21.2%), which was similar to the findings of Alizadeh et al. [19], although their mean age and duration of diabetes were higher than the current study. Bener et al. [17] reported a higher prevalence (36.6%) of co-occurrence than that of the current study, which may be due to the difference in inclusion criteria. Bener et al. [17] included participants from a highly endogamous population, some were smokers, and measurement of VI was based on self-reported VI. Shin et al. [15] and Kim et al. [19] found no relationship between the prevalence of diabetes-associated VI and HL. However, Shin et al. [15] did indicate an association between the severity of diabetes-associated VI and HL. A finding similar to that of Ooley et al. [18], although their mean

age was higher than that of Shin et al. [15] and the current study. Bener et al. [17] found this association for high frequency HL, and although the current study did not investigate the severity of diabetes-associated VI, significant correlations were found between VI and high frequency and extended high frequency HL bilaterally in the current study.

From the current study and numerous clinical prevalence studies, it is evident that adults with diabetes are at higher risk of developing diabetes-associated VI and HL [1-20]. Early detection is crucial to delay the progression of these disorders, as well as to improve quality of life of those affected [1-14]. Many mHealth tools have been developed to reduce cost of traditional care by enabling lay healthcare workers to administer screenings [26-29]. Hence, the use of mHealth technology has the potential to facilitate the evaluation of hearing and vision screenings in settings where access to these services are limited, specifically for adults with diabetes. Additionally, the findings of the current study advocates for future research on this high-risk population using mHealth technology in developing countries.

The smartphone-based hearing test enabled the use of EHF audiometry and DIN tests which are not regularly assessed in clinical settings [23-24, 27-28]. Li et al. [22] and Vignesh et al. [24] found EHF audiometry to be useful in detecting early onset of HL in adults with diabetes. Additionally, research suggests that diabetes may damage central auditory processing leading to impaired speech recognition-in-noise and therefore, the inclusion of DIN testing assists in measuring auditory processing and provides clinically valuable information about real-life communication difficulties, prompting appropriate intervention and counselling [2, 21].

The current study was completed on a small sample of adults with diabetes, and therefore the results found in this study may show inflated or understated estimations of the presence of VI and HL. Another limitation identified was the disproportionate number of females in the study and, therefore, the effect of gender could not be observed. The sensitivity and specificity of the mHealth tools used were not determined, and was considered a limitation in the current study. Future research may consider the inclusion of a control group to facilitate comparisons regarding combined screening of VI and HL in adults with diabetes and those without the disease.

A single smartphone utilized different applications to evaluate both hearing and vision in adults with diabetes. Significant correlations were found between VI and high frequency HL in this population suggesting a possible link between diabetes-associated VI and HL, which supports previous literature demonstrating increased risk of these sensory impairments in this population [15-20]. The presence of hypertension significantly increased the risk of HL in adults with diabetes. Findings of this study emphasizes the importance of regular hearing and vision screening in adults with diabetes, and that mHealth tools can be an accessible alternative to promote early detection and awareness of hearing and vision services in developing countries.

Statements and Declarations

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CHAPTER FOUR: DISCUSSION AND CONCLUSION

4.1 Discussion of findings

The purpose of this study was to describe the use of mHealth tools in evaluating the auditory and visual functioning of adults with diabetes. The HearTest™ revealed more than one-third of the ears examined in this study (37.8%) exhibited the presence of HL. Furthermore, the South African English DIN test identified a high prevalence of poor speech recognition-in-noise abilities, affecting nearly two-thirds of the participants (63.6%). PeekAcuity™ observed less than one-third of the eyes examined (27.3%) experienced vision problems. Moreover, the current study revealed a noteworthy co-occurrence of HL and VI, affecting approximately one-fifth of the participants (21.2%). These findings highlight the convenience and effective means of detecting HL and VI using mHealth tools in this population.

Hearing evaluation

Literature indicated that adults with diabetes are twice as likely to acquire a hearing loss than adults without diabetes (Horikawa et al., 2013). The current study's prevalence of HL (37.8%) is similar to the studies by Bener et al. (2016), Hlayisi et al. (2018) and Pemmaiah et al. (2011) who reported prevalence rates between 36.4 - 45%. In this study, no significant correlations were found for HL (all PTAs) and duration of diabetes, a finding similar to Bhaskar et al. (2014) and Idugboe et al. (2018). On the contrary, several studies reported significant association between the presence of HL and increased duration (Al-Rubeaan et al., 2021; Hlayisi et al., 2018; Pemmaiah & Srinivas, 2011; Sachdeva & Azim, 2018). The discrepancy may be attributed to the shorter mean duration of diabetes among the current study's participants (five years) compared to the majority of these studies (Al-Rubeaan et al., 2021; Hlayisi et al., 2018; Pemmaiah & Srinivas, 2011; Sachdeva & Azim, 2018).

EHF hearing loss was prevalent in majority of the participants (86.4%) which is consistent with literature indicating diabetes-associated HL presents predominately at higher frequencies (>9 kHz) (Das et al., 2017; Li et al., 2020; Vignesh et al., 2014). Unsurprisingly, increase in age significantly correlated with high frequency PTAs and

EHF-PTAs which is consistent with literature (Bornman et al., 2018; Kakarlapudi et al., 2003; Oh et al., 2014). Kakarlapudi et al. (2003) attributed this association to the accelerated dual effect of diabetes and increase in age on the auditory system.The prevalence of EHF hearing loss in the current study is significantly higher than the findings by Li et al. (2020) who reported prevalence of 63.1%, however, this discrepancy was expected as Li et al. (2020) utilized an inclusion criteria of normal hearing participants with diabetes, which normal hearing was considered for thresholds below 15 dB HL at conventional frequencies (0.5 – 8 kHz).

EHF hearing loss is reported to negatively affect speech perception in the presence of noise (Falazadeh et al., 2020; Prabhu & Shanthala, 2016; Vignesh et al., 2015; Zadeh et al., 2019). Therefore, the high prevalence of failed DIN tests (63.6%), and the significant correlation between elevated EHF PTAs and DIN tests were expected in this study (Falazadeh et al., 2020; Prabhu & Shanthala, 2016; Vignesh et al., 2015; Zadeh et al., 2019). DIN test scores were also found to significantly correlate with elevated conventional and high frequency PTAs. Falahzadeh et al. (2020) attributed impaired speech recognition abilities in adults with diabetes to the damage to central auditory processing caused by high sugal levels.

Additionally, almost two-thirds of the participants (60.6%) in the current study reported the presence of hypertension, which was similar to the prevalence of hypertension (56%) reported by Hlayisi et al. (2018). Although hypertension was not found to be a signficiant predictor of HL, it was found to have a significant association with elevated PTAs across frequencies. This suggests that individuals with both hypertension and diabetes are more prone to HL, a finding that was confirmed by several studies (Al-Rubeaan et al., 2021; Bener et al., 2016; Duck et al., 1997; Verhulst et al., 2019).

Vision screening

The current study found that less than one-third (27.3%) of the participants failed the vision screening which was found to be typical of diabetes-associated VI in the current population (22.2 - 28.6%) (Bener et al., 2016; Kahloun et al., 2014; Ooley et al., 2017; Wang et al., 2021). However, several studies reported significantly lower prevalence rates between 2.84 -11% and this may be due to the difference in access of vision in high-income countries compared the setting of the current study (De Fine et al., 2011; Prasad et al., 2001; Zhang et al., 2008). Jingi et al. (2015) found a higher prevalence

(42.1%) than the current study with similar mean duration of diabetes, and due perhaps to their inclusion of participants with blindess. Additionally, the current study found significant association between the use of both insulin injection and oral medication, and VI. A finding similar to All-Till et al. (2005) although they also found a significant association for insulin therapy and VI. No other significant associations were found for VI and sex, age, duration of disease and presence of comorbidities. Kim et al. (2019) confirmed these findings besides association with age. Several studies found age, duration of diabetes, and presence of hypertension to be risk factors of diabetes-associated VI (de Fine et al., 2011; Kahloun et al., 2014; Lee et al., 2015; Rani et al., 2012; Zhang et al., 2008). This discrepancy may be due to difference in inclusion criteria, including, inclusion of participants older than 60 years, longer mean duration than the current study, and known comorbidities of VI in the general population.

Co-occurrence of HL and VI

Literature indicated varying prevalence rates of co-occurring HL and diabetes-associated VI between 14.6% - 40.6% (Ashkezari et al., 2018; Bener et al., 2016; Ooley et al., 2017; Shin et al., 2021). This wide range may be due to the difference in classification of VI, and inclusion criteria (including larger age range, and history of comorbidities HL and VI). The present study found a prevalence of co-occurring HL and VI in twenty-one percent (21.2%) of the participants, which was similar to the findings of Alizadeh et al. (2022), although their mean duration and age were higher than the current study (7.3 and 59.8 respectively). Bener et al. (2017) reported a higher prevalence of co-occurrence (36.6%) in the same age group as the current study. This may be due to the difference in inclusion criteria as Bener et al. (2017) included participants from a highly endogamous population, some were smokers, and measurement of VI was based on self-reported VI. Kim et al. (2019) and Shin et al. (2021) found no relationship between the prevalence of diabetes-associated VI and HL, however Shin et al. (2021) did indicate association with severity of diabetes-associated VI and HL. A finding similar to that of Ooley et al. (2017), although their mean age was higher than that of Shin et al. (2021) and the current study. Significant correlations between VI and high frequency and extended high frequency HL bilaterally were found in the current study, as did Ashkezari et al. (2018), although their reported mean age of participants were significantly higher than the current study.

Additionally, in the current study, VI in the left eyes significantly correlated with HL (PTA) in left ears, and right eyes and right ears. While the current study's findings may suggest a potential link between VI and HL in adults with diabetes, further research is need to establish a causal relationship between these co-occurring sensory impairments and diabetes.

4.2 Clinical implications

From this study and numerous clinical prevalence studies, it is clear that people with diabetes are at higher risk for developing HL and VI. Early detection is crucial to delay the progression of these disorders, as well as to manage cases to improve quality of life. The use of mHealth tools has significantly improved over the past few years (Bastawrous et al., 2015; Eksteen et al., 2019; Oosthuizen et al., 2023; Osei & Mashamba-Thompson, 2021; Swanepoel et al., 2014). Advancements in technology and the widespread availability of mobile devices have resulted in the development of more sophisticated and user-friendly mHealth tools (Akter & Ray, 2010; WHO, 2011). There are now thousands of health-related apps available on app stores, ranging from fitness apps to apps that monitor blood glucose levels and medication adherence. Many apps have also been developed to reduce cost of traditional care using a task shifting approach, by ensuring that the tools can be operated by lay healthcare workers (Eksteen et al., 2019; Manus et al., 2021; Oosthuizen et al., 2023; Rono et al., 2018).

The findings of the current study emphasizes the importance of incorporating routine hearing and vision screenings in the management plan for this population in clinical practice. The use of mHealth technology has the potential to facilitate the evaluation of hearing and vision in settings where access to these services is limited (Eksteen et al., 2019; Manus et al., 2021; Oosthuizen et al., 2023; Rono et al., 2018; Swanepoel et al., 2014; Swanepoel et al., 2016).

Based on the demonstrated feasibility of utilizing community healthcare workers (CHWs) for hearing and vision screenings in previous studies, this study proposes a protocol for improving access and early detection of hearing and visual impairment in adults with diabetes in developing countries (Eksteen et al., 2019; Manus et al., 2021; Oosthuizen et al., 2023; Swanepoel et al., 2016; Yousuf Hussein et al., 2018). Figure 1 illustrates an example of the first step in raising awareness of diabetes-associated HL and VI and can be distributed in diabetic clinics in developing countries. This could

serve as the primary point of care and offers a convenient and accessible screening option for adults with diabetes, who can self-screen their hearing in the comfort of their home. However, it is important to note that PeekAcuity™ cannot be used as a self-screening tool due to the need for a specific distance between the smartphone and the individual being screened. Hence, vision screening at home was not considered as the primary point of care for adults with diabetes.

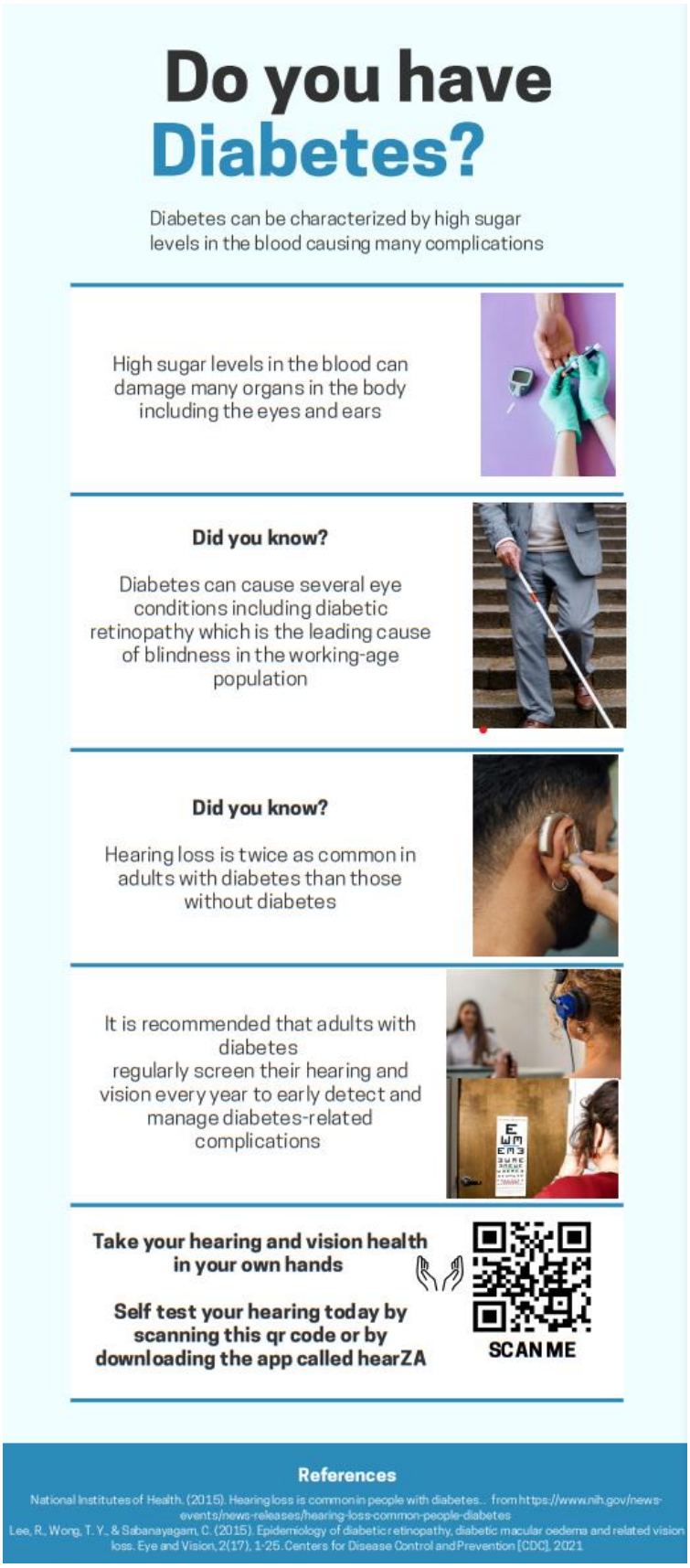

Figure 1. *Example of poster that can be distributed in diabetes clinics*

Proposed home-based screening for early detection of sensory impairments

There are very few validated vision screening apps available namely, the PeekAcuity™ app, Kay ISight professional app, Smart Optometry and the Mvt (My Vision Track) app (Aruljyothi et al., 2021). While previous studies have demonstrated the accuracy and reliability of the PeekAcuity™ app, which was used in the current study, the app has not been validated for self-screening purposes (Aruljyothi et al., 2021; Bastawrous et al. 2015; de Vencia et al., 2018). Both Kay ISight professional and Smart Optometry apps have been developed and validated to conduct vision screenings administered by healthcare/eye care professionals. The Mvt (My Vision Track) app offers a comprehensive vision monitoring and surveillance system for age-related macular degeneration and diabetic retinopathy. With the ability for users to self-screen their vision at home, the results are automatically uploaded to their treating physician or eye specialist's portal for monitoring purposes. Although this app is highly relevant for the target population of the current study, the app may not be a feasible option for individuals living in developing countries as the app requires the use of an iPhone and includes a monthly fee of about $9 (Aruljyothi et al., 2021).

Due to the lack of validated home-based vision screening apps, and the inability of PeekAcuity™ to be used as a self-screening tool, the current study suggests a home-based hearing screening as the first step in detecting sensory impairments in this population (De Sousa et al., 2020; Phanguphangu & Ross, 2021). The South African English DIN test has already establishedhigh test-retest reliability of self-administered hearing screenings and self-screening also has the potential to boost self-efficacy, and empower adults with diabetes to take control of their hearing health (De Sousa et al., 2020).

Figure 2 illustrates the potential protocol of home-based screenings for early detection and monitoring of sensory impairments. Individuals can download the South African English DIN test with the use of the QR code on the example poster (Figure 1) or by downloading the app directly from the App stores (i.e. Google play/Apple store). Individuals who self-screen at home and pass the screening will be reminded on an annual basis to screen their hearing through the in-app notifications. Individuals who fail the screening, will automatically be rescreened to reduce the referral rates to audiologists (De Sousa et al., 2018; Eksteen et al., 2019). The South African English

DIN test will inform the individual who failed the screening to consult a medical professional for further testing and/or a referral to a clinic can be made. At this point, individuals will be reminded of the importance of vision screening as it is as important as hearing screening by the CHWs at the referral clinic. CHWs can administer dual hearing and vision screening to adults with diabetes. Individuals who fail hearing and/or vision screening will be rescreened to reduce false positives. When two failed hearing screenings are obtained, behavioural audiometry will be conducted. When behavioural audiometry detects HL, the individual will be retested and then referred to an audiologist for diagnostic assessment and intervention. Individuals who fail the vision screening twice will also be referred to an optometrist for diagnostic assessment and intervention. The mHealth application will notify individuals of their referral appointments with the audiologist and/or optometrist via text message (SMS). Additionally, those who pass the screenings will be reminded to screen their hearing and vision annually due to high risk of diabetes-associated sensory impairment. The use of notifications/text messages have shown to improve adherence and follow-up rates (Eksteen et al., 2019; Free et al., 2013).

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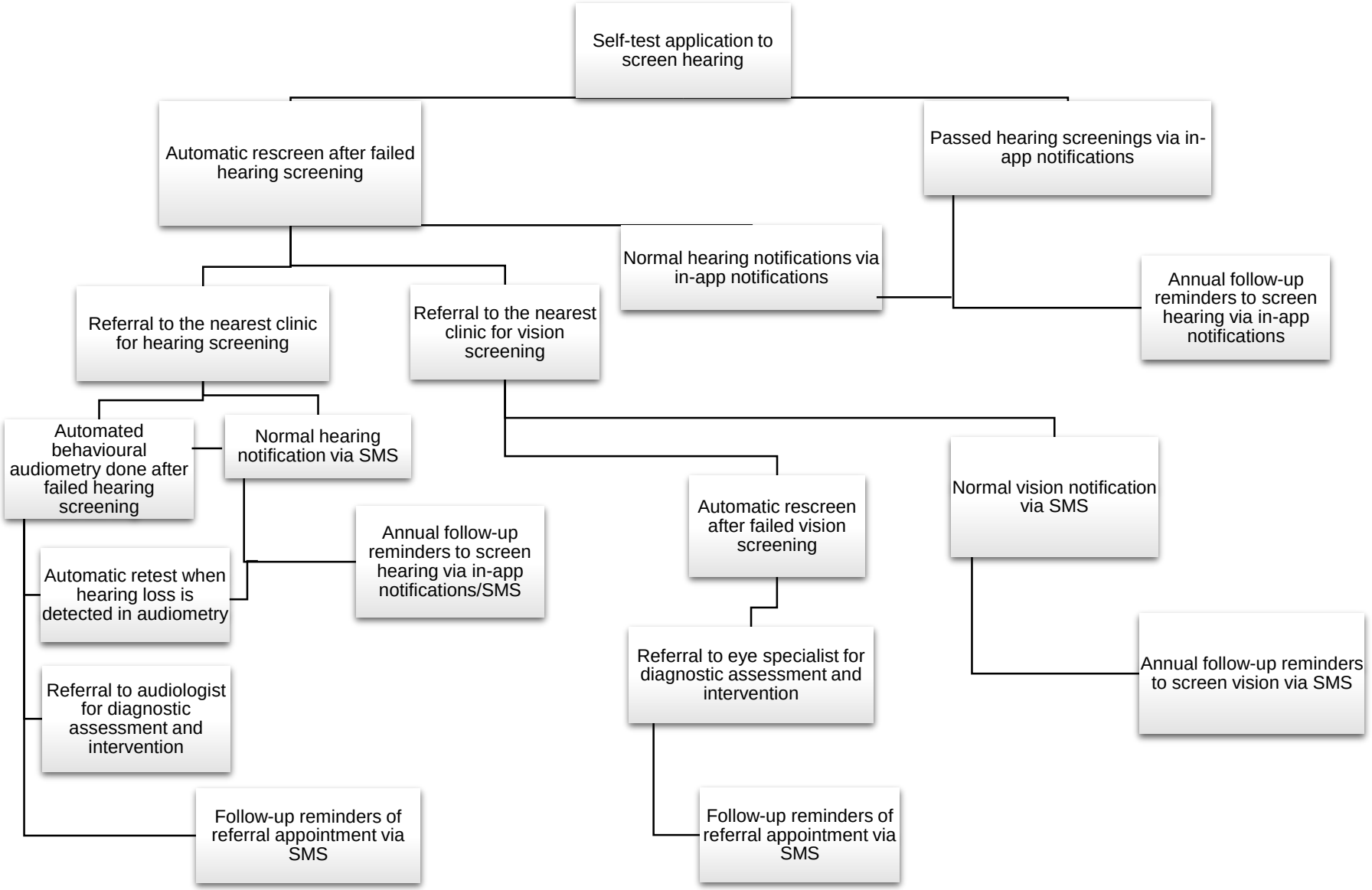
Self-test application to screen hearing
Automatic rescreen after failed hearing screening
Passed hearing screenings via in-app notifications
Normal hearing notifications via in-app notifications
Annual follow-up reminders to screen hearing via in-app notifications
Referral to the nearest clinic for hearing screening
Referral to the nearest clinic for vision screening
Automated behavioural audiometry done after failed hearing screening
Normal hearing notification via SMS
Annual follow-up reminders to screen hearing via in-app notifications/SMS
Automatic retest when hearing loss is detected in audiometry
Referral to audiologist for diagnostic assessment and intervention
Follow-up reminders of referral appointment via SMS
Automatic rescreen after failed vision screening
Normal vision notification via SMS
Referral to eye specialist for diagnostic assessment and intervention
Annual follow-up reminders to screen vision via SMS
Follow-up reminders of referral appointment via SMS

Figure 2. *Proposed home-based screening for early detection of sensory impairments*

Proposed community-based dual hearing and vision screening model

Most of the community-based dual hearing and vision screening were conducted on young children and school-going aged children (Eksteen et al., 2019; Hussein et al., 2018; Manus et al., 2021; Saunders et al., 2007). Literature indicates that the incorporation of CHWs in dual hearing and vision screening programs resulted in increased awareness of HL and VI within communities due to CHWs being members of the community and thus, relatable to the communities (Eksteen et al., 2019; Oosthuizen et al., 2023). The use of CHWs and a single smartphone device to conduct both hearing and vison screening has shown to be an effective community-based service delivery model (Eksteen et al., 2019; Manus et al., 2021; Oosthuizen et al., 2023; Saunders et al., 2007). This mHealth service-delivery model was also found to be cost-effective as screening cost per child ranged from $5.63 - $6.67, and screenings did not require the involvement of ear and eye specialists unless diagnostic assessments and intervention were required (Eksteen et al., 2019; Manus et al., 2021; Saunders et al., 2007; Oosthuizen et al., 2023). Figure 3 illustrates the pathway of a potential community-based dual hearing and vision screening program.

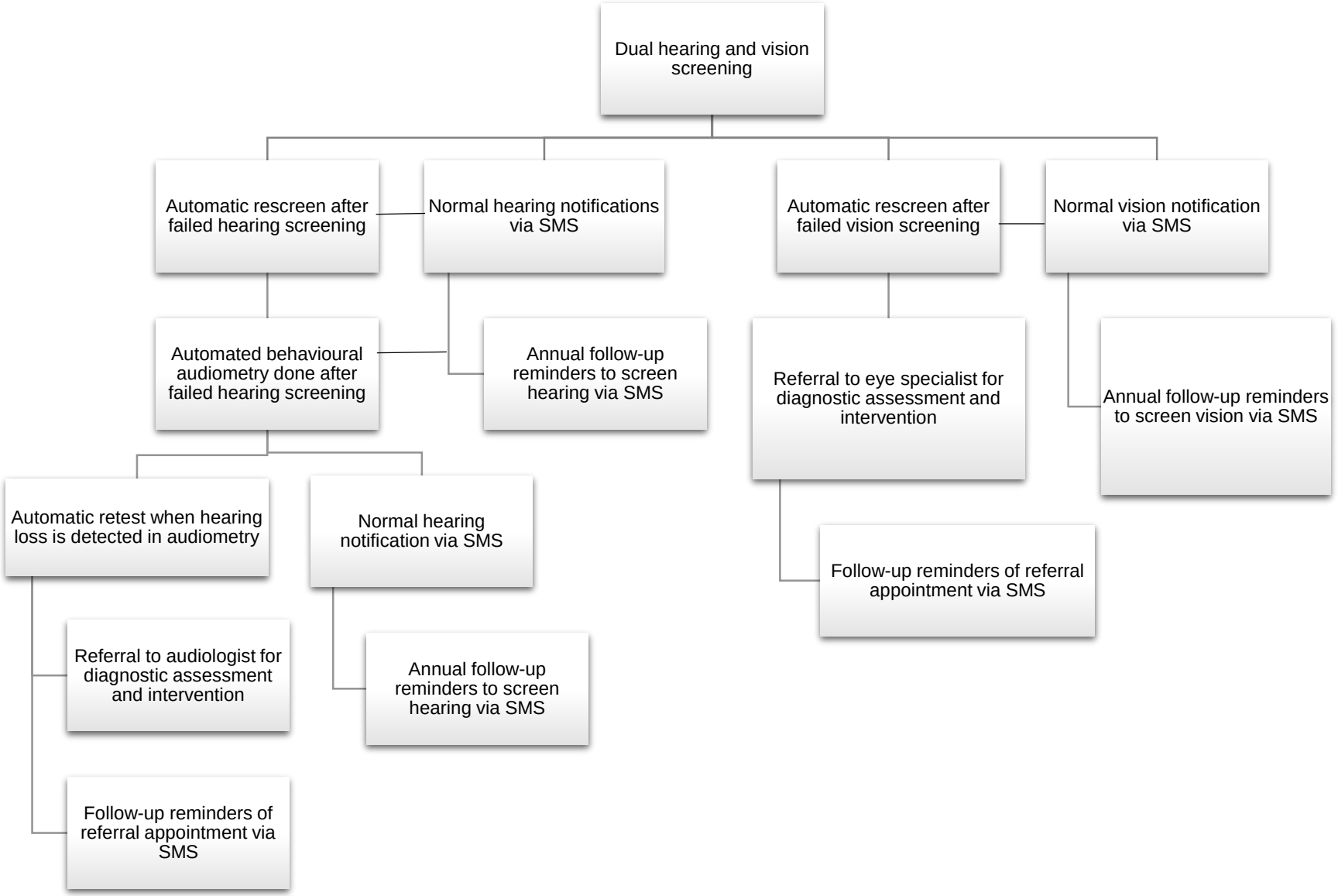

Figure 3. *Proposed community-based dual hearing and vision screening model*

4.3 Critical evaluation

Strengths of the study

This study used one smartphone device to evaluate both hearing and vision. This suggests the potential usefulness of mHealth technology in decentralising hearing and vision services in socioeconomically diverse settings. The HearTest™ enabled EHF audiometry, which is not usually assessed in clinical settings due to equipment limitations (Vignesh et al., 2015; Zadeh et al., 2019). EHF audiometry has been reported to be useful in detecting early onset of HL, specifically in adults with diabetes, and hence the use of EHF audiometry in this study was found to be invaluable (Das et al., 2017; Li et al., 2020; Vignesh et al., 2015). Additionally, the current study's use of the South African English DIN test assisted in measuring auditory processing functioning and provided clinically valuable information about real-life communication difficulties, prompting appropriate intervention and counselling (Hall, 2021; Zadeh et al., 2019).

To the researcher's knowledge, this is the first study to evaluate both hearing and vision in adults with diabetes using mHealth technology. Therefore, this study addressed the research gap in this area and enables future research on the use of mHealth technology in the evaluation of hearing and vision in this population. By using mHealth tools, this study offers a low-cost option for the evaluation of hearing and vision in adults with diabetes living in developing countries, where resources may be limited.

Limitations of the study

The current study has been subjected to several limitations and the results thereof should be inferred with caution. Due to the small sample size, the results may show inflated or understated estimations of HL and VI in adults with diabetes. Additionally, the study had a disproportionate number of female participants to male participants. This was identified as a limitation as the sample size did not provide a gender balanced representation of adults with diabetes and therefore, the effect of gender could not be observed. Additionally, another limitation was that the participant variables such as personal and medical history were self-reported and not verified. Moreover, this study's findings were not compared to the gold standard of testing, hence the accuracy

of the mHealth tools used in this, including the sensitivity and specificity, were not determined. This was identified as limitation due to the lack of direct comparison to the gold standard. Lastly, this study acknowledged that the lack of a diagnostic vision assessment was a limitation due to the inclusion of a diagnostic hearing assessment and speech-in-noise screening tool.

4.4 Future research

Future studies should include an age-matched control group and larger sample size to provide a more accurate depiction of dual screening for HL and VI in adults with diabetes. Furthermore, future research should include a balanced representation of both male and female participants to enable a more comprehensive understanding of the impact of gender on hearing and vision of this population. To enhance reliability and validity of the findings, future research should also incorporate objective measures and verified data collection methods, instead of relying solely on self-reported participant variables. Moreover, future studies should include direct comparison with gold standard testing to determine the accuracy of the mHealth tools used to allow for a thorough evaluation of their performance and effectiveness in detecting HL and VI in this population. Lastly, future studies should explore the feasibility of a dual hearing and vision screening program focused on adults with diabetes implemented by CHWs. By addressing these areas in future research, there can be a further advancement in understanding the role of mHealth tools in evaluating sensory impairments, optimizing their utilizations, and enhancing the overall care and management of adults with diabetes.

4.5 Conclusion

The significant correlations found between VI and high frequency HL in the current may suggest a possible link between these sensory impairments, which supports previous literature demonstrating increased risk of diabetes-associated sensory impairments in this population. The presence of hypertension significantly contributed to the increased risk of HL in adults with diabetes. Findings of this study emphasizes the importance of regular hearing and vision screening in adults with diabetes, and the inclusion of EHF audiometry and DIN test may be useful tools in early detection of early onset HL in this population. The use of validated mHealth technology has the potential to improve overall access and quality of hearing and vision services for

individuals residing in developing countries. In this study, a single smartphone utilized different mHealth applications to screen for both hearing and visual impairment in adults with diabetes. These findings suggest that mHealth tools can be an accessible alternative to promote earlier detection and awareness for hearing and vision services, specifically for adults with diabetes in developing countries. By investigating the use of mHealth tools, we can enhance the assessment and management of sensory impairments in adults with diabetes. The findings have the potential to contribute to improved healthcare outcomes and quality of life for individuals with diabetes, and inform policymakers and healthcare providers about the benefits of integrating mHealth technology in the evaluation process.

CHAPTER FIVE: REFERENCES

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CHAPTER SIX: APPENDICES

6.1 APPENDIX A: Ethical clearance from the Faculty of Health Sciences

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 18 March 2022 and Expires 18 March 2027.
- IORG #: IORG0001762 OMB No. 0990-0278 Approved for use through August 31, 2023.

Faculty of Health Sciences **Research Ethics Committee**

14 April 2022

Approval Certificate
Annual Renewal

Dear Miss LC Fredericks,

Ethics Reference No.: HUM010/0121 – Line 4
Title: The usefulness of mHealth tools in detecting changes in hearing and vision in adults with diabetes mellitus

The **Annual Renewal** as supported by documents received between 2022-04-07 and 2022-04-13 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2022-04-13 as resolved by its quorate meeting.

Please note the following about your ethics approval:

- Renewal of ethics approval is valid for 1 year, subsequent annual renewal will become due on 2023-04-14.
- Please remember to use your protocol number (HUM010/0121) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:

- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

On behalf of the FHS REC, Dr R Sommers
MBChB, MMed (Int), MPharmMed, PhD
Deputy Chairperson *of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria*

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health)

Research Ethics Committee
Room 4-60, Level 4, Tswelopele Building
University of Pretoria, Private Bag x323
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Tel +27 (0)12 356 3084
Email: deepeka.behari@up.ac.za
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Fakulteit Gesondheidswetenskappe
Lefapha la Disaense tša Maphelo

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IORG #: IORG0001762 OMB No. 0990-0279 Approved for use through February 28, 2022 and Expires: 03/04/2023.

Faculty of Health Sciences **Research Ethics Committee**

23 June 2021

Endorsement Notice

Dear Miss LC Fredericks

Ethics Reference No: HUM010/0121
Title: The usefulness of mHealth tools in detecting changes in hearing and vision in adults with diabetes mellitus

The **New Application** as supported by documents received between 2021-02-15 and 2021-06-17 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2021-06-17 as resolved by its quorate meeting.

Please note the following about your ethics approval:

- Ethics Approval is valid for 1 year and needs to be renewed annually by 2022-06-23.
- Please remember to use your protocol number (HUM010/0121) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

Ethics approval is subject to the following:

- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

the signed and approved letters (X3) from the stakeholders.

We wish you the best with your research.

Yours sincerely

On behalf of the FHS REC, Dr R Sommers
MBChB, MMed (Int), MPharmMed, PhD
Deputy Chairperson *of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria*

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes, Second Edition 2015 (Department of Health).

Research Ethics Committee
Room 4-60, Level 4, Tswelopele Building
University of Pretoria, Private Bag x323
Gezina 0031, South Africa
Tel +27 (0)12 356 3084
Email: deepeka.behari@up.ac.za
www.up.ac.za

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6.2 APPENDIX B: Gauteng Department of Health Clearance

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

STEVE BIKO ACADEMIC HOSPITAL

Enquiries: Dr JS Mangwane
Tel No: +2712 3452018
Fax No: +2712 354 2151
E-mail: joseph.mangwane@gauteng.gov.za

For attention: Lauren Fredericks

NHRD Ref Number: GP_202202_056

Re: REQUEST FOR PERMISION TO CONDUCT RESEARCH AT STEVE BIKO ACADEMIC HOSPITAL

TITLE: Usefulness of mHealth tools in detecting abnormalities in hearing and vision in adults with Diabetes Mellitus

Permission is hereby granted for the above-mentioned research to be conducted at Steve Biko Academic Hospital. This is done in accordance to the "Promotion of access to information act No 2 of 2000".

Please note that in addition to receiving approval from Hospital Research Committee, the researcher is expected to seek permission from all relevant department. Furthermore, collection of data and consent for participation remain the responsibility of the researcher.

The hospital will not incur extra cost as a result of the research being conducted within the hospital.

You are also required to submit your final report or summary of your findings and recommendations to the office of the CEO.

STATUS OF APPLICATION: Approvec

Date: 2022-04-20

Dr. J S. Mangwane
Manager: Medical Service

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Enquiries: Dr. Manei Letebele-Hartell
Tel: +27 12 451 9036
E-mail: Troy.Mashabela@gauteng.gov.za

TSHWANE RESEARCH COMMITTEE: CLEARANCE CERTIFICATE

DATE ISSUED: 08/04/2021
PROJECT NUMBER: 19/2021
NHRD REFERENCE NUMBER: GP_202103_023

TOPIC: The usefulness of mHealth tools in detecting changes in hearing and vision in adults with diabetes mellitus at a South African District Hospital

Name of the Lead Researcher:	Miss Lauren Fredericks
Name of the Supervisor:	Dr. Barbara Heinze Mrs Karina De Sousa
Facilities:	ODI District Hospital
Name of the Department:	University of Pretoria

NB: THIS OFFICE REQUEST A FULL REPORT ON THE OUTCOME OF THE RESEARCH DONE AND

NOTE THAT RESUBMISSION OF THE PROTOCOL BY RESEARCHER(S) IS REQUIRED IF THERE IS DEPARTURE FROM THE PROTOCOL PROCEDURES AS APPROVED BY THE COMMITTEE.

DECISION OF THE COMMITTEE: APPROVED

.....
Dr. Mpho Moshime-Shabangu
Deputy Chairperson: Tshwane Research Committee
Date: 9/04/2021

.....
Mr. Mothomohe Pitsi
Chief Director: Tshwane District Health
Date: 12/04/2021

PROF NDUMANDO
ACD

6.3 APPENDIX C: Signed permission letters from stakeholders

UNIVERSITEIT VAN PRETORIA
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YUNIBESITHI YA PRETORIA

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Humanities 100. Since 1919

Department of Speech-Language Pathology and Audiology

LETTER TO REQUEST PERMISSION TO CONDUCT RESEARCH STUDY AT STEVE BIKO ACADEMIC HOSPITAL

Steve Biko Academic Hospital – Diabetic Clinic

17 November 2021

Professor Paul Rheeder
Head of Diabetic Clinic
Steve Biko Academic Hospital
Pretoria

Dear Professor Paul Rheeder,

APPLICATION FOR PERMISSION TO CONDUCT RESEARCH STUDY

The title of this study is: **The usefulness of mHealth tools in detecting abnormalities in hearing and vision in adults with diabetes mellitus**

The study is approved by the University of Pretoria's Research Ethics committee of the Faculty of Humanities and the Faculty of Health Sciences (HUM010/0121).

I, Lauren Fredericks, kindly request permission to conduct a research study using the patients of the Diabetic Clinic of Steve Biko Academic Hospital. I will also require access to the patient files and information. Their permission to use their clinical information documented in their files is requested in the participant consent form. The research study will entail a brief self-report questionnaire, diagnostic hearing test and visual acuity screening.

The request is lodged with you in terms of the requirements of Promotion of Access to Information Act No.2 of 2000.

I intend to publish the results of this research study in an international peer-reviewed journal and/or at meetings like symposia, congresses, or other meetings of such nature. I intend to protect the personal identity of the patients by assigning each patient a random code number.

With thanks and kind regards,

Miss Lauren Fredericks
Student
U15089178@tuks.co.za

Mrs. Karina Swanepoel
Research Supervisor
karina.swanepoel@up.ac.za

Dr Leigh Biagio De Jagar
Research co-supervisor
Leigh.biagio@up.ac.za

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PERMISSION FOR THE USE OF INFORMATION OF ADULTS WITH DIABETES MELLITUS FROM THE DIABETES CLINIC IN STEVE BIKO ACADEMIC HOSPITAL (SBAH)

Herewith I, **Professor Paul Rheeder** give written permission that the researcher may approach patients of the Steve Biko Academic Hospital's Diabetic Clinic and use the information of Type II Diabetes adults from the Diabetes clinic for the research project titled: Co-occurrence of hearing and visual acuity loss in adults with Type II diabetes. I also give permission to act as research collaborator.

.....

Professor Paul Rheeder
Head: Diabetic Clinic of Steve Biko Academic Hospital Consultant
Email: paul.rheeder@up.ac.za
Coordinator: Diabetic Clinic

17/11/21
.....
Date

PROF P. RHEEDER
MMed (Int), PhD
MP0297577

University of Pretoria, Private Bag X20
Hatfield 0028, South Africa
Tel +27 (0)12 420 2357
Fax +27 (0)12 420 3517
www.up.ac.za

Fakulteit Geesteswetenskappe
Departement Spraak-Taalpatologie en Oudiologie
Lefapha la Bomotho
Kgoro ya Phatholotši ya Polelo-Maleme le Go kwa

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Lefapha la Bomotho

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Department of Speech-Language Pathology and Audiology

LETTER TO REQUEST PERMISSION TO CONDUCT A RESEARCH STUDY ON ADULTS WITH DIABETES MELLITUS AT ODI DISTRICT HOSPITAL
Odi District Hospital – Diabetic Clinic

22 April 2021

Mr. A Musie
Chief Executive Officer
Odi District Hospital
Mabopane, Pretoria

Dear Mr. A Musie

APPLICATION FOR PERMISSION TO CONDUCT A RESEARCH STUDY

The title of this study is: **The usefulness of mHealth tools in detecting changes in hearing and vision in adults with diabetes mellitus**

The study is approved by the University of Pretoria's Research Ethics committee of the Faculties of Humanities and Health Science: (HUM010/0121)

I, Lauren Fredericks, kindly request permission to conduct a research study on the patients of the Diabetic Clinic at Odi District Hospital. I will also require access to the patient files and information. The research study will entail a brief self-report questionnaire, hearing screening and visual acuity screening.

The request is lodged with you in terms of the requirements of Promotion of Access to Information Act No.2 of 2000. Thus, I would like to request access to the individuals between the ages of 18 and 60 years who have diabetes mellitus as well as their clinical files.

I intend to publish the results of this research study in an international peer-reviewed journal and/or at meetings like symposia, congresses, or other meetings of such nature. We intend to protect the personal identity of the patients by assigning each patient a random code number. We will not proceed with the research study until we have received approval from the Faculty of Humanities and Health Science Research Ethics Committee – University of Pretoria.

With thanks and kind regards,

Miss Lauren Fredericks
Research student
u15089178@tuks.co.za

Dr Barbara Heinze
Academic supervisor
barbara.heinze@up.ac.za

Mrs Karina Swanepoel
Research supervisor
karina.swanepoel@up.ac.za

PERMISSION TO DO THE ABOVE RESEARCH STUDY AT ODI DISTRICT HOSPITAL AND TO ACCESS THE INFORMATION AS REQUIRED, IS HEREBY APPROVED, ON CONDITION THAT THERE WILL BE NO COST TO THE HOSPITAL

.....

Mr A. Musie
Chief Executive Officer
Odi District Hospital

Date: 22/04/2021.

ODI DISTRICT HOSPITAL
OFFICE OF THE CEO
Official Stamp
22 -04- 2021
PRIVATE BAG X509
MABOPANE 0190
GAUTENG DEPARTMENT OF HEALTH

ODI DISTRICT HOSPITAL
OFFICE OF THE CEO
22 -04- 2021
PRIVATE BAG X509
MABOPANE 0190
GAUTENG DEPARTMENT OF HEALTH

University of Pretoria, Private Bag X20
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Tel +27 (0)12 420 2357
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Departement Spraak-Taalpatologie en Oudiologie
Lefapha la Bomotho
Kgoro ya Phatholotši ya Polelo-Maleme le Go kwa

6.4 APPENDIX D: Voluntary and informed consent forms

UNIVERSITEIT VAN PRETORIA
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Faculty of Humanities
Department of Speech-Language Pathology and Audiology

STUDY TITLE: The usefulness of mHealth tools in detecting abnormalities in hearing and vision in adults with diabetes mellitus

SPONSOR: N/A

PRINCIPAL INVESTIGATORS: Miss Lauren Fredericks

INSTITUTION: University of Pretoria

DATE AND TIME OF FIRST INFORMED CONSENT DISCUSSION:

Date	**Month**	**Year**

:
Time

Dear Prospective Participant

Dear Mr. / Mrs. .....

1) INTRODUCTION

You are invited to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should first be screened for Covid-19 and thereafter, review Covid-19 protocols. Secondly, you need to fully understand what is involved in this study. You should not agree to take part unless you are completely happy about all the procedures involved.

2) COVID-19 SCREENING AND PROTOCOL

Prior to the commence of this study, you will be screened for Covid-19. Thereafter, the following protocols for your safety will be implemented:

- You and the primary investigator will be required to wear a face mask correctly throughout interaction and testing. The primary investigator will make use of a face shield for further prevention of the spread of Covid-19.
- The primary investigator will ensure the physical distance of 2 meters between you and other participants in waiting area.

- The primary investigator will ensure the waiting area and the area of testing are well-ventilated.
- The primary investigator will ensure to regularly decontaminate all frequently touched surfaces in the waiting area and the area of testing, and all the equipment used in testing before and after consulting with you.
- The primary investigator will practice good hand hygiene by hand washing with soap and water for at least 20 seconds and sanitizing of hands with at least 70% alcohol. Hand washing and/or sanitizing will be done before seeing you, before the procedure, after seeing you and after touching your surroundings and file. Your hands will also be sanitized before and after testing.

3) THE NATURE AND PURPOSE OF THE STUDY

The main aim of this study is to determine the usefulness of mHealth tools in detecting changes in hearing and vision in adults with diabetes mellitus. Testing will be done prior to your appointment at the Diabetes Clinic.

All the research data and/or documents referring to the above-mentioned study will be stored anonymously for 15 years.

4) EXPLANATION OF PROCEDURES TO BE FOLLOWED

You will undergo a procedure that will last for 20 minutes at the Diabetic Clinic at Odi District Hospital. A hearing assessment and vision screening will be conducted as part of your routine medical tests before your appointment with the doctor. We will collect clinical information from your hospital file and the following procedures will be included in the assessment: otoscopy, hearing screenings, and visual acuity screening. You will also be required to complete a questionnaire (see summary).

Summary of the tests that will be used in this research study:

Screening Category	Test	Expected from participant
Case History	Self-report questionnaire	You will be required to answer a few questions regarding your hearing and vision
Hearing assessment	Otoscopy	Inspection of the ear canal and ear drum with an otoscope, while you are seated upright
	Tympanometry	A probe will be placed in your ear to check for any middle ear problems or infections
	Pure tone audiometry screening	You will be required to raise your hand when a beep sound is heard through the headphones

	(smartphone application)	
	Digits-in-Noise screening (smartphone application)	You will hear some numerical digits in background noise and you will be required to dial those numbers into the smartphone
Visual acuity screening	Peek Acuity screening (smartphone application)	You will be required to point your hand in the direction of the letter "E" i.e. left, right, up or down

5) RISK AND DISCOMFORT INVOLVED

There are no medical risks or discomforts associated with this study. If you do not want to take part any more, you may decide at any time during the study not to carry on – no one will force you to carry on. No one will be cross or upset with you if you don't want to, and your doctor will still look after you.

6) POSSIBLE BENEFITS OF THIS STUDY

There will be no direct benefit. The indirect benefit is that you will be aware of your hearing and visual status. If a hearing impairment is identified, you will be referred to the Department of Speech-Language Pathology and Audiology at Odi hospital for further investigation. If a visual Impairment is identified, you will be referred to the Eye Clinic at Odi district hospital for further investigation.

7) COMPENSATION

You will not be paid for participating in the study; no extra costs are expected to be concurred by you or by the hospital.

8) WHAT ARE YOUR RIGHTS AS A PARTICIPANT

Your participation in this research study is voluntary. You can withdraw from the study at any time; data already collected will be excluded from the study. This will not affect your treatment at the Diabetes Clinic.

9) ETHICS APPROVAL

This Protocol was submitted to the Faculty of Health Sciences and Humanities Research Ethics Committees, University of Pretoria, telephone numbers 012 356 3084 / 012 356 3085 and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations

guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

10) INFORMATION AND CONTACT PERSON

If you have any questions about the study, feel free to contact me:

Miss Lauren Fredericks: 078 798 8905 or, u15089178@tuks.co.za

11) CONFIDENTIALITY AND ANONYMITY

Personal information and the results of the tests from you will be kept strictly confidential. A numeric code will be allocated to you; the researcher and supervisors will only know this code. Results will be anonymously used in an article. All the results will be stored safely in a password-protected format for a period of 15 years, as per university policy; this data may be used for future research.

12) CONSENT TO PARTICIPATE IN THIS STUDY

I have read this information document and I understand the above information. I hereby agree to participate in the above-mentioned research project. I have read the above information and understand what is required of me in this research study. I acknowledge that my results may be used anonymously for research purposes.

I am aware that I participate voluntarily and that I may withdraw from the research study at any time.

I have received a signed copy of this informed consent agreement.

Participant's name (Please print)	Date
Participant's signature	Date
Researcher's name (Please print)	Date
Researcher's signature	Date

6.5 APPENDIX E: Covid-19 screening

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Faculty of Humanities
Department of Speech-Language Pathology and Audiology

	Date	Name & Surname	Have you been screened at the entry of the hospital?	Do you have any symptoms of general body pain or headaches?	Do you have a loss of smell or taste?	Do you have any nausea, vomiting or diarrhea?	Do you have shortness of breath?	Do you have any coughs, sore throat or fever?
1.			YES/NO	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
2.			YES/NO	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
3.			YES/NO	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
4.			YES/NO	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
5.			YES/NO	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
6.			YES/NO	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
7.			YES/NO	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO
8.			YES/NO	YES/NO	YES/NO	YES/NO	YES/NO	YES/NO

6.6 APPENDIX F: Feedback letter (Referral required)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
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Faculty of Humanities
Department of Speech-Language Pathology and Audiology

PARTICIPANT FEEDBACK LETTER

THE USE OF MHEALTH TOOLS IN THE EVALUATION OF BOTH HEARING AND VISION IN ADULTS WITH DIABETES

Participant number: ……..... Date of assessment: ……

Dear Participant,

Thank you for participating in the above-mentioned study. The following tests were performed:

Hearing assessment

- ☐ Otoscopy
- ☐ Tympanometry
- ☐ Pure tone audiometry with extended high frequency testing
- ☐ Digits in Noise

Visual Acuity Screening

- ☐ Peak Acuity Test

Considering the test results obtained, it is recommended that you visit an:

- ☐ Audiologist for a diagnostic hearing evaluation
- ☐ Ophthalmologist for a further diagnostic evaluation

Reasons for referral

_____

_____

Kind Regards,

Miss Lauren Fredericks
Student
U15089178@tuks.co.za

Mrs. Karina De Sousa
Academic supervisor
Karina.swanepoel@up.co.za

Professor Leigh Biagio de Jager
Academic supervisor
leigh.biagio@up.ac.za

6.7 APPENDIX G: Data collection sheet

UNIVERSITEIT VAN PRETORIA
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Faculty of Humanities
Department of Speech-Language Pathology and Audiology

DATA COLLECTION SHEET

Participant number:……..	Sex: Male or Female
Age: …..	HbA1c Level:
Type of Diabetes: Type 1 or Type 2	Use of ototoxic medication: Yes or No
Medications: Insulin injections or Oral glucose lowering	Neurological disorders: ……

PART 1: SELF-REPORT QUESTIONNAIRE

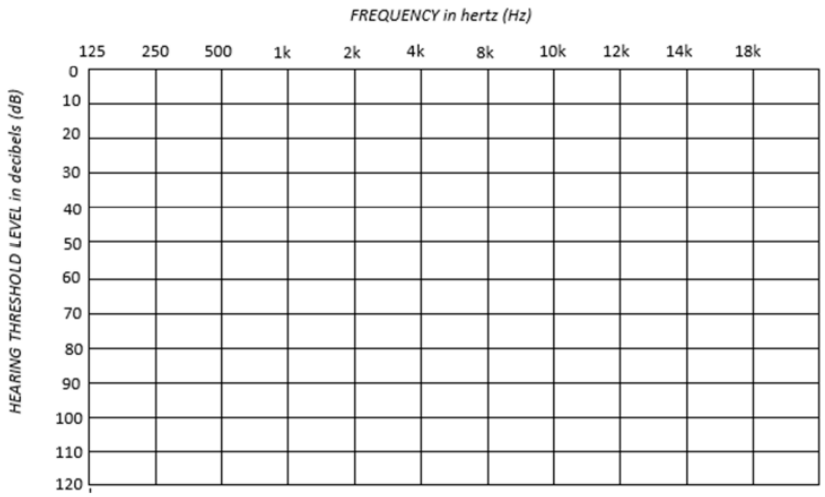
Please write and/or circle where applicable:

1. Which year were you diagnosed with diabetes mellitus?
2. Do you have any other chronic illnesses? i.e high blood pressure or heart disease
3. Are you currently a smoker? Yes or No
4. Have you ever worked in a loud environment? Yes or No
5. Are you pregnant or been pregnant in the last three months? Yes or No
6. Do you have a history of ear infections or surgeries? Yes or No
7. Do you have a history of eye problems or surgeries? Yes or No
8. Have you had any trauma to the head/ear/eye? Yes or No
9. Do you have a family history of hearing loss or vision loss? Yes or No
10. Do you struggle with hearing? Yes or No
11. Do you wear spectacles for a visual impairment? Yes or No

PART 2: AUDIOLOGICAL EXAMINATION

Otoscopic Examination
R
L

Tympanometry		
	R	**L**
Tympanogram		
Middle Ear Pressure		
Static Compliance		
Ear Canal Volume		



DIN SCORE (SNR)	

PART 3: VISUAL ACUITY SCREENING PASS / REFER

LogMAR Score		
Right eye		**PASS / REFER**
Left eye		**PASS / REFER**

University of Pretoria, Private Bag X20
Hatfield 0028, South Africa
Tel +27 (0)12 420 2357
Fax +27 (0)12 420 3517

Fakulteit Geesteswetenskappe
Departement Spraak-Taalpatologie en Oudiologie
Lefapha la Bomotho
Kgoro ya Phatholotši ya Polelo-Maleme le Go kwa

6.8 APPENDIX H: Feedback Form (Normal Results)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

PARTICIPANT FEEDBACK LETTER

THE USE OF MHEALTH TOOLS IN THE EVALUATION OF BOTH HEARING AND VISION IN ADULTS WITH DIABETES

Participant number: ……..... Date of assessment: ……

Dear Participant,

Thank you for participating in the above-mentioned study. The following screening tests were performed:

Hearing assessment

- ☐ Otoscopy
- ☐ Tympanometry
- ☐ Pure tone audiometry with extended high frequency testing
- ☐ Digits in Noise

Visual Acuity Screening

- ☐ Peak Acuity Test

There is no need for further assessment as you obtained normal screening results for hearing and vision. It is only recommended that you visit the Department of Speech-Language and Audiology and Eye Clinic annually for a hearing and visual screening.

Kind Regards,

Miss Lauren Fredericks
Student
U15089178@tuks.co.za

Professor Leigh Biagio de Jager
Academic supervisor
leigh.biagio@up.ac.za

Mrs. Karina De Sousa
Academic supervisor
Karina.swanepoel@up.co.za

6.9 APPENDIX I: Proof Of Submission

Gmail

Lauren Fredericks <u15089178@tuks.co.za>

JDDC-D-23-00191 - Submission Confirmation

International Journal of Diabetes in Developing Countries (JDDC) <em@editorialmanager.com> Fri, 31 Mar at 13:02
Reply to: International Journal of Diabetes in Developing Countries (JDDC) <gursimaran.kaur@springer.com>
To: Lauren Fredericks <u15089178@tuks.co.za>

Dear Miss Fredericks,

Thank you for submitting your manuscript, The use of mHealth tools in the evaluation of both hearing and vision in adults with diabetes, to International Journal of Diabetes in Developing Countries.

The submission id is: JDDC-D-23-00191
Please refer to this number in any future correspondence.

During the review process, you can keep track of the status of your manuscript by accessing the journal's website.

Your username is: Laurenfredericks2022
If you forgot your password, you can click the 'Send Login Details' link on the EM Login page at https://www.editorialmanager.com/jddc/.

Should you require any further assistance please feel free to e-mail the Editorial Office by clicking on "Contact Us" in the menu bar at the top of the screen.

With kind regards,
Springer Journals Editorial Office
International Journal of Diabetes in Developing Countries

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