

Temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds.

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List of abbreviation and acronyms

AC	Air Conduction
ASHA	American Speech-Langauge Hearing Association
AFT-R	Auditory Fusion Test - Revised
BC	Bone Conduction
САР	Central Auditory Processing
CANS	Central Auditory Nervous System
dB	Decibel
FPL	Fasting Plasma Glucose Level
GDT	Gap Detection Threshold
GIN	Gaps-in-noise
HRQL	Health Related Quality of Life
HL	Hearing level
IDF	International Diabetes Federation
Ms	Millisecond
OAD	Oral antidiabetic
ΡΤΑ	Pure Tone Average
RESCOM	Departmental Research and Ethics Committee
RGDT	Random Gap Detection Test
SD	Standard Deviation
SL	Sensation Level
WHO	World Health Organisation

Abstract

Diabetes is one of the most prominent health emergencies of the 21st century, affecting millions of people worldwide. An estimate of 415 million individuals had diabetes in 2015, with more than 10% of those individuals living in the Sub-Saharan Africa region. Diabetes is classified according to aetiology. Diabetes mellitus type II accounts for more than 90% of cases. Since the disease is initially asymptomatic, 30% to 85% of cases remaining undiagnosed. Due to this delay in diagnosis approximately 20% of the individuals will have developed secondary complications. Auditory complications are often associated with diabetes; however, the extent and nature of these auditory manifestations are still unknown.

The main aim of this study was to determine and compare the temporal resolution abilities of adults with diabetes mellitus type II with normal pure tone thresholds to the findings of healthy age and gender matched controls without diabetes mellitus type II.

A descriptive between-group comparative research design was utilized in this study. Purposive convenience sampling was employed to recruit individuals with and without diabetes mellitus type II.

Fifty-six age and gender-matched participants (28 diabetic, 28 non-diabetic) between the ages of 20 to 60 years participated in the study. Pure tone audiometry was used to determine hearing thresholds while temporal resolution abilities, specifically the gap detection threshold, were determined using the GIN test and the RGDT. Psychometric functions were also constructed to determine differences between the two participant groups in terms of gap detection threshold as a function of gap duration (GIN test).

A statistically significant difference of p<0.001 was obtained for the mean gap detection threshold between the two groups for the GIN test. No significant differences were obtained for the total percentage correct scores between the two groups. Results for the RGDT regarding the arithmetic mean gap detection

thresholds indicated no statistically significant difference (p=0.101) between the diabetic group and the non-diabetic group at all test frequencies. Finally, psychometric functions constructed for the participant groups with and without diabetes type II revealed that the gap durations that best distinguish the two groups are 5, 6 and 7 ms

Evidence of the present study suggests a strong association between diabetes mellitus type II and temporal resolution abilities (gap detection threshold). As temporal resolution is closely linked to speech in noise, more studies are needed in this regard.

Key words

Diabetes mellitus type II Temporal resolution Gaps-in-noise (GIN) test Random Gap Detection Test (RGDT) Gap detection threshold Speech perception in noise

CHAPTER 1: INTRODUCTION

1.1 General background

Diabetes is increasing dramatically worldwide and is more far-reaching than previously thought (IDF, 2015; WHO, 2016). Diabetes no longer affects wealthy nations alone as people from low and middle income countries become progressively more affected (IDF, 2015). The greatest increase is expected to be in Africa with a 111% projected growth in the diagnoses of diabetes by 2025 (Sanju & Kumar, 2016). The International Diabetes Federation (IDF) estimated that 415 million individuals had diabetes in 2015 and reported that 14.2 million (10%) of those individuals live in Sub-Saharan Africa. By 2040 these figures are projected to increase to a global prevalence of 642 million and to 34.2 million in Sub-Saharan Africa (IDF, 2015). This can be considered as a true epidemic.

Due to the dramatic increase of diabetes, heath care systems and the global economy become burdened not only by medical costs, but indirectly by the serious complications associated with the disease (WHO, 2016). The complications induced by diabetes lead to physical and psychological consequences that negatively alter the health related quality of life (HRQL) of individuals with diabetes (Chatterjee, Khunti, & Davies, 2017; WHO, 2016). Additional consequences include productivity deterioration, loss of wages, and premature mortality. Mathers and Loncar (2006) estimated that by 2030 diabetes will be the seventh leading cause of mortality. However, due to the relationship between the growth in the prevalence of diabetes and the increasing lifespan of these individuals, the types of morbidity associated with diabetes and the complications of the condition may be altered (WHO, 2016).

Additionally, Wexler et al. (2006) revealed that microvascular complications, heart failure, and depression were each strong independent correlates of decreased HRQL in individuals with diabetes mellitus type II, with depression being the strongest correlate. Additionally, the high number of medications constituted a statistically significant factor in impaired HRQL in these individuals (Wexler et al., 2006).

As diabetes leads to poorer HRQL for the significant number of people affected, it may be considered a major global health concern and therefore research in this field is urgently needed. As mentioned, individuals with diabetes tend to have poorer HRQL than non-diabetics particularly regarding physical functioning and overall health, due to the disease and the complications that arise from it. Thus, these aspects should be considered in the treatment of these individuals.

1.2 Epidemiology of diabetes mellitus

Diabetes can be classified as a metabolic disorder characterised by high blood sugar (hyperglycaemia), and abnormal functioning of insulin secretion and action, with disturbances in metabolic acids (American Diabetes Association, 2013). Diabetes is caused by irregularities in the secretion of insulin, which is responsible for the regulating blood glucose throughout the body. Diabetes is commonly classified as either type I or type II, with the biggest differences between the types of diabetes the ability to retain insulin.

Diabetes mellitus type I is an immune-mediated disorder as there is destruction of the B-cells within the pancreas, causing complete insulin secretion dysfunction which requires lifelong insulin treatment. This type accounts for only 5% to 10% of individuals with diabetes while diabetes mellitus type II accounts for the majority of cases of diabetes (American Diabetes Association, 2013).

Diabetes mellitus type II can be described as insulin resistance with slight (not absolute) insulin deficiency and no destruction of B-cells (American Diabetes Association, 2013). These individuals' cells are unable to use insulin optimally, which may lead to abnormal carbohydrate metabolism resulting in hyperglycaemia. Most individuals fail to notice the rise in blood sugar levels due to its slow increase over time.

1.3 Diabetes mellitus type II

Diabetes mellitus type II is a major public health problem and accounts for more than 90% of cases of diabetes (American Diabetes Association, 2009). Hyperglycaemia in its earliest form is not profound enough for individuals to observe any diabetic indicators and therefore these individuals do not seek immediate medical attention

(Frisina, Mapes, Kim, Frisina, & Frisina, 2006). This clarifies why 30% to 85% of individuals with diabetes remain undiagnosed for long periods of time (Amod et al., 2012). It is only when complications emerge that the diabetes diagnosis is made. What makes the situation more serious is the fact that the longer diabetes remains undiagnosed and untreated, the greater the medical complications will be (WHO, 2016).

Although diabetes mellitus type II is incurable it remains a manageable condition. Treatment of diabetes mellitus type II involves lifestyle changes, exercise, weight loss, and various medications such as Metformin (George, Brujin, Will, & Howard-Thompson, 2015). Medical management includes medications which aim to lower blood glucose levels by targeting multiple areas of the body. While numerous hypoglycaemic agents are also used as treatment, metformin, an oral antidiabetic, is the first line treatment option (Chaudhari, Vallarino, Law, & Seifeldin, 2016). Metformin is proven to reduce complications associated with diabetes mellitus type II such as cardiovascular problems, as well as mortality rate (George, Brujin, Will, & Howard-Thompson, 2015; Holman, Paul, Bethel, Matthews, & Neil, 2008). Studies report that early detection and treatment with oral antidiabetic (OAD) may delay and even prevent the development of diabetes mellitus type II and the complications associated with it (Phung, Sood, Sill, & Coleman, 2011).

Increased risk of stroke, myocardial infarction, microvascular complications and vascular insufficiency, and cognitive impairments are just some of the health implications associated with diabetes mellitus type II (Chaudhari et al., 2016; Sima, 2010). In addition, hearing loss as a complication of diabetes mellitus type II has been the topic of focus for many clinical researchers for the past few decades but with varying results.

1.4 The effect of diabetes mellitus type II on the auditory system

The inner ear is located within the temporal bone of the skull (Cunningham & Tucci, 2017). This intricate structure houses the cochlea and the vestibular system, both sharing the same blood supply and innervated by the eighth cranial nerve. These structures are dependent on microcirculation provided by the cochlea which is tasked with supplying oxygen and glucose rich blood to the inner ear.

Diabetes mellitus type II affects the auditory system and its functioning in numerous ways (Akinpelu, Mujica-Mota, & Daniel, 2014). The effects can either be cochlear or retrocochlear, or can be combined with pathophysiological mechanisms such as neuropathy, neuronal degeneration, and microangiopathy (Joshi, Galagali, & Singh, 2017). Spiral ganglion atrophy, myelin sheath degeneration, reduced nerve fibers in the spiral lamina, and thickening of the basilar membrane vessels of the stria vascularis, which is situated within the cochlea, can all manifest because of diabetes mellitus type II (Fukushima et al., 2006).

Intense metabolic activity occurs within the stria vascularis, which relies on glucose since it does not have the capability to store energy. Consequently, when changes in blood metabolism occur (as with hyperglycaemia), activity within this structure becomes disrupted resulting in impaired cochlear stability and ultimately hearing loss (Botelho, Da Silva Carvalho, & Silva, 2014; Wolfe, 2011).

Apart from hyperglycaemia, diabetes mellitus type II can also cause insulin secretion abnormalities, which may lead to alterations in the metabolism of carbohydrates, proteins, and fats. These nutrients accumulate in the circulation system and may cause microvascular and macrovascular damage (American Diabetes Association, 2013).

Diabetes mellitus type II may moreover cause direct damage to the auditory nerves due to hyperglycaemia, which impedes blood flow not only to the auditory nerves but also to the arteries which supply the auditory nerves with nutrients (Fukushima et al., 2006). The pathology behind numerous complications such as sensorineural hearing loss associated with diabetes mellitus type II is diabetic microangiopathy (Cano et al., 2010; Özel, ÖzkiriŞ, Gencer, & Saydam, 2014). Mishra et al. (2016) also stated that microangiopathy is the leading cause of hearing loss in individuals with diabetes mellitus type II. This condition is characterized by diffused thickening of the basilar membrane, while smaller parts of the inner ear are also affected leading to reduced oxygen supply to the cochlea and ultimately loss of hearing (Mishra, Sanju, & Kumar, 2016). An additional contributing factor to sensorineural hearing loss in the diabetic population is that diabetes mellitus type II affects not only the cochlear structures, but the pathway from the brainstem up to the cortex as well (Bajaj, Puthuchery, Bhat,

& Ranjan, 2014). Damage to the structures along the auditory pathway will result in abnormal auditory processing test findings, as these tests depend on normal auditory pathway functioning (Bajaj et al., 2014; Diaz de León-Morales, Jáuregui-Renaud, Garay-Sevilla, Hernández-Prado, & Malacara-Hernández, 2005).

One area that necessitates further investigation is the correlation between the duration of diabetes mellitus type II and the incidence of hearing loss as no clear consensus exists. Several studies report that the duration of diabetes mellitus type II has a minimal effect on the prevalence of hearing loss (Dalton, Cruickshanks, Klein, Klein, & Wiley, 1998; Sasso et al., 1999), while more recent studies state that a correlation does exist (Bamanie & Al-Noury, 2011; Joshi et al., 2017). Hearing loss is said to be more likely if diabetes mellitus type II is present for longer than 10 years (Bamanie & Al-Noury, 2011). Likewise, Joshi et al. (2017) reported that thresholds were found to increase at each frequency tested with an increase in the duration (up to 10 years) of diabetes mellitus. This highlights the association between diabetes duration and the decline in hearing function.

International literature reveals no consensus for the correlation between diabetes mellitus type II and hearing loss as no cause-effect relationship exists (American Diabetes Association, 2009). Although a substantial group of studies revealed an association between diabetes mellitus type II and sensorineural hearing impairment, all showed varying results. Sensorineural hearing loss reportedly occurs in 13.1% of diabetics in contrast to only 10.3% of non-diabetics (Kakarlapudi, Sawyer, & Staecker, 2003). A systematic review conducted by Akinpelu et al. (2014) showed that individuals with diabetes mellitus type II had a significantly higher incidence of hearing loss when compared with individuals without diabetes mellitus type II. Furthermore, hearing thresholds of individuals with diabetes mellitus type II tend to be higher at all frequencies tested compared to hearing thresholds of healthy individuals (Konrad-Martin et al., 2010; Zivkovic-Marinkov, E Milisavljevic, Stankovic, Zivic, & Bojanovic, 2016). A meta-analysis conducted also reported this finding but thresholds were statistically significantly higher only at 6000 Hz and 8000 Hz (Akinpelu et al., 2014). The high frequencies showed a bilateral mild to moderate sloping hearing loss with high variability among thresholds. This inconsistency may be explained by atrophy and stria vascularis thickening proven to occur in individuals with diabetes mellitus type II (Vignesh, Jaya, Moses, & Muraleedharan, 2014).

Some reports on hearing loss in individuals with diabetes mellitus type II indicated a sudden onset sensorineural loss affecting only the low and mid frequencies (Bamanie & Al-Noury, 2011; Maia & Campos, 2005). Other researchers, however, noted a gradual progressive bilateral sensorineural hearing loss, specifically at the higher frequencies (Karabulut et al., 2014). The shared finding seems to be a high-frequency hearing loss (Diaz de León-Morales et al., 2005; Kakarlapudi et al., 2003). The presence of hearing loss in the high frequency region means that it usually goes undetected or is misdiagnosed as presbycusis and not noted as a direct result of the diabetes. High-frequency hearing loss affects the quality of life of individuals with diabetes mellitus type II as it becomes increasingly difficult to understand speech in noisy environments (Akinpelu et al., 2014). As a result of the auditory-related sequelae, diabetes mellitus type II will also affect auditory processing.

1.5 The effect of diabetes mellitus type II on temporal processing

"The efficiency and the effectiveness of the central nervous system (CNS) to utilize auditory information" is called Central Auditory Processing (CAP) (ASHA, 2005). CAP refers to auditory processes and mechanisms responsible for sound localization and lateralization; auditory discrimination; auditory pattern recognition and temporal aspects of audition. These aspects include temporal resolution, temporal masking, temporal integration, and temporal ordering (ASHA, 2005). Temporal processing is an important component of auditory processing.

Temporal processing can be defined as the precise processing of the timing aspects integrated in sound stimuli (Samelli & Schochat, 2008). According to Chermak and Lee (2005), temporal processing of auditory signals can be divided into four categories: temporal ordering, temporal integration, temporal masking, and temporal resolution. The latter will be discussed in detail as this is the focus of the study. Temporal resolution can be described as the auditory system's ability to detect fast changes in auditory stimuli over time – a integral part of speech recognition and language acquisition (Iliadou, Bamiou, Chermak, & Nimatoudis, 2014). Temporal resolution is the shortest time in which a listener can discriminate between two

auditory signals, usually in the range of two to three ms (Musiek et al., 2005). Temporal resolution is usually assessed by measuring a person's gap detection threshold (GDT). The GDT is the shortest gap or silent period within noise a listener can detect (Musiek et al., 2005). Listeners often struggle with tasks that entail understanding speech in noisy and reverberant listening conditions, especially when a high-frequency hearing loss is present (Bajaj et al., 2014). Individuals who struggle to perceive speech in noise do not have a problem with audibility but rather have difficulty understanding what is being said.

Various reasons have been reported for speech-in-noise difficulties both among individuals with normal hearing and individuals with hearing loss. In the past, researchers indicated that peripheral hearing sensitivity plays an important role (Humes & Roberts, 1990; van Rooij & Plomp, 1990) while more recently others consider temporal resolution to be a vital factor in predicting speech recognition performance in noise (George, Festen, & Houtgast, 2006; Gordon-Salant & Cole, 2016). Omidvar et al. (2013) support this position by stating that adequate temporal resolution abilities are required for speech perception because temporal resolution provides the listener with information regarding voicing, syllables, consonants, and phrases present within the speech signal. Other researchers state that temporal resolution is important for understanding speech in quiet as well as in challenging listening situations since listeners must first determine the temporal cues and the duration of the speech and silent segments in order to comprehend what is being said (Vermeire et al., 2016). Furthermore, when noise is present spectral and temporal cues become less clear to the listeners, resulting in poorer interpretation of these signals (Vermeire et al., 2016).

In addition, poor speech perception in noise may be due to poor processing of the auditory signal in a given frequency region due to loss of audibility (Mishra et al., 2016). When audibility is lost, auditory processes become weakened along with supra-threshold processing of signals such as intensity and frequency, and temporal processing errors occur in the frequency region of the hearing loss (Moore, 1996). However, the frequency region that corresponds with the hearing loss does not only restrict processing difficulties but can affect neighboring frequencies as well (Wang, Salvi, & Powers, 1996). A fairly recent study also confirmed this phenomenon (Feng,

Yin, Kiefte, & Wang, 2010). Poorer temporal resolution performance was detected in the low-frequency regions among participants with high frequency sensorineural hearing loss (Feng et al., 2010). It is possible that despite normal hearing sensitivity in the low-frequency region, deterioration in temporal processing may be caused by processing difficulties that extend beyond the low-frequency range. In contrast Hwang, Kim, and Lee (2017) demonstrated that listeners with hearing loss performed more poorly than normal hearing listeners on tasks of sentence-in-noise recognition, working memory, and temporal resolution, which is in accordance with other studies (Lee, 2013; Lee, 2015).

Understanding speech in noise is only one of the difficulties experienced by diabetic individuals and has remained the focus of many studies. However, there is a shortage of published research regarding the impact of diabetes mellitus type II on temporal resolution. Research conducted on this feature demonstrated that individuals with diabetes mellitus type II present with poorer temporal resolution abilities compared to non-diabetics (Mishra et al., 2016). This is the only known research that investigated temporal resolution abilities among diabetics, and it revealed intriguing results. Mishra et al. (2016) found a statistically significant difference in gap detection threshold between individuals with diabetes mellitus type Il presenting with decreased hearing sensitivity in the high frequencies and agematched individuals without diabetes with normal hearing. However, Mishra et al.'s (2016) findings can be interpreted based on the nature of hearing loss most commonly observed in individuals with diabetes mellitus type II which is high frequency hearing loss (Diaz de León-Morales et al., 2005; Kakarlapudi et al., 2003). The decreased gap detection threshold found among the diabetic participants compared to the healthy participants may directly be linked to the decreased hearing sensitivity in the high frequencies present among the diabetic participants. Interpretation of these findings remain difficult considering the lack of literature on GDT among individuals with diabetes. However, it is suggested that these findings can be attributed to widened auditory filters and poor central auditory processing (Mishra et al., 2016).

Supporting Mishra et al.'s (2016) statement, Omidvar et al.'s (2013) explanation is that temporal resolution allows an individual to separate acoustic stimuli over time

which is critical for speech perception in noise. These researchers provided evidence that temporal resolution enables individuals to process temporal cues at varying rates by indicating that temporal resolution and speech in noise skills can be evaluated using the same assessment tools, suggesting that the same mechanisms underlie both (Omidvar, Jafari, Tahaei, & Salehi, 2013). Additional support for the hypothesis that good temporal resolution is required to process the cues within speech signals comes from Vermeire et al. (2016). They stated that deficits in temporal resolution are associated with impaired word and sentence identification in both fluctuating and constant noise situations.

Researchers also began to focus their attention on the neural systems that contribute to speech perception in noise, since the impact of diabetes mellitus type II extends beyond the auditory threshold and also affects the central auditory nervous system (CANS). Wong et al.'s (2010) study showed that various relay stations namely the caudal and rostral middle frontal gyrus, superior frontal gyrus, and the superior temporal region were predictors of speech perception in noise performance in a challenging 0 dB signal to noise ratio (SNR) situation (Wong, Ettlinger, Sheppard, Gunasekera, & Dhar, 2010). Auditory brainstem responses in the diabetes mellitus type II population also attract researchers' attention since the temporal cues listeners require for speech perception are stored within the brainstem via synchronous firing of neurons (Bajaj et al., 2014). Impaired auditory brainstem responses have been found in individuals with diabetes mellitus type II (Bajaj et al., 2014; Diaz de León-Morales et al., 2005; Gupta, Mohd, Hasan, & Siddigi, 2010). Prolonged wave III and V latencies and increased inter-wave latencies for I - III, I -V and III - V have been reported by these researchers. The results suggest damage at the relay stations in the CANS leads to delayed transfer of the auditory signal along the auditory pathway in individuals with diabetes mellitus type II at the brainstem and midbrain level. The destruction that occur at the relay stations of the CANS results in transmission difficulties of the auditory signal is also suggestive of neuropathy at the brainstem and midbrain level. Therefore, the auditory processing problems individuals with diabetes mellitus type II display might be attributed to the involvement of CNS structures that may contribute to the speech perception in noise difficulties in these individuals (Bajaj et al., 2014).

Due to the strong link between speech perception in noise and temporal resolution function, therefore, it is hypothesised that individuals with diabetes mellitus type II will display temporal resolution deficits.

1.6 Rationale

The dramatic increase of diabetes mellitus type II along with the serious complications associated with this disease are causes of concern regarding its effect on various parts of the body, including the auditory system. Due to the negative consequences it holds for HRQL, a non-life-threatening complication such as hearing loss can be easily overlooked.

Diabetes mellitus type II is a well-known risk factor and a poor prognostic indicator of sensorineural hearing loss, but the potential impact of diabetes mellitus type II on individuals' temporal resolution abilities is not well recognised yet. It is therefore important to monitor individuals with diabetes mellitus type II for temporal resolution deficits to acquire a better understanding of the components involved in speech perception in noise abilities.

High frequency sensorineural hearing loss will significantly affect speech perception in noise, not only making daily communication difficult but also impacting quality of life negatively. Likewise, deficits in temporal resolution may result in auditory complaints that include difficulty hearing and understanding speech in background noise (Chermak & Lee, 2005). Mishra et al. (2016) stated that poor temporal resolution abilities of individuals with diabetes mellitus type II can be the result of extended auditory filters and poor central auditory processing. This decline in auditory processing skills may have a long-term effect on the communication skills of people with diabetes mellitus type II (Bajaj et al., 2014).

Researchers have raised awareness of how crucial communication is to human existence and that without it, quality of life deteriorates (Bajaj et al., 2014). However, most individuals diagnosed with diabetes mellitus type II are unaware of the long-term impact this disease can have on their communication competence and on their independence. Likewise, individuals are often uninformed and oblivious to the fact

that diabetes mellitus type II can lead to high-frequency hearing loss and that this in return will impede their speech perception ability in noise.

In addition to speech in noise difficulties, symptomatic conditions namely microvascular complications, depression and cardiac arrest, and treatment intensity proved to contribute to decreased HRQL in individuals with diabetes mellitus type II, with depression being the greatest contributor (Wexler et al., 2006). Although diabetes mellitus type II is incurable the restriction of symptomatic complications and treating depression seem to hold the most promise in improving the HRQL in these individuals. In addition, studies report that early detection and treatment with an OAD may delay the development of diabetes mellitus type II along with its complications.

Diabetes mellitus type II is irreversible. Therefore, early identification followed by medical management is vital and must include audiological care. The role of the audiologist in managing individuals with this disease is crucial since it will assist diabetics to minimize further comorbidities such as otologic impairments, help them to achieve maximal function, and ultimately improve their independence and HRQL. This is important as numerous studies fail to monitor auditory functioning in these individuals after the diagnosis has been made. Auditory functions in early diagnosed diabetes mellitus type II individuals can and should be monitored since it could lead to improved treatment, management, and quality of life in these individuals. This can be achieved by integrating diabetes management in the audiologist's scope of practice to ensure healthier patients.

There is currently a need for further research to investigate the speech in noise problems that normal hearing individuals experience through alternating the task as well as the stimulus intricacy. This can be achieved through implementing gap detection tests as it relates to speech perception. The results could serve as baseline data for comparison in studying the impact of various conditions, including diabetes. Practitioners need this information to develop a holistic view of the temporal resolution abilities, which are critical for speech perception in noise, in individuals with diabetes mellitus type II.

CHAPTER 2: METHODOLOGY

2.1 Introduction

This chapter presents a critical discussion of what the study entailed in terms of its aim, research procedures, and the crucial ethical considerations that were considered and implemented throughout the research process. Furthermore, the procedure used for participant selection, materials and apparatus used, data collection procedures as well as the methods implemented for statistical analyses are all described in depth in this chapter.

2.2 Research aim

The main aim of the study was to determine the temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds.

2.3 Research design

The research was based on a descriptive between-group comparative design with an experimental group (participants with diabetes mellitus type II) and a control group (participants without diabetes mellitus type II). The auditory temporal resolution abilities of the participants in the two groups were determined and compared (Leedy & Ormrod, 2015). In a descriptive comparative design, the independent variable is not manipulated. As it was hypothesised that diabetes mellitus type II could be the cause of temporal resolution deficits seen in individuals with this disease, the independent variable was the temporal resolution abilities investigated in this study. The compilation of the groups was not random as potential participants had to adhere to rigorous selection criteria to be included in either the experimental or the control group of the study (Cantrell, 2011). A guantitative approach was used as this study utilised numerical data. The objective was to create statistical figures to determine whether diabetes mellitus type II would affect temporal resolution abilities in a group of adults. In a quantitative research study, the researcher chooses methods that allows for the objective measurement of the variables of interest. This study sought to identify relationships among certain variables and, based on the results obtained to confirm or modify existing theories and at the end draw

conclusions about the research questions (Leedy & Ormrod, 2015; Welman, Kruger, & Mitchell, 2005).

2.4 Ethical considerations

Specific ethical aspects should be considered in all research activities, particularly when humans are the focus of the research. Ethical approval of this study was obtained from the Research and Ethics Committee of the Faculty of Health Sciences (Appendix A) as well as from the Research and Ethics Committee of the Faculty of Humanities (Appendix B). The following ethical aspects were considered in this study:

2.4.1 Permission from relevant authorities

Permission to use diabetes type II patients as participants for this study was obtained from the Head of the Diabetic Clinic at Steve Biko Academic Hospital (Appendix C) who also granted permission to access records and files of the patients (Appendix D). The CEO of Steve Biko Academic Hospital granted permission to conduct the research study at the hospital (Appendix D). Furthermore, permission was also obtained to recruit diabetes type II patients from two private clinics which are both located in Pretoria, Gauteng (Appendices E and F).

2.4.2 Informed consent

Obtaining informed consent is not only an ethical obligation but also a legal requirement since written informed consent needs to be granted before data collection can commence (Raab, 2004). Failure to obtain informed consent may result in serious legal and ethical consequences (Leedy & Ormrod, 2015). The informed consent form described the nature of the research study and the nature of the participants' involvement in the study (Leedy & Ormrod, 2015). Participation was voluntary. Participants received verbal and written information on what the study entailed, what was expected of them, and what their rights were throughout the research process. This included the right to withdraw from the study at any time without any negative consequences. All information provided to the participants utilised terminology that could be understood by laypersons. Written informed consent the informed consent letter (Appendix G).

2.4.3 Confidentiality

In this research study the participants' identity and personal information remained confidential. An alpha-numerical (e.g. A001) number was allocated to each participant after which all personal identifiers were removed.

2.4.4 Referrals

Once data collection commenced, if a hearing loss or other otologic condition (e.g. otitis media) was noted in a participant, the participant received contact information of local audiologists and Ear-, Nose- and Throat Specialists for further management of their condition (Appendices J & K). Likewise, if the participants were diagnosed with auditory processing difficulties, they were referred to the Department of Speech-Language Pathology and Audiology at the University of Pretoria for further testing (Appendix K). All the participants who required further management were given informational counseling regarding the importance of consulting these health professionals for the management of their condition.

2.4.5 Avoidance of harm

When participating in a study the risks should not be greater than the risks involved in one's everyday living (Leedy & Ormrod, 2015; Maxwell & Satake, 2006). There were no risks involved in participating in this study and the participants were not exposed to any physical or psychological harm (Welman et al., 2005). This aspect was clarified in the informed consent letter (Appendix G) and ensured understanding by the participants that the current study did not entail any medical risks or discomfort.

2.4.6 Honesty

Results of any study must be reported in a complete and honest manner without misrepresenting the research procedures carried out or misleading the participants about the nature of the findings (Leedy & Ormrod, 2015; Maxwell & Satake, 2006). Participants were given access to their own test results and if requested were provided with the overall results of the study.

2.4.7 Data storage

According to the policy of the University of Pretoria, data from this research study will be archived at the Department of Speech-Language Pathology and Audiology at the University of Pretoria in digital and hard copy for a period of 15 years. No identifying information of participants was included in these data files.

2.5 Participants

A specific sampling method was used by which the participants were selected, and specific selection criteria were formulated that participants had to adhere to for continued participation. Various materials and apparatus were used, and certain procedures were employed to select the participants.

2.5.1 Sampling method

Participants were selected by means of purposive convenience sampling. This sampling method was selected so that participants who were readily available and agreed to participate could be included. In purposive sampling, people are chosen with a particular purpose in mind (Leedy & Ormrod, 2015; Maxwell & Satake, 2006). Participants for the experimental group were chosen purposively according to specific criteria namely the age, the hearing status and diabetes status, while the participants for the control group were matched to the experimental group for gender and age. The control group included family members, friends, and colleagues who were readily available.

2.5.2 Participant selection criteria

Fifty-six participants took part in the study. The experimental group consisted of 28 participants diagnosed with diabetes mellitus type II who were recruited from the Diabetic Clinic at Steve Biko Academic Hospital and from two private clinics located in the Gauteng province.

The following participant selection criteria were used to select the participants with diabetes mellitus type II:

• Participants who were between 20 and 60 years of age were selected to participate in the study. This age range was chosen since the average age of

adults who develop diabetes mellitus type II is 45 years and older (National Library of Medicine, 2016). Patients often do not present with hyperglycaemic symptoms when they are young, therefore the majority of patients are only diagnosed at a later stage. However, with greater awareness of diabetes mellitus type II some participants might be diagnosed earlier (Frisina et al., 2006).

- Participants diagnosed with diabetes mellitus type II were included based on the diagnostic criteria of the American Diabetes Association (American Diabetes Association, 2013). The criteria for the diagnoses of diabetes mellitus type II include Fasting Plasma Glucose level (FPL) higher or equal to 126 mg/dL (7.0 mmol/L), two hour 200 mg/dL or higher plasma glucose level during an Oral Glucose Tolerance Test, and a random plasma glucose level of 200 mg/dL (11.1 mmol/L) or higher for patients with symptoms of a hyperglycaemic crisis (American Diabetes Association, 2013).
- Hearing sensitivity of the participants had to be normal based on the PTA (500, 1000 and 2000 Hz) thresholds of ≤20 dB HL (Jerger & Jerger, 1980). Normal peripheral hearing is a prerequisite for central auditory tests, as a peripheral hearing loss affects the reliability of the assessment (American Academy of Audiology (AAA), 2010).
- The diagnosis of diabetes mellitus type II had to have been confirmed by the treating physician at the respective clinics from which the participants were recruited.

The control group consisted of 28 volunteers (21 participants were tested, and seven participants were individually matched to two participants from the control group) such as colleagues, acquaintances, family, and friends who did not have diabetes mellitus type I or diabetes mellitus type II during the time of testing. This control group was matched to the experimental group of diabetes mellitus type II participants for age and gender. The following selection criteria were adhered to for the selection of the control group:

 Clear history of current diabetes mellitus status, previous testing for diabetes mellitus and family history of diabetes mellitus type II. In the absence of blood sugar control medication, blood glucose levels had to be within the normal limits of less than 7.8 mmol/L two hours after eating (American Diabetes Association, 2019).

- It was essential that all participants presented with normal peripheral hearing.
 Participants were included if they had a pure tone average (PTA) better than 20 dB HL (Jerger & Jerger, 1980).
- Participants had to present with normal middle ear functioning. Acoustic immittance testing (tympanometry and acoustic reflex measurements) should have indicated normal results in both ears (Type A Tympanogram, static compliance of 0.3 to 1.7 ml, a tympanometric peak pressure of -100 to 50 daPa, an ear canal volume of 0.6 -2.0 ml and stapedial acoustic reflex thresholds that range between 70 and 95 dB HL at 500 Hz and 2000 Hz (Kramer, 2014). Normal acoustic immittance results were required to ensure normal pure tone thresholds and normal middle ear functioning which was needed to ensure reliable test results.

The exclusion criteria for both the experimental and control groups were as follows;

- A PTA (500, 1000 and 2000 Hz) worse than 20 dB HL (Jerger & Jerger, 1980). The presence of a peripheral hearing loss can affect the processing of sound and may affect speech understanding in background noise (American Academy of Audiology (AAA), 2010).
- Absent ipsilateral stapedial acoustic reflexes at 500 Hz and 2000 Hz, indicating reflex values ≥90 dB HL. Normal acoustic immittance results are indispensable to ensure normal pure tone thresholds and auditory processing abilities (Musiek & Chermak, 2013).
- Middle ear pathology. A condition such as otitis media could influence central auditory processing as well as speech perception in noise (Groenen, Grul, Maassen, & Van Bon, 1996).
- A history of recreational and/or occupational noise exposure. One of the major causes of adult-onset hearing loss is occupational noise (Nelson, Nelson, Concha-Barrientos, & Fingerhut, 2005). Hair cells in the cochlea are damaged due to chronic noise exposure and metabolic changes caused by hypoxia (insufficient oxygen supply to tissues and organs of the body) resulting from noise induced capillary vasoconstriction (Ferrite & Santana, 2005). Therefore,

participants with previous exposure to recreational and/or occupational noise were excluded from the study to keep the effect of diabetes mellitus type II on temporal resolution function as absolute as possible.

No past or present use of ototoxic medications. Aminoglycosides, an umbrella term for antibiotics usually used in the treatment of life threatening illnesses (Tuberculosis, human immunodeficiency virus and cancer) are known to cause permanent hearing loss (Cannizzaro et al., 2014). Ototoxic medication can cause otologic side effects such as tinnitus and vestibular problems (Bisht & Bist, 2011). Thus, to ensure the independent study of the effect of diabetes mellitus type II on the auditory system, individuals identified with this risk were excluded from the study.

2.5.3 Material and apparatus for participant selection

Table 1 summarizes the equipment that was used for the selection of the participants:

Apparatus	Motivation	Calibration	
Otoscope (Welch-Allyn REF 22861)	The otoscope was used to examine the outer ear canal and eardrum. This was done to ensure that no signs of middle ear pathology were visible, no occlusion of the ear canal was present, and no foreign objects were present within the ear canal.	N/a	
GSI 61 Audiometer	The GSI 61 Welch-Allyn audiometer and Interacoustics AC40 clinical audiometer are	February 2018	
Interacoustics AC40 Clinical Audiometer	diagnostic two-channel audiometers for air, bone, speech, and masking tests and were used to determine accurate thresholds across all the test frequencies (125 Hz to 8000 Hz).	August 2017	
GSI Tympstar Interacoustics Impedance Audiometer AZ26	Both the GSI Tympstar and the Interacoustics Impedance Audiometer AZ26 were used to assess middle ear functioning in the participants to ensure that all participants presented with normal middle ear function.	February 2018 August 2017	
Material	Motivation	Appendix	
Informed consent	A letter of consent was given to each participant who was willing to participate. Since participants were 18 years and older they were responsible for their own decision to participate in the study.	Appendix G	
Questionnaire	Each participant (experimental and control group participants) completed a self- administrated questionnaire that revealed background history pertaining to their hearing as well as their diabetes status. This information	Appendix H	

Table 1. Materials and apparatus for participant selection

To obtain the information required for participant selection in conjunction with the participant selection criteria, certain apparatus and materials were used (Table 1).

2.5.4 Procedure for participant selection

An outline of the procedures that were performed in order to select the participants is presented in Figure 1, which is followed by a detailed description of the various aspects.

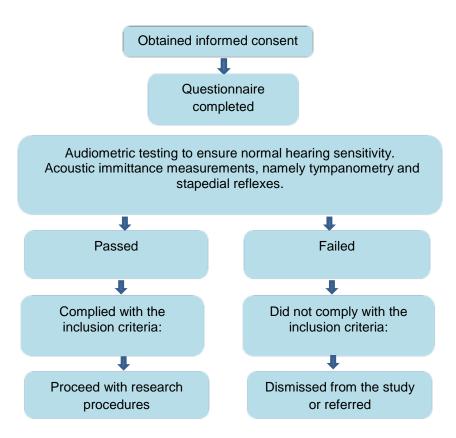


Figure 1. Procedures for participant selection

Prior to the procedures that were used to select participants, informed consent (Appendix G) was obtained from the potential participants followed by completion of a self-administrated questionnaire (Appendix H). A set of tests for both the experimental group and control group included blood glucose testing, otoscopy, acoustic immittance measurements and pure tone audiometry and were administered to ensure normal audiometric results. These tests were administrated at the Department of Speech-Language Pathology and Audiology, at the University of Pretoria, for the control group. The experimental group underwent their testing either at the Audiology Department of Steve Biko Academic Hospital or at the Department of Speech-Language Pathology and Audiology. The following procedures were administered prior to the procedures conducted for data collection.

Blood glucose testing

Blood glucose levels of every participant from both the diabetic and non-diabetic participant group was tested using the Care Sens blood glucose monitoring system. Participants with diabetes mellitus type II were included based on the diagnostic criteria of the American Diabetes Association (American Diabetes Association, 2013). Despite the diabetes diagnosis already confirmed for participants with diabetes mellitus type II, their blood glucose levels were tested to allow for comparison with the blood glucose levels of the non-diabetic participants. Non-diabetic participants blood glucose levels had to be less than 7.8mmol/L two hours after eating to be included in the study.

• Otoscopy

Otoscopy was performed on both ears of each participant to ensure the absence of occluded ear canals, discharge, and foreign objects that may prevent insertion of probes. These contraindications may contribute to alteration of immittance and audiometric test results (Diefendorf, 2009). Normal results can be described as a healthy ear canal and eardrum with minimal wax and a light reflex present. Results were recorded on a data collection sheet (Appendix I). In the case of an abnormality, the researcher attended to it if within the scope of practice of a registered audiologist. Otherwise, appropriate referrals (Appendices J & K) were made along with excluding the participant from the study.

• Immittance testing

Immittance testing namely tympanometry and testing for ipsilateral acoustic reflexes was conducted to ensure normal middle ear function. Three parameters namely middle ear pressure, compliance and ear canal volume were used to assess middle ear function. Only participants with normal results, Type A tympanograms (static compliance of 0.3 to 1.7 ml, a tympanometric peak pressure of -100 to 50 daPa, and an ear canal volume of 0.6 -2.0 ml) were included in the study. Any results that did not comply with the normal limits as stated by Jerger (1970) were considered to be abnormal and were classified according to type (Jerger, 1970). If middle ear pathologies were observed the appropriate referrals were made (Appendices J & K). The acoustic reflex involves the bilateral contraction of the middle ear muscles in response to high-intensity sounds (Gelfand, 2009). This measurement is used as a cross check method to determine the presence of middle ear pathology. Ipsilateral acoustic reflexes were elicited and measured at 500 and 2000 Hz. Present ipsilateral acoustic reflexes elicited at 80-90 dB HL were classified as normal while no reflexes (≥90 dB HL) present at any of the frequencies are classified as abnormal test results. Both tympanometry and acoustic reflex testing were necessary as participants with middle ear pathology had to be excluded from the study.

• Pure tone audiometry

Pure tone audiometry aims to determine an individual's hearing sensitivity across a frequency range of 500 to 8000 Hz. Participants with thresholds exceeding the normal pure tone average of 20 dB HL were excluded from the study. Air conduction and bone conduction thresholds ≤20 dB HL were considered to be normal (Northern & Downs, 2002).

2.5.5 Description of study participants

The participants involved in the current study will be described according to their demographic features and their audiological status.

• Study population

A total of 56 adults participated in the study, which comprised of two groups. The first group consisted of 28 participants with diabetes mellitus type II and the second

group of 28 controls without diabetes type II. Table 2 displays the demographic features of both groups of participants.

• •	-	•	• •	
	All (n=56)	Diabetic group (n=28)	Non-diabetic group (n=28)	<i>P</i> value
Age (Years)	50.05 (±0.2)	50.2 (±7.2)	49.9 (±7.7)	0.137
Gender (%)				
Male	34 (60.7%)	17 (60.7%)	17 (60.7%)	-
Female	22 (39.3%)	11 (39.3%)	11 (39.3%)	-
Disease duration (Years)		· · ·	· /	
1 – 5	-	16 (57.2%)	-	-
6 – 10	-	6 (21.4%)	-	-
11 – 15	-	2 (7.1%)	-	-
16 – 20	-	4 (14.3%)	-	-
Blood Glucose (mmol/l)	-	9.44 (±3.5)	6.26 (±0.8)	0.001*

Table 2. Demographic features of participants from both groups

 \pm = Standard Deviation, %= Percentage, $^{p} \leq 0.05$ statistically significant.

The mean age of the two groups were very similar (diabetic group: 50.2 years, ±7.2, range 29 to 60; control group: 49.9 years, ±7.7, range 27 to 60) indicating no statistically significant difference between the two study groups (p=0.137; Wilcoxon exact rank test). Due to the difficulty in finding exact age matches between the experimental and control group, the researcher allowed a two year age difference between the age of the diabetic participants and their age-matched control participants. An equal number of male and female participants was tested for both groups, 17 males (60.7%) and 11 females (39.3%). Most of the diabetes mellitus type II participants, 16 of 28 participants (57.1%), received their diabetes diagnosis one to five years ago. In addition, the diabetes mellitus type II participants had a mean blood glucose level of 9.44 mmol/L (±3.5) compared to 6.26 mmol/L (±0.8), which indicated a significant difference in blood glucose levels between the two groups (p<0.001; Paired t-test). These blood glucose levels refer to the blood glucose levels of both groups of participants with and without diabetes mellitus type II two hours after eating.

Audiological assessment

Table 3 shows the mean and standard deviation of the pure tone average (PTA) calculated from AC pure tone audiometry thresholds ranging from 500, 1000 and 2000 Hz, for the right and left ears combined. This was done by calculating the right and left ears PTA, adding the PTA's together, and dividing the sum by a factor of 2.

 Table 3. Mean and standard deviation pure tone average (PTA) for the diabetic and non-diabetic group.

Group	n	Mean	Standard deviation	<i>P</i> value Two sample t-test
Diabetic	56	11.48	4.51	0.232
Non-diabetic	56	10.74	4.72	0.232

**p*≤0.05 statistically significant.

AC pure tone audiometry thresholds for test frequencies of 250 Hz to 8000 Hz were determined for each ear of the participants. For this study a three frequency PTA was used to classify hearing sensitivity. Both groups presented with normal hearing based on the mean PTA results (diabetic group mean PTA=11.48, ±4.51; non-diabetic group mean PTA=10.74, ±4.72). There was no significant difference (p=0.232) observed for the mean PTA across the diabetic and non-diabetic group although, the mean PTA of the non-diabetic group was 0.74 dB lower than that of the diabetic group.

2.6 Data collection

Data collection involved the use of certain materials and apparatus and the administration of specific procedures.

2.6.1 Material and apparatus for data collection

Temporal resolution abilities were evaluated using the Gaps-in-noise (GIN) test and the Random Gap Detection Test (RGDT). An Interacoustics AC40 clinical audiometer (calibrated in August 2017) as well as a GSI 61 Audiometer (calibrated in February 2018), TDH-39 matched earphones and the Sansui CD210 CD player was used for the GIN test and the RGDT.

• Gaps-in-noise (GIN) test

Musiek and his associates developed the GIN test from traditional gap-detection procedures as a clinical way of measuring temporal resolution abilities in individuals with possible central auditory deficits (Musiek et al., 2005). This test seeks to identify

the shortest duration of a gap or silence within a sound a listener can detect (Musiek et al., 2005). Chermak and Lee (2005) describe this procedure as a monaural presentation of zero to three gap sets in 6-second intervals of white noise at 50 dB SL, with a period of 2 to 20 ms between these gaps. The location, number, and duration of the gaps per noise segment vary throughout the test for a total of 60 gaps presented in each of four lists (Musiek et al., 2005). The gaps vary in length to reduce the chance of listeners guessing correctly and to obtain statistically sound results (Braga, Pereira, & Dias, 2015). The GIN is suitable for both adults and school aged children and has been used as a research tool across a variety of populations. Temporal resolution function is specifically assessed by the GIN and has been studied across different age categories (Braga et al., 2015), in normal hearing individuals and individuals with hearing loss (Hwang, Kim, & Lee, 2017), in tinnitus patients (Boyen, Başkent, & Van Dijk, 2015), those with central auditory lesions (Musiek et al., 2005) and lastly in individuals with diabetes mellitus type II (Mishra et al., 2016). This test gives insight into the neural integrity of the central auditory nervous system and is sensitive to lesions of the CANS. The sensitivity of this test is 72% and its specificity is 94%. Therefore, the GIN test has been described as a worthy tool to assess temporal resolution deficits in the brainstem and cortical lesions (Musiek et al., 2005).

• Random Gap Detection Test (RGDT)

The RGDT was developed by R. Keith in the year 2000 and is used clinically to assess temporal resolution abilities with the purpose to examine the shortest time interval a listener can detect, namely the temporal acuity threshold (Braga et al., 2015). This test is an adapted form of the Auditory Fusion Test-Revised (AFT-R) (Dias, Jutras, Acrani, & Pereira, 2012). Although both these tests are similar in administration, certain differences need to be acknowledged. Randomised interpulse intervals with both click and tonal stimuli are used by the RDGT, with the aim to measure gap detection threshold. In contrast, the AFT-R seeks to measure the fusion threshold by following an ascending or descending presentation of tonal stimuli. The RGDT consists of a binaural presentation of a gap set in pure tone stimulus pairs, at frequencies of 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. The gaps randomly increase and decrease in duration, changing from 0 to 2, 5, 10, 25, 20, 25, 30 and 40 ms intervals (Zaidan, Garcia, Tedesco, & Baran, 2008). There are four

subsets in the RGDT. Subset 1 and 3 are practice subsets presenting ascending inter-pulse intervals, while subset 2 and 4 (actual tonal or click subsets) randomly present inter-pulse intervals (Chermak & Lee, 2005).

The two gap detection tests, the GIN test and the RGDT, vary across a number of dimensions such as their reported measure, stimulus type, response mode and presentation mode. A summary of these two tests follows in Table 4.

Parameters	GIN	RGDT				
Measures	Gap detection	Gap detection				
Lateralization	Monaural	Binaural				
Stimulus level	50 dB SL, re: PTA	50 dB SL, re: PTA				
Stimuli	Gaps within 6 ms of broadband noise	Tones and clicks				
Gap duration	2 – 20 ms	2 – 40 ms				
Norms: Mean/SD	6.0 – 7.8 ms / 2.5 – 5.3 ms					
Response type Motor Verbal						
Response task	esponse task Press a button Say 1 or 2 or show 1 or 2					
Calculated measure Shortest IPI that leads detection of a gap in 4 o presentations		Shortest IPI that leads to the perception of two tones or clicks				
Test time 20 minutes 15 minutes						

Table 4. The difference between the GIN test and RGDT

*dB (decibels), SL (saturation level), PTA (pure ton average), ms (milliseconds), IPI (interpulse interval)

*Adapted from Chermak & Lee (2005).

Table 4 summarizes the two tests in terms of their different parameters which makes it easy to distinguish between the tests.

2.6.2 Procedures for data collection

The pilot study that was conducted before data collection procedures commenced will be described first followed by a detailed description of the research procedures for the main study.

• Pilot study

Prior to the collection of data, a pilot study was conducted to enhance the validity and reliability of the test procedures (Leedy & Ormrod, 2015). Additionally, the objectives of conducting a pilot study was to determine the feasibility of the research procedures, to establish the amount of time required to conduct the test procedures and lastly to decide whether the methodology, sampling, research materials and analysis planned are appropriate (Strydom, 2002). Therefore, the pilot study made the researcher aware of the possible limitations present in the research design and allowed the researcher to make the needed modifications in time for the primary research process. The pilot study thus allowed for improved planning of all the aspects the researcher intended to include in the research process. The data collection procedures were administered to participants who adhered to the same selection criteria as the study sample (Welman et al., 2005). The two participants were requested to read the informed consent letter (Appendix G) and complete the questionnaire (Appendix H). Feedback regarding the questions asked in the questionnaire as well as the structure of both documents was encouraged, allowing the researcher to make the necessary alterations. Secondly, screening procedures namely otoscopy, immittance testing, and pure tone audiometry were conducted, after which the participants underwent the GIN test and lastly the RGDT. The participants gave feedback about the test procedures, with a view to reducing difficulties that might interfere with test results in the main study. The duration of the entire test procedure was 50 minutes. The results showed satisfactory outcomes and no changes regarding the test procedures were deemed necessary.

• Gaps-in-noise (GIN) test

A total of three lists, each containing 60 gaps, were used in the entire study. These lists were randomised for each participant, but the participant listened to only two of the three lists, one list for the right ear and the other for the left ear. Previous studies indicate high inter-list consistency, no ear dominance and no significant differences across lists for either ear (Musiek et al., 2005; Samelli & Schochat, 2008). The test was always presented monaurally. The participants were seated within a soundproof booth and earphones were placed over their ears. The participants were told that they would hear short 6 second bursts of noise and that there would be a very short period of zero to three silences or gaps within the burst. The participants were instructed to press a button each time a gap was detected. If a gap occurred and the subject did not press the button, it was counted as an error. A false-positive was recorded if no gap occurred but the subject pressed the button. If two or more false responses occurred within the first five trials, the test was stopped, and the instructions were repeated. If the participant's response was not in time with a gap,

the test was stopped, and the participant was asked how many gaps were heard. If the correct total was given these responses were considered correct.

A score sheet was used to record the noise segment number, the time interval at which the gap occurred, plus the duration of the gap for each noise segment. Scoring was calculated for each ear separately. After the gaps perceived by the participants were counted, the approximate gap detection threshold (abbreviated GDTh) was determined. This entailed determining the shortest interval detected in four of the six presentations and could be used to identify central auditory nervous system lesions. In addition, scoring entailed computing the total number of correct responses for all gaps and subtracting the false positives. To determine the percentage correct responses a certain calculation was used namely, amount correct – false positives/60 x 100 = % GIN Score (Musiek et al., 2005). The total GIN score was determined by calculating the number of trails and then multiplying the number with 100 to reach a percentage score (Musiek et al., 2005).

Results obtained from the GIN test were considered normal when the approximate gap detection threshold was less than 8 ms and the calculated percentage (the number of correct responses) was less than 54% (Weihing, Musiek, & Shinn, 2007). Norms included a mean gap detection duration of 4.9 ms and a standard deviation of 1 ms in adults with normal hearing (Musiek et al., 2005). Therefore, it is clear that the GIN test has two parameters to assess temporal resolution function, namely gap detection threshold and the percentage of correct responses.

• Random Gap Detection Test (RGDT)

The RGDT was presented binaurally at 50 dB SL, determined by the pure tone average (PTA) calculated for each ear, with a gap set that consisted of pure tone stimulus pairs, at frequencies 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. The gaps randomly increased and decreased in duration, changing from 0 to 2, 5, 10, 25, 20, 25, 30 and 40 ms intervals (Zaidan et al., 2008). Four subsets were used. Subset 1 included nine click pairs which were presented in ascending inter-pulse intervals. In subset 2 nine randomised tone pairs were presented at four frequencies namely 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Subset 3 consisted of nine click pairs with

ascending inter-pulse intervals. Lastly, in subset 4 the click pairs presented were divided into nine randomised inter-pulse intervals. Each participant was instructed to count the number of tones or clicks heard, with options being one or two tones or clicks. This was done for all subsets. The participant was told to either give a verbal response or to respond by raising one or two fingers. A 4.5 second time interval was used between the test items to give the participant time to respond. Scoring of the RGDT entailed determining the threshold of gap detection which was the shortest time interval at which the participants remarked that two tones were perceived at each tested subset. After the mean gap detection threshold was determined for each tested frequency (RGDTh), the arithmetic mean was determined to obtain the final gap detection threshold (abbreviated RGDT_Th) across the four test frequencies subsets, which excludes the gap detection thresholds obtained for the click subsets. A "pass" was achieved by the participants if their gap detection threshold occurred at ≤ 20 ms with a mean gap detection value of 8 ms (Musiek et al., 2005).

2.7 Reliability and validity

Validity can be described as the degree to which the measurement that is used to collect data is accurately measuring the intended data (Leedy & Ormrod, 2015). Another definition provided by Welman et al. (2005) states that validity is the degree to which the research outcomes truthfully represent what is truly occurring in the situation. Several types of validity were of importance throughout this research study (Leedy & Ormrod, 2015):

- Construct validity is the extent to which a research tool measures an element that cannot be observed but can be assumed from participant behaviour.
- Content validity can be referred to as the degree in which the measurements used to obtain data collection is accurately measuring the intended data.

Validity was ensured in the following manner in this research study:

 Construct validity (Leedy & Ormrod, 2015) was assured by conducting a pilot study before data collection commenced and by using a questionnaire (Appendix H). By being present during the completion of the questionnaire and during the test procedures, the researcher was able to provide clear explanations and instructions along with receiving feedback from the participants.

- Content validity was assured by making use of two different validated standardised instruments that were both developed specifically to measure gap detection, both has been used in various research studies hereby improving the validity of the study.
- Rigorous participant selection criteria were crucial in minimizing confounding factors. Participants who presented with external or middle ear pathology, hearing loss or a neurological disorder were excluded from the study as these factors could have influenced the data obtained in a negative manner.

Reliability can be described as the degree to which the measurement of data collection displays consistency and accuracy (Leedy & Ormrod, 2015). When considering the research findings and the credibility of the findings, it is reliability that is the subject of discussion (Welman et al., 2005). Reliability was guaranteed in numerous ways during the research process (Leedy & Ormrod, 2015):

- The informed consent letter (Appendix G) ensured that the participants understood the nature and the aim of the study. It also ensured that participants were aware of their rights with regard to participation in the study and gave their consent to participate.
- The entire test procedure was critically assessed by a pilot study to ensure dependability and feasibility of the tests. Any limitations were identified and were corrected.
- Calibration of equipment in February 2018 controlled for errors during measurement. Daily calibration of the CD player was done to avoid inconsistent results.
- Representative reliability was enhanced by matching the target population (individuals with diabetes mellitus type II) with control participants in terms of age and gender (Leedy & Ormrod, 2015).
- Participants received clear instructions allowing them to have a sufficient understanding of how they had to respond during the test procedures. Any uncertainty could have influenced the accuracy of the results.

- Reliability of the study was increased by making use of standardised test for data collection purposes.
- Reliability was further increased by measuring pure tone and gap detection thresholds in a controlled test environment namely a soundproof booth.

2.8 Statistical analyses

STATA 15 and R 3.5.0 were used to perform analyses. Descriptive statistics such as means ± standard deviation, median, 25th and 75th percentiles, numbers and percentages were used to describe the data depending on the distribution of the data. To determine differences between those with diabetes mellitus type II and controls without diabetes mellitus type II a two group matched comparison of continuous and categorical data was used since healthy participants were matched to diabetes mellitus type II participants for age and gender. Where data was not normally distributed the Wilcoxon matched pairs test was used and alternatively in the case of normally distributed data the paired t-test was used (StataCorp, 2017). For the mean GIN test gap detection threshold left and right ears were combined, and groups were compared with a linear mixed model which takes the clustering of data of individuals into account. Residuals were then checked for normality and outliners. *P* values of ≤ 0.05 were reported as statistically significant. This study was exploratory therefore no primary hypothesis existed upon which sample size calculation could be based. Therefore, an online A-priori sample size t-test calculator was used. This calculator showed the researcher the minimum required total sample size including the sample size per-group for a two-tailed hypothesis t-test study. The calculation considered the probability level, the anticipated effect size, and the desired statistical power level (Table 5).

Parameters	Parameter values
Anticipated effect size (Cohen's d)	0.8
Desired statistical power level	0.8
Probability level	0.05
Results	
Minimum total sample size (two-tailed hypothesis)	52
Minimum sample size per group (two-tailed hypothesis)	26

Table 5. A-priori sample size t-test calcu	lation results
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The Cohen's *d* effect considers the differences between the two groups in the study (Graham, 2018). Since the researcher expected the difference to be large, a power of 0.8 was used. A probability level of 0.05 was used to allow for 5% error. The calculation was made based on these parameters, suggesting a minimum sample size of 26 participants per group and a total sample size of 52 participants should be used to obtain statistically significant results (Soper, 2018).

CHAPTER 3: RESULTS

The results of temporal resolution tests were obtained from 28 participants with diabetes mellitus type II and were compared with the results obtained from 28 age and gender-matched control participants without diabetes mellitus type II. In this chapter the results of the GIN test, specifically the gap detection threshold (GDTh), and the percentage of correct responses for each study group are depicted in table format and in figures. Moreover the results of the RGDT are also tabulated indicating the gap detection thresholds for each group of participants. Lastly psychometric function curves were created to indicate the differences between the two groups in terms of GDTh as a function of gap duration applicable to the GIN test. The results will be discussed in the follow manner;

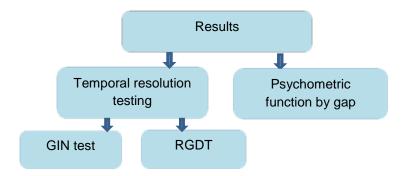


Figure 2. Process for discussion of results

Below the results will be discussed according to the structure that has been presented in Figure 2. Therefore, temporal resolution testing will be discussed first in terms of the GIN test followed by discussion of RGDT. Lastly psychometric function by gap duration will be discussed.

3.1 Temporal resolution testing

The results for the GIN test and the RGDT were as follows.

3.1.2 GIN test

The GIN test consisted of two parameters within which temporal resolution performance could be measured, namely the gap detection threshold (GDTh) and

the total percentage of correct responses. The differences between the ears in each participant group are firstly reported and then the results of the two parameters are displayed.

Comparison between the right and left ears

The GDTHs for the left and right ears of both groups of participants are displayed in Table 6.

Group	n	Ear	Mean	SD	25 th percentile	50 th percentile	75 th percentile	P value Wilcoxon matched pairs test
Diabetic	28	Right	7.18	2.20	6.00	6.00	9.00	0.267
		Left	7.54	2.01	6.00	8.00	8.00	
Non-diabetic	28	Right	6.14	1.58	5.00	6.00	7.00	0.129
		Left	6.46	1.55	5.00	6.00	8.00	

Table 6. GIN: GDTHs for the left and right ears.

*p≤0.05 statistically significant

The results in Table 6 indicate that the mean GDTh of the right ears of the diabetic participant group was 7.18 ms and the mean GDTh for the left ears was 7.54 ms. The participants in the non-diabetic group displayed better GDTHs for each ear (mean GDTh 6.14 ms for the right ear and 6.46 ms for the left ear). However, it is clear from Table 6 that no statistically significant difference was obtained between the right and left ears within the diabetic (p=0.267) and non-diabetic participant groups (p=0.129). This indicates similarity in responses between ears.

Gap detection thresholds and percentage of correct responses

The mean GDTHs of the diabetic and non-diabetic participant groups for both ears combined are displayed in Table 7.

Group	n	Mean	SD	25 th	50 th	75 th	P value
				percentile	percentile	percentile	Mixed model
Diabetic	56	7.36	2.09	6.00	6.00	8.00	0.007*
Non-diabetic	56	6.30	1.56	5.00	6.00	8.00	0.007*
* <i>p</i> ≤0.05 statistically significant							

The participants in the diabetic group obtained a mean GDTh of 7.36 ms while the participants in the non-diabetic group obtained a mean GDTh of 6.30 ms. As indicated in Table 6 no statistically significant difference was obtained between the ears tested within each group. However, when the results of the left and right ears were combined and compared with a mixed model a significant difference was obtained (Table 7). The mean difference between the two groups was 1.05 ms (p<0.001). In addition to the mean GDTh results for each participant group, the results for the number of participants who failed the GIN test based on the GDTh parameter were also analysed. Normal gap detection thresholds are defined as <8 ms. Based on the GDTh results for the right ear, 10 out of 28 (35.7%) diabetic participants failed, compared to only seven non-diabetic participants who failed of 28 participants (25%). The results for the left ear showed that 15 of 28 diabetic participants failed (53.6%) compared to only nine of 28 (32.1%) non-diabetic participants failing. These results, based on the pass and fail criteria elicited for each participant group, indicated no significant difference when within group comparisons were made for the right ear (p=0.5488; Exact symmetry test) and for the left ear (p=0.2379; Exact symmetry test). The mean percentage of correct responses obtained for each group is displayed in Table 8.

Group	n	Mean	SD	25 th percentile	50 th percentile	75 th percentile	P value Paired T-test
Diabetic	28	57.68	9.47	51.50	59.00	64.00	0.00
Non-diabetic	28	61.75	8.83	54.50	62.00	68.00	0.08

Table 8. GIN	percentages	of correct	responses	for both	aroups.

**p*≤0.05 statistically significant

As shown in Table 8, the mean percentages of correct responses for each gap length, across all gaps detected for each test list used, indicated little variability between the two participant groups. The mean percentage of correct responses for the participants in the diabetic group (57.68%, ±9.47) was 4.07% lower than for the non-diabetic participants (control group) who obtained 61.75% with a SD of 8.83. However, despite a poorer performance from the diabetic participant group no statistically significant difference was found between the participant groups (p=0.08). Furthermore, the total percentage of correct responses was considered to determine a pass or fail outcome. The total percentage of correct responses needs to be ≥ 54% to be considered normal. The diabetic participant group performed more poorly with 10 (35.7%) participants scoring ≤54% while only six participants (21.4%) from the

non-diabetic participant group failed this aspect of the GIN test. These results indicated no significant difference between the two participant groups (p=0.388, Exact symmetry test). Moreover, the mean percentages of correct responses across test lists used in this study were not indicated due to high inter-list equivalency (Musiek et al., 2005; Samelli & Schochat, 2008).

3.1.3 RGDT

The results for the RGDT, specifically the gap detection threshold results obtained for each participant group, are provided below.

• Gap detection threshold

For each frequency tested, 500 to 4000 Hz, a gap detection threshold was determined namely the shortest gap duration where the participant perceived two tones. The approximate gap detection threshold was calculated (RGDTh) once the gap detection values for each frequency had been determined. The RGDT_Th is the mean of all the gap detection thresholds across the test frequencies. Table 9 displays descriptive statistics of the RGDT results obtained for both groups separately and the *p*-values calculated to compare the two groups.

Table 9. The approximate (RGDTh) and mean gap detection thresholds (RGDT_Th) of the diabetic and non-diabetic groups.

Group	Diabetic	group (n=	Non-diabetic group (n=28)						
Frequencies	Mean	SD	Min	Мах	Mean	SD	Min	Мах	P value Wilcoxon rank- sum test
500 HZ	8.89	9.75	0	40	6.32	5.38	0	20	0.4774
1000 HZ	9.86	12.34	0	40	5.18	3.13	2	10	0.555
2000 HZ	8.75	10.09	0	40	5.61	4.17	0	20	0.304
4000 HZ	8.46	6.51	2	25	6.04	4.23	0	15	0.187
RGDT_Th	9.09	8.89			5.68	3.10			0.101

*p≤0.05 statistically significant

The approximate RGDTh of the participants in the diabetic group was not significantly different from that of the participants in the non-diabetic group at the frequencies of 500 Hz (p=0.478), 1000 Hz (p=0.555), 2000 Hz (p=0.304) and 4000 Hz (p=0.187). The mean RGDT_Th calculated for the non-diabetic group (5.68 ms) was within the normal limits of <8 ms, while the diabetic participant group's mean RGDT_Th (9.09 ms) fell just outside the norm. The calculated p-values for the mean

RGDT_Th between the diabetic and non-diabetic participant groups were not statistically significant (p=0.101).

3.2 Psychometric functions by gap duration

Additional statistical analyses involved the construction of psychometric functions. This was done to determine differences between the two participant groups in terms of GDTh as a function of gap duration applicable to the GIN test. The generation of these psychometric functions involved determining the mean percentage of correct identification for each gap duration for both study groups, for ears separately (Figure 2 and 3) and ears combined (Figure 4). The mean GDTs and correct responses for each test list were not investigated as high inter-list consistency has been confirmed by other studies (Musiek et al., 2005; Samelli & Schochat, 2008). By using the formula introduced by He et al. (1999) the probabilities of correct responses for gaps from 2 ms to 20 ms were calculated (Table 10). These calculations were used to construct the expected psychometric function and were compared to the observed functions for percentage correct identification by gap duration for the two participant groups (Figures 3, 4 and 5).

Gap duration	Probability of percent correct responses
2 ms	4. 76%
3 ms	17.92%
4 ms	50%
5 ms	88.10%
6 ms	98.23%
8 ms	99.98%
10 ms	100%
12 ms	100%
15 ms	100%
20 ms	100%

Table 10. Probability of perceiving gaps up to 20 ms (Samelli & Schochat,2008).

Table 10 shows that normal hearing individuals perform poorly at gap duration of 2 and 3 ms but begin to show improvement at 4 ms with a 50% correct responses score. Normal hearing individuals are expected to reach 100% correct responses from 10 to 20 ms.

The right ear's mean percentage of correct identification across each gap duration for both the diabetic and non-diabetic participant group are shown in Figure 3.

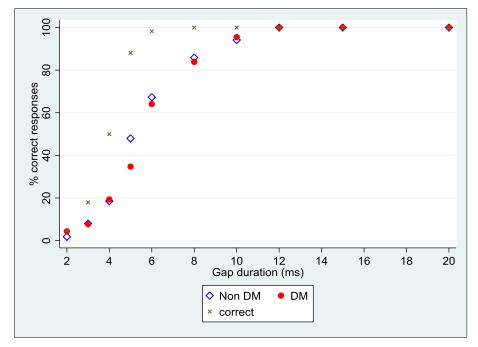


Figure 3. Psychometric functions by gap duration for the right ear across both the diabetic and non-diabetic participant groups.

Figure 3 shows that the DM participant group (red circles) displayed better results than the Non DM participant group (blue diamonds) only at 2 ms and 10 ms. Thus, the percentage of correct responses of the Non DM group was higher than for the DM group at each gap duration (except 2 and 10 ms) or were equally good at certain gap durations (3, 4, 12, 15, 20 ms). In addition, the Non DM participant group only began to show a noticeably better percentage of correct responses than the DM participant group at 5 to 8 ms.

Figure 4 shows the left ear's percentage of correct responses across both groups of participants.

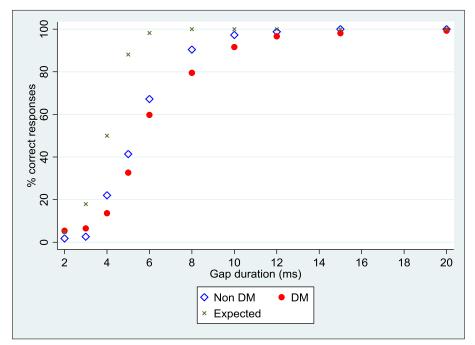


Figure 4. Psychometric functions by gap duration for the left ear across both the diabetic and non-diabetic participant groups.

The trend of the results depicted in Figure 4 is similar to that in Figure 3, showing that the Non DM participant group performed better than the DM participant group at each gap duration except at 2 and 3 ms. In contrast to Figure 3 where the Non DM participant group only began to display noticeably better results at 5, 6, and 8 ms for the right ear, Figure 4 shows that the Non DM participant group performed better at 4, 5, 6, 8 and 10 ms for the left ear.

The mean GDThs for each gap duration for the left and right ears were combined and the results are presented in Figure 5.

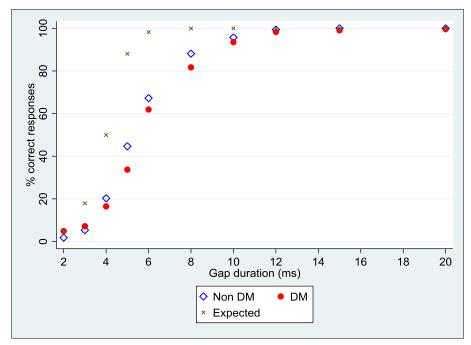


Figure 5. Psychometric functions by gap duration for ears combined for both the diabetic and non-diabetic participant groups.

Figure 5 shows that the observed psychometric function for the Non DM participant group is marginally steeper than those displayed for the DM participant group only at certain gap durations (5, 6 and 7 ms). The observed percentage of correct scores for both the DM and Non DM participant group was well below the expected percentage in the 3 to 8 ms gap duration range. However, the biggest separation for the percentage of correct responses between the two participant groups (not compared to the expected function) occurred in the 5, 6, and 7 ms gap duration region. This is in accordance with Musiek et al.'s (2005) study. Moreover, the greatest separation was seen at 5 ms gap duration, with the Non DM participant group's performance being considerably better than that of the DM group. Increase in the steepness of the observed functions was seen at 15 and 20 ms.

CHAPTER 4: DISCUSSION, CLINICAL IMPLICATIONS AND CONCLUSION

4.1 Discussion

The aim of this research study was to determine the temporal processing, specifically the temporal resolution abilities, in an adult participant group with diabetes mellitus type II and to compare the results obtained to results from an ageand gender-matched participant group without diabetes mellitus type II. The aim was achieved by gap detection tests namely the GIN test and the RGDT. The discussion of the results is structured according to the presentation of the results in chapter 3.

4.1.1 Temporal resolution testing

The gap detection tests conducted namely the GIN test and the RGDT are discussed below.

4.1.2 GIN test

The GIN test will be discussed in terms of an in-group comparison between the right and left ears and the differences between the two participant groups in terms of the gap detection thresholds and the percentage of correct responses.

• Comparison between the right and left ears

No significant differences were obtained between the left and right ears of the two study groups respectively with regards to the mean GDTh. The diabetic participant group's mean GDTh for the right and left ear were very similar but the non-diabetic group displayed slightly better GDThs. These results are in agreement with results from other studies which revealed similar gap detection thresholds for the right and left ears across their study groups (Braga et al., 2015; Musiek et al., 2005; Samelli & Schochat, 2008). These results suggest that the GIN test can be administered binaurally in clinical practice. However, a recent study conducted by Pirasteh et al. (2018) found contrasting results between their diabetes type II and non-diabetes study groups. The diabetic participant's approximate GDTh for the right and left ears (8.1 ms and 9.4 ms) were significantly different compared to the non-diabetic group's GDTh for the right and left ears (5.5 ms and 6.1 ms).

Gap detection thresholds and percentage of correct responses

The current study showed a statistically significant difference between the mean gap detection thresholds of the diabetic (7.36 ms) and the non-diabetic (6.30 ms) groups. Braga et al. (2015) were the only researchers who found a marginally similar, although longer GDT of 8 ms. Musiek et al. (2005) and John et al. (2012) observed slightly better results than the current study with mean gap detection thresholds of 4.9 ms and 4.7 ms respectively. Samelli and Schochat (2008) reported even better results (4.2 ms). Mishra et al. (2016) and Pirasteh et al. (2018) are the only known studies to also investigate temporal resolution abilities in individuals with diabetes mellitus type II. In Mishra et al.'s (2016) study a GDT of 6.49 ms (±0.91) was obtained for the diabetic group and a GDT of 3.33 ms (±0.79) for the control group indicating a statistically significant difference between the two groups. Although Pirasteh et al. (2018) reported on the GDT for each ear separately, their results are similar to the current study's GDT for both study groups. There are two possible reasons why the results of these studies (John, Hall, & Kreisman, 2012; Mishra et al., 2016; Musiek et al., 2005; Samelli & Schochat, 2008) differ from those of the current study.

Firstly, a younger group of participants was selected for participation in these studies. The arithmetic mean age of the participants across these studies (John et al., 2012; Mishra et al., 2016; Musiek et al., 2005; Samelli & Schochat, 2008) was 24. 67 years (SD of 0.65) compared to 50.05 years (SD of 0.21) in the current study. Mean gap detection values obtained by Musiek et al. (2005), Samelli and Scochat (2008), and Braga et al. (2015) support information that the lowest values for GDT are seen in young adults with normal hearing. Numerous studies revealed greater GDTs for older individuals compared to younger individuals (He, Horwitz, Dubno, & Mills, 1999; Lister, Besing, & Koehnke, 2002; Snell, 1997) due to age-related declines in temporal processing abilities which include gap detection. John et al. (2012) support this statement by revealing that there is a 0.55 ms increase in GDTs every 10 years. Furthermore, John et al. (2012) indicated that despite statistically controlling for hearing loss, age remained a valid predictor of GDTs.

Temporal resolution is vital for the comprehension of speech in both noisy and quiet conditions (Gordon-Salant & Cole, 2016; Vermeire et al., 2016) and older individuals

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are known to struggle more with speech recognition in noise than younger individuals. This is often attributed to the inability to hear critical speech information and reduction in the clarity of temporal cues in the speech signal (Mishra et al., 2016). Supporting the hypothesis that adequate temporal resolution is required to process cues integrated in speech, Vermeire et al. (2016) stated that deficits in temporal resolution are associated with impaired word and sentence identification in both fluctuating and constant noise situations. Furthermore, the anatomical and physiological changes that occur with aging in the peripheral auditory system also play a role along with temporal resolution and temporal patterning deficits (Gordon-Salant & Cole, 2016). However, in contrast to this research, a decline in auditory processing due to increasing age was not found by Schoof and Rosen (2014) who reported no significant difference in mean gap detection threshold between younger and older individuals (Schoof & Rosen, 2014).

Although not within the scope of this study it has been reported in previous research that temporal resolution is vital to speech recognition performance in noise (George et al., 2006; Gordon-Salant & Cole, 2016). Studies conducted by Bajaj et al. (2014) and Mishra et al. (2016) revealed that individuals with diabetes mellitus type II present with deficits regarding speech recognition in noise. Individuals with diabetes have been shown to be less able to use the quiet segments within fluctuating noise to understand speech, which suggests that their temporal resolution abilities are impaired. Other researchers state that temporal resolution is important for understanding speech in quiet and in challenging listening situations, since listeners must first determine the temporal cues and the duration of the speech and silent segments in order to comprehend what is being said (Vermeire et al., 2016). Furthermore, when noise is present spectral and temporal information becomes unclear to the listeners, resulting in poor interpretation of these cues (Vermeire et al., 2016). A strong link exists between speech perception in noise and temporal resolution function. Omidvar et al. (2013) support this statement by revealing that adequate temporal resolution abilities are required since temporal resolution enables individuals to separate acoustic signals over time, which is critical for speech perception in noise (Omidvar et al., 2013). It may thus be speculated that the temporal resolution deficits displayed by the diabetic participant group in the current study, may contribute to speech recognition in noise difficulties.

Others state that working memory and attention are key contributors to speech in noise perception, since older individuals have reduced cognitive processing capacity available to understand speech in noisy situations (Gordon-Salant & Cole, 2016). Better speech perception in noise performance was seen in adults with superior working memory than in those with poorer working memory. This finding implies that age-related decline in working memory can negatively influence the speech perception of older adults (Lee, 2015). In addition to these observations by Lee (2015), Harris et al. (2009) noted that older adults try to compensate for changes in auditory processing by applying more attention to the task. However, as task difficulty increases (for example with gap detection tasks), more strain is placed on cognitive processes which makes it difficult to compensate for the age-related changes in auditory processing, resulting in worsening performance in gap detection (Harris, Eckert, Ahlstrom, & Dubno, 2010). Although working memory and attention are reportedly key factors needed by older individuals to understand speech in noise, the current study cannot reinforce this finding as cognitive capacities such as working memory and attention were not part of the current study's research question.

Secondly, the results from the aforementioned studies (John et al., 2012; Mishra et al., 2016; Musiek et al., 2005; Samelli & Schochat, 2008) were obtained from normal hearing participants, identical to the participants of this study. However, the participants from the latter named studies (excluding participants from Mishra et al.'s (2016) study) had no other confounding factors present such as diabetes mellitus type II. Hyperglycaemia in its earliest form is asymptomatic, leading to individuals delaying medical treatment (Frisina et al., 2006). This is important to note, as the longer diabetes mellitus type II remains undiagnosed and untreated, the greater the medical complications will become (WHO, 2016). Hyperglycaemia can also cause changes to the central nervous system and consequently to auditory processing functioning (Seraji, Mohammadkhani, Nasliesfahani, & Jalaie, 2018). These changes in turn disturb temporal processing, hence affecting temporal resolution. Investigation of auditory brainstem responses in this population has received increasing attention since the temporal cues listeners require for speech perception are stored within the brainstem via synchronous firing of neurons (Bajaj et al., 2014). Several studies have revealed prolonged wave III and V latencies and increased inter-wave latencies I to III, I to V and III to V in individuals with diabetes mellitus type

II (Bajaj et al., 2014; Diaz de León-Morales et al., 2005; Gupta et al., 2010). These findings indicate neuropathy at the brainstem and midbrain level along with damage at the relay stations in the CANS. This means that there might be a delay in transfer of the auditory signal along the auditory pathway in individuals with diabetes mellitus type II. Another explanation for the prolonged and increased wave latencies found is that this disease targets the inner ear and auditory pathway due to the occurrence of metabolic activity within these structures (Diaz de León-Morales et al., 2005). Furthermore, tests that measure responses at the auditory cortex and brainstem level interpret the results based on the timing of the responses. Clinically available tests that also evaluate the timing of responses are the GIN and RGDT tests, which was used in the current study.

Although various reasons exist for the inconsistencies between these studies regarding the mean gap detection thresholds and age (John et al., 2012; Mishra et al., 2016; Musiek et al., 2005; Samelli & Schochat, 2008) the scope of this study was to investigate the influence of diabetes mellitus type II on temporal resolution. By using a control group the confounding influence of age was controlled for. Research by Mishra et al. (2016), focussing on auditory temporal resolution abilities in individuals with diabetes mellitus type II confirms the results of the current study. Similar to the current study, Mishra et al. (2016) administered the GDT test to 15 participants with diabetes mellitus type II and 15 healthy normal hearing participants aged between 30 and 40 years. However, the diabetic participants of Mishra et al.'s (2016) study had an accompanying high-frequency hearing loss. They attributed the difference in GDT to poor auditory processing and widened auditory filters, as the frequencies that display a hearing loss not only restrict processing difficulties but also impact neighbouring frequencies. They concluded that the temporal resolution deficits seen in the participants with diabetes mellitus type II may be attributed to central auditory processing degeneration and the detrimental effect of this disease on the central auditory system (Mishra et al., 2016). In addition, Pirasteh et al. (2018) conducted the GIN test on 30 participants with diabetes mellitus type II and 30 healthy normal hearing participants. The results showed that the GDT for the right and left ears of the diabetic group and the percentage of correct answers were statistically significantly different from the non-diabetic group. Pirasteh et al.'s (2018) study, in conjunction with Musiek et al.'s (2005) study, concluded that individuals

with diabetes mellitus type II may have some degree of CANS processing lesions since individuals with CANS involvement present with weaker temporal resolution function (Musiek et al., 2005).

The second parameter used to assess temporal resolution function is the total percentage of correct responses of the GIN test. The current study showed a small but not significant difference of 4.07% regarding the percentage of correct responses between the two participant groups. The diabetic participant group obtained 57.58% while the percentage of correct responses for the non-diabetic participant group were 61.75%. The accepted norm for the total percentage of correct responses, for individuals 12 years and older, is \geq 54%. The norm does differ from what was obtained in the current study, however it was not within this study's scope to clarify the differences between the South African population and international norms. Moreover, Musiek et al. (2005) stated that researchers making use of the GIN test should develop their own norms for the target population being studied.

Samelli and Schochat (2012) reported that their normal hearing participants obtained 67.25% correct gap detection responses compared to 70% correct gap detection responses by the normal hearing participants from Musiek et al.'s (2005) study. Mishra et al.'s (2016) study did not indicate the percentage of correct responses for their diabetic group compared to the non-diabetic participant group as they used the GDT test and not the GIN test. Pirasteh et al. (2018) compared the percentage of correct responses between their two study groups. An ingroup comparison of the total percentage of correct responses for the diabetic group for the right and left ears were 52.0% and 48.30% respectively, which had a significant difference compared to the non-diabetic group's results of 66.0% for both the right and left ears. This justifies the need for further investigation as the current study did not obtain any significant differences regarding the percentage of correct responses for the two participant groups.

The diabetic participant group in the current study was expected to perform more poorly than the non-diabetic participant group on both sections of the GIN test, namely the gap detection threshold and the percentage of correct responses. This prediction was proved accurate. The researcher is of the opinion that the statistically significant difference in the mean GDTh (p<0.001) between the diabetic and nondiabetic participant group, and the poorer percentage of correct gap detection responses demonstrated by the diabetic participants, may cause speech perception in noise deficits, but may be attributed to the diabetes mellitus type II condition.

The GIN test proved to be effective in detecting temporal resolution deficits among the diabetes mellitus type II participant group, which suggests that the GIN test might be clinically valuable and could be used together with additional auditory processing tests or with speech in noise evaluations to delve deeper into the processing difficulties caused by this disease.

4.1.3 RGDT

The current study's gap detection threshold for the RGDT will be discussed in conjunction with the results from previously published studies.

• Gap detection threshold

According to the calculated *p*-values the gap detection thresholds evaluated with the RGDT, termed RGDT_Th, were not significantly different for the two participant groups. In the current study a mean RGDT_Th of less than 10 ms was obtained for both the diabetic and the non-diabetic participant group. These mean gap detection threshold results were in accordance with results recorded by authors who studied participants in an age group (20 to 40 years) similar to the age group of the current study (Gallo, 2012; Zaidan et al., 2008). The weaker performance observed for the diabetic group could arise from auditory processing deficits that accompany diabetes mellitus type II which affects specific temporal aspects of audition such as temporal gap detection. The diabetic group had RGDT maximum thresholds of 40 ms at 500, 1000 and 2000 Hz while the maximum threshold for the non-diabetic group was 25 ms. Yalcinkaya et al. (2009) revealed that participants with RGDT_Th of more than 20 ms are likely to have temporal processing deficits. Difficulties arise when trying to explain the results found for the RGDT, as it is of the researcher's opinion that there is an absence of specific literature on RGDT_Th in individuals with diabetes mellitus type II.

Furthermore, participants from both groups obtained better gap detection thresholds for the GIN test than the RGDT. Iliadou et al. (2014) also found better thresholds for the GIN test compared to the RGDT in children with central auditory processing disorders and in adults with psychosis. The inconsistencies between the results of these tests could be attributed to the time it takes to conduct each test. The RGDT presents one trial for each gap interval between pairs of pure tones while the GIN test presents six trials for each gap duration. Therefore, the difference in the speed of administration is a possible cause for the threshold differences found between the GIN and RGDT tests. Another explanation could be that the GIN test demands less attention than the RGDT. The GIN test alerts the listener to upcoming gaps by announcing a number before each noise segment, whereas the RGDT gives the frequency specification to be tested followed by pairs of nine pure tones. An additional, more likely cause could be that the RGDT appears to emulate, in part, auditory fusion (Chermak & Lee, 2005) while the GIN test reflects true auditory gap detection (Chermak & Lee, 2005). Chermak and Lee (2005) argue that the RGDT measures a process that requires a combination of auditory fusion and gap detection.

4.1.4 Psychometric function by gap duration

Based on the number of correct responses per gap duration for both study groups, psychometric functions by gap duration were plotted for each left and right ear of the participant groups separately (Figure 1 and 2) and ears combined (Figure 3). The aim of constructing a gap duration performance curve was to determine at which gap duration the diabetic participant group were most likely to show the poorest gap detection performance. For both participant groups, the percentage of correct responses for 2 ms and 3 ms were less than 10%. For 4 ms the percentage was approximately 20%. At the 6 ms interval, the total percentage of correct responses increased considerably, reaching 62% to 68%. Finally, for gaps equal to or greater than 8 ms, the percentage of correct responses was constantly above 82%. Although the psychometric functions calculated for the two participant groups in the current study were similar, they were dissimilar to the expected function reported by He et al. (1999), with the observed scores falling greatly below the expected values at 4, 5, and 6 ms. The gap durations that seem to best distinguish the two groups are 5, 6 and 7 ms, with 5 ms being the greatest distinguisher. This is in accordance with

Musiek et al.'s (2005) study which found the biggest separation between their two functions calculated for normal hearing participants and participants with CANS involvement, at 4 to 6 ms gap duration. This information may be useful for future temporal processing screening procedures in the diabetic population. Testing at gap durations of 5 to 7 ms will take less time than testing at each individual gap duration. Moreover, if a participant performs poorly at these specific "screening gap durations", the entire test could be administered. However, if the participant does well at the "screening gap durations" the clinician can move on to other procedures (Musiek et al., 2005).

4.2 Clinical implications of the study

It is evident from literature that diabetes mellitus type II not only causes damage to the hearing organ and its structures (Akinpelu et al., 2014; Frisina et al., 2006; Karabulut et al., 2014) but also affects the functioning of the CANS negatively (Bajaj et al., 2014; Diaz de León-Morales et al., 2005; Gupta et al., 2010; Seraji et al., 2018). These damaging effects may have implications for temporal resolution functioning and the closely related ability of speech perception in noise. Audiologists should be fully aware whether their patients suffer from diabetes mellitus type II and if they do, should implement a monitoring program to record changes in hearing sensitivity and temporal processing functions over time. In addition, diabetologists and/or clinicians responsible for diagnosis, treatment, and intervention in cases of diabetes mellitus should possess the necessary knowledge to refer their patients annually for audiological evaluations. Patients diagnosed with diabetes mellitus type Il should be informed of the increased prevalence and incidence of hearing loss that may accompany this disease as it negatively influences productivity, social wellbeing, and quality of life (Chatterjee et al., 2017; WHO, 2016). Furthermore, screening of all diabetes mellitus type II patients is recommended within clinical settings to obtain a holistic perspective on temporal resolution abilities and consequently, a better understanding of the mechanisms underlying speech in noise recognition. This is important as diabetes mellitus type II may also affect CANS functioning (Diaz de León-Morales et al., 2005; Gupta et al., 2010; Seraji et al., 2018), speech recognition performance in noise (Bajaj et al., 2014), and temporal resolution abilities (Mishra et al., 2016). The GIN test and RGDT can be used clinically to obtain a baseline for temporal processing, specifically temporal resolution

abilities, in individuals diagnosed with diabetes mellitus type II. Annual follow up audiometric testing may determine whether a decline in gap detection performance occurred.

4.3 Critical evaluation of the study

Both the strengths and limitations of this study were carefully determined based on the study's findings. These are discussed below.

4.3.2 Strengths of the study

- The study included the individual assessment of 28 individuals with diabetes mellitus type II and 28 individuals without this disorder using the GIN test and the RGDT. The current study is one of only a few studies to determine temporal resolution abilities in individuals with diabetes mellitus type II. Furthermore, to the researcher's knowledge previous studies only investigated the diabetic population's performance on the GIN test but never previously on the RGDT. This study allowed examination of temporal resolution performance across both gap detection tests allowing correlations to be made regarding which test is more sensitive to this disorder.
- The research design allowed for the experimental participant group (diabetic group) to be age- and gender-matched to the control participant group (non-diabetic group) which minimized possible confounds.
- The GIN offers the audiologist a quick and reliable method for assessing gap detection while minimizing cognitive load and verbal demand.
- The GIN test and the RGDT can provide insight into the effect of diabetes mellitus type II on the neural integrity of the CANS and may possibly fill a void in auditory processing assessments overall.
- The use of tonal stimuli in the RGDT allows the researcher to determine the participants' frequency specific temporal resolution abilities. In addition, peripheral hearing loss can influence temporal resolution. Therefore, conducting the RGDT at frequencies with normal hearing sensitivity can reduce this potential confound.

4.3.3 Limitations of the study

- The small sample size (n=28) may be a possible limitation of this study. Larger sample sizes should be tested and compared in future studies.
- The use of broad band stimuli in the GIN test may be dependent on the perception of high-frequency components of the stimuli. Therefore, possible age effects seen in the GIN may be attributable to age differences in highfrequency hearing sensitivity (John et al., 2012).
- The limited number of trials in the RGDT may influence the test's reliability when it is used to evaluate participants with CANS involvement.
- A lack of otoacoustic emission (OAE) recordings in examining cochlear lesions associated with normal hearing, as Oxenham and Bacon reported that small cochlear lesions could interfere with the cochlear amplification mechanism and affect temporal resolution abilities (Oxenham & Bacon, 2003).

4.4 Future research

A few recommendations for future research studies are discussed below:

- As diabetes mellitus type II progresses the frequencies that are affected first are the high frequencies. It may thus be suspected that the extended high frequencies are already influenced. This yields good justification for extended high frequency testing in individuals with diabetes mellitus type II.
- The effect that the use of tonal stimuli instead of broadband noise may have on participants' test performance can show interesting results in future studies using the GIN test.
- Quality of life studies specifically for individuals with diabetes mellitus type II
 using standardised questionnaires should be considered for future studies as
 there is a lack of research in this regard.
- Future research should investigate the influence of diabetes-control medication on temporal resolution test results.
- The use of tests that require more cognitive effort can also be used in future research studies.
- Future research should include the effect of aging on the GIN test. This should be done to closely examine the maturation and aging of the auditory

system and their affect on temporal resolution, since aging impairs processes within the CANS.

- Examination of the correlation between the duration of diabetes mellitus type II and the components of the GIN test could determine if patients who have diabetes mellitus type II for a longer duration are more likely to be affected by temporal processing difficulties.
- Future studies using the RGDT can employ the extended version of the RGDT when it becomes apparent that shorter pairs of pure tones yield inconclusive results, as the extended version includes silent intervals larger than 40 ms.
- Further studies are needed to examine the presence of impairment in the peripheral and CANS, especially regarding possible damage to speech recognition in different listening conditions that may link to temporal processing difficulties, in diabetic patients.
- Studies investigating auditory brainstem responses in the diabetic population revealed prolonged absolute and inter-wave latencies (Bajaj et al., 2014; Diaz de León-Morales et al., 2005; Gupta et al., 2010) suggesting neuropathy at the brainstem and midbrain level. Only a few studies have documented central nervous system dysfunction in diabetes mellitus suggesting central neuropathy. Therefore, future studies should investigate the effect of diabetes mellitus on the central nervous system employing tests such as the P300 and Mismatch Negativity to assess higher level auditory processing.

4.5 Conclusion

It can be concluded that individuals with diabetes mellitus type II may present with temporal resolution deficits which could contribute to speech recognition in noise difficulties. This was evidenced by longer gap detection thresholds compared to the thresholds for healthy control participants on both the GIN test and the RGDT, although unlike the GIN test the RGDT did not show a statistically significant difference for the gap detection thresholds between the two participant groups. A greater understanding of the effect that diabetes mellitus has on the human body is not fully known yet. Therefore additional research can shed the light on the course and the extended influence this disease holds especially since its prevalence continues to increase worldwide.

"The diabetes tsunami is here. And we in South Africa are in trouble." Dr Larry Distiller (Health24.com, 2014)

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Appendices

Appendix A

- The Research Ethics Connective, Faculty Health Sciences University of Pietunia complies with ICH SCF putternes and the US Federal white Assurance.
- FVVA 00052567: Approval of 22 May 2002 and Express 05/20/2022
- IRB 0000 3228 IDR(50001782 Approved dd 20154(2014 and Expres 03/14/2020



UNIVERSITEIT VAN PRETORIA UNIVERSITY OF PRETORIA YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

1/02/2018

Approval Certificate New Application

Ethics Reference No: 39/2018

Title: Temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds

Dear Most Lonite Ethera

The New Application as supported by documents specified in your cover letter dated 24/01/2018 for your research received on the 24/01/2018, was approved by the Faculty of Health Sciences Research Ethics Committee on its guorate meeting of 31/01/2018.

Please note the following about your ethics approval

- Ethics Approval is valid for 1 year
- Please remember to use your protocol number (39/2018) 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, or monitor the conduct of your research.

Ethics approval is subject to the following:

- The ethics soproval is conditional on the receipt of 6 monthly written Progress Reports and
- The othics approval is conditional on the research being conducted as stipulated by the data is 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

Sumes

Dr R Boltimers; MBChB, MMed (Int), MPharMed.PhD Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretonia

The Faculty of Health Sciences Research Ethics Committee complies with the EA 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 norma 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 Estition 2018 (Department of Health)

📽 012 356 3064 deepeka behanillup.ac.za / fheetsch@un.ac.za 👘 titlp.//www.un.ec.za/heattertsca 🖂 Private Bag X323, Arcadia, 0007 - Tawelopele Building, Level 4, Room 60 / 61, 31 Bophelo Road, Gezina, Pietoria

Appendix B



UNIVERSITEIT VAN PRETORIA UNIVERSITY OF PRETORIA YUNIBESITHI YA PRETORIA

> Faculty of Humanities Research Ethics Committee

26 March

Dear Ms Ehlers

Project:

Researcher: Supervisor: Department: Reference number: Temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds L Ehlers Drs L Pottas and M Soer Speech-Language Pathology and Audiology 14207932 GW20180401HS)

Thank you for the application that was submitted for ethics review

I have pleasure in informing you that the Research Ethics Committee formally approv d the above study at a meeting held on 26 March 2018. Data collection may therefore committee.

Please note that this approval is based on the assumption that the research will be midout along the lines laid out in the proposal. Should your actual research depart signition from the proposed research, it will be necessary to apply for a new research approviate and ethical clearance.

We wish you success with the project.

Sincerely

Prof Maxi Schoeman Deputy Dean: Postgraduate and Research Ethics Faculty of Humanities UNIVERSITY OF PRETORIA e-mail: tracey.andrew@up.ac.za

cc: Drs L Pottas and M Soer (Supervisor) Dr J van der Linde (HoD)

Appendix C



UNIVERSITY OF PRETORIA TURIVERSITY OF PRETORIA Faculty of Humanitles Department of Speech-Language Pathology and Audiotogy

Appendix C

Prof Rheeder The HEAD: Steve Biko Academic Hospital - Diabetic Clinic PRETORIA

Dear Prof Rheeder

REQUEST FOR PERMISSION TO PERFORM PRACTICAL RESEARCH TESTING LIZELLE EHLERS – STUDENT NUMBER 14207932

I am a registered student at the Department of Speech-Language Pathology and Audiclogy, University of Pretoria. I am required to write a dissertation, resulting from a research project, under the supervision of Dr. L Pottas (Audiologist) and Dr. M Soer (Audiologist). The research study will only proceed once the Faculty Research Proposal and Ethics Committee has approved the proposal and data collection instrument(s). The following information from the research is shared with you.

The envisioned title of the study is Temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds.

The goal of the study is to determine the temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds, using the Gaps-In-Noise (GIN) test and the Random Gap Detection Test (RGDT).

The target population of the study is a group of 80 adults, both male and female, between 20 to 60 years of age with and without diabetes mellitus type II and normal hearing.

All identifiable information in the files and records will be handled with strict confidentiality. Participants will be asked to give written informed consent before any participant selection or experimental procedures are performed. The participants will hereby be given a choice to participate in the study. The informed consent form will describe the nature of the research study and the nature of the participants' participation in the study. Study participation will be on voluntary basis. Participants will receive verbal and written information on what the study entails, what is expected of them and what their rights are throughout the research process. This includes the right to withdraw from the study at any time.

According to the policy of the University of Pretoria, data from this research study will be archived at the Department of Speech-Language Pathology and Audiology at the University of Pretoria in digital and hard copy for a period of 15 years. No identifying information for participants will be included in these data files.

I intend to do the empirical part of the study through means of 10-15 open-and closedended structured questions with the identified adults. An audiological diagnostic test battery and an auditory processing test will follow the questionnaire namely the Gaps-In-Noise (GIN) test and the Random Gap Detection Test (RGDT). Testing of the control group will be performed at the Department of Speech-Language Pathology and Audiology at the University of Pretoria.

This request will not result in any demands from you or your staff. No cost will be acquired by this request.

I take responsibility to provide you with a copy of the final report - if required.

It would be appreciated if you will consider this request and grant written permission _____ (on an official letterhead of your agency) to proceed with the research project, at your earliest convenience.

Please contact me should you require additional information.

Kind regards

LEL/S

Ms. Lizellé Ehlers Student

Dr. L Pottas (Supervisor)

Dr. M Soer (Supervisor)

Cleaker

Prof Rheeder (Head of Steve Biko Academic Hospital- Diabetic Clinic

Dr. Jestinie van der Linde (Acting Head of the Department Speech-Language Pathology and Audiology)

> Faktiteit Gesterweitenskappe Departement Sprasi-Yaulpetologie en Oudiologie Lefapha la Bomothe Kgoro ya Phatholocii ya Palelo-Malstric le Go iow

Appendix D

:0	CON
he [CEO] Chief Exec	utive Officer of SBA Hospital
te: Permission to d	to research at Hospital
TILE OF STUDY:	Exportal readention abilities of indeviduals with ind with ant dry 2 with normal pure fore there the e reservant Head of Department HODI Park & White Signature of the I'mps
	you in terms of the requirements of the Promotion of Access to Information Act. No. 2 of 2000.
am a researcher / sugent am working with bove topic on the hospital	the Department of Audiology at the University of Pretona / Hospital herewith request permission on behalf of all of us to conduct a study on the clinic grounds. This study involves access to patient records. This study involves clinical research.
he researchers request ac	cess to the following information: clinical files, record books and data bases.
We intend to publish the fino ymposia, congresses, or of	dings of the study in a professional journal and/ or to present them at professional meetings like ther meetings of such a nature.
Ve intend to protect the per	sonal identity of the patients by assigning each individual a random code number.
Ve undertake not to procee Ethics Committee, Universit	d with the study until we have received approval from the Faculty of Health Sciences Research y of Pretoria.
ours sincerely	1, on behall d
K Khoo	de llorder 1. 11 PIP
Khee	de me fleede hizelle lehlers
<u>F Khee</u>	de un fleede hizelle lehlers
the Name K Khee	de un fleede hizelle lehlers
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to access the condition that Title and name of Ch	do the research study at this hospital / clinic and information as requested, is hereby approved, or there will be no cost to the hospital. ief Executive Officen 2+ 55 Montaword inic: Steve Brue personne Morpital

Appendix E



Faculty of Humanities Department of Speech-Language Pathology and Audiology

Appendix

Dr B Kloppers Diabetologist: Travel Medicine Clinic Hatfield Pretoria

Dear Dr Kloppers

REQUEST FOR PERMISSION TO OBTAIN DIABETES TYPE 2 PASIENTS

Supervisor: Dr. L Pottas and Dr. M Soer Interviewers: Lizelle Ehlers Tel: 012 347 8849 or 074 581 4903 E-mail: ehlers.lizelle0915@gmail.com

I am a registered master's student in B. Communication Pathology (Audiology) at the Department of Speech Language Pathology and Audiology at the University of Pretoria. I am required write a dissertation, resulting to conduct a research project, under the supervision of Dr L Pottas and Dr M Soer. The research study only commenced after the approved the research proposal and data collection instruments.

The title of my study is Temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds.

The University of Pretoria's Research Proposal and Ethics Committees requires that a researcher should ensure informed consent from a respondent before commencing with the research. Details regarding my research study follows below;

The purpose of the study is to determine the temporal resolution abilities in individuals with and without diabetes mellitus type II with normal pure tone thresholds, using the Gaps-In-Noise (GIN) test and the Random Gap Detection Test (RGDT).

The target population of the study is a group of 80 adults, both male and female, between the 20 – 60 years of age with and without diabetes mellitus type II and normal hearing. All identifiable information in the files and records will be handled with strict confidentiality. Participants will be asked to give written informed consent before any participant selection or experimental procedures are performed. The participants will hereby be given a choice to participate in the study. Study participation will be voluntary in nature. Participants will receive verbal and written information on what the study entails, what is expected of them and what their rights are throughout the research process. This includes the right to withdraw from the study at any time.

According the policy of the University of Pretoria, data from this research study will be achieved at the Department of Speech-Language Pathology and Audiology at the University of Pretoria in digital and hard copy for a period of 15 years. No identifying information for participants will be included in these data files.

A self-administrated questionnaire form will be given to the participant. The purpose of this questionnaire is to exclude the participants that do not adhere to the selection criteria of the study. A set of tests will be administered to ensure that the participant's middle ear functioning, hearing and processing of sound is normal.

After which, the Gaps-In-Noise (GIN) test will then be administered. Headphones will be placed over the participant's ears and he/she will then be requested to listen to noise that has gaps or silent periods of varying duration within the noise. The participant will need to press the button provided every time a gap is heard.

Thereafter, the Random Gap Detection Test (RGDT) will be performed. The participant will be requested to count the number of clicks that is presented to both ears, while simultaneously gaps are present between the clicks presented to you. The participant will have to respond verbally or non-verbally by raising one finger (if one gap is heard) or two fingers (if two gaps are heard).

Testing of the experimental group will occur at the Audiology Department of Steve Biko Academic Hospital while the control group will undergo their testing at the Department of Speech-Language Pathology and Audiology at the University of Pretoria.

This request will not result in any demands from you or your staff. No cost will be acquired by this request.

I take responsibility to provide you with a copy of the final report - if required.

It would be appreciated if you will consider this request and grant written permission or by indicating by signing a copy of this letter.

Please contact me at 074 581 4903 should you require additional information.

Kind regards

1.BAL Lizelle Ehlers (Student)

Dr B Kloppers (DiaBetologist)

28/03/2018

Date

28/03/2018

Date

Dr. L Pottas (Supervisor)

28/3/2018 Date

110.6

Dr. M Soer (Supervisor)

28/03/18

Date

28 -03-2018

Dr. J. van der Linde Date (ACTING HEAD: Department of Speech-Language Pathology and Audiology)

> Fakulteit Geesteswetenskappe Departement Spraak-Taalpatologie en Oudiologie Lefapha la Bomotho Kgpro ya PhatholotSi ya Polelo-Maleme le Go kwa

> > 71

Appendix F



Faculty of Humanities Department of Speech-Language Pathology and Audiology

Appendix

Hannes Snyman: Snyman's Diet Clinic Pharmacist Waterkloof Ridge Pharmacy Pretoria

Dear Mr Snyman

REQUEST FOR PERMISSION TO OBTAIN DIABETES TYPE 2 PASIENTS

Supervisor: Dr. L Pottas and Dr. M Soer Interviewers: Lizelle Ehlers Tel: 012 347 8849 or 074 581 4903 E-mail: ehlers.lizelle0915@gmail.com

I am a registered master's student in B. Communication Pathology (Audiology) at the Department of Speech Language Pathology and Audiology at the University of Pretoria. I am required write a dissertation, resulting to conduct a research project, under the supervision of Dr L Pottas and Dr M Soer. The research study only commenced after the approved the research proposal and data collection instruments.

The title of my study is Temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds.

The University of Pretoria's Research Proposal and Ethics Committees requires that a researcher should ensure informed consent from a respondent before commencing with the research. Details regarding my research study follows below;

The purpose of the study is to determine the temporal resolution abilities in individuals with and without diabetes mellitus type II with normal pure tone thresholds, using the Gaps-In-Noise (GIN) test and the Random Gap Detection Test (RGDT).

The target population of the study is a group of 80 adults, both male and female, between the 20 – 60 years of age with and without diabetes mellitus type II and normal hearing

All identifiable information in the files and records will be handled with strict confidentiality. Participants will be asked to give written informed consent before any participant selection or experimental procedures are performed. The participants will hereby be given a choice to participate in the study. Study participation will be voluntary in nature. Participants will receive verbal and written information on what the study entails, what is expected of them and what their rights are throughout the research process. This includes the right to withdraw from the study at any time.

According the policy of the University of Pretoria, data from this research study will be achieved at the Department of Speech-Language Pathology and Audiology at the University of Pretoria in digital and hard copy for a period of 15 years. No identifying information for participants will be included in these data files.

A self-administrated questionnaire form will be given to the participant. The purpose of this questionnaire is to exclude the participants that do not adhere to the selection criteria of the study. A set of tests will be administered to ensure that the participant's middle ear functioning, hearing and processing of sound is normal.

After which, the Gaps-In-Noise (GIN) test will then be administered. Headphones will be placed over the participant's ears and he/she will then be requested to listen to noise that has gaps or silent periods of varying duration within the noise. The participant will need to press the button provided every time a gap is heard.

Thereafter, the Random Gap Detection Test (RGDT) will be performed. The participant will be requested to count the number of clicks that is presented to both ears, while simultaneously gaps are present between the clicks presented to you. The participant will have to respond verbally or non-verbally by raising one finger (if one gap is heard) or two fingers (if two gaps are heard).

Testing of the experimental group will occur at the Audiology Department of Steve Biko Academic Hospital while the control group will undergo their testing at the Department of Speech-Language Pathology and Audiology at the University of Pretoria.

This request will not result in any demands from you or your staff. No cost will be acquired by this request.

I take responsibility to provide you with a copy of the final report - if required.

It would be appreciated if you will consider this request and grant written permission or by indicating by signing a copy of this letter.

Please contact me at 074 581 4903 should you require additional information.

Kind regards

Lizelle Ehlers (Student)

nan (Pharmacist) н

28/03/2018 Date

28/03/2018 Date

Dr. L Pottas (Supervisor)

20/3/2010

Date

1les Dr. M Soer (Supervisor)

28/3/18 Date

18-03-201

Date Dr. J. van der Linde (ACTING HEAD: Department of Speech-Language Pathology and Audiology)

> Fakulteit Geesteswetenskappe Departement Spriale Taslpacologie en Oudiotogie Lefapha la Bomothe Kgoro ya Phatholotik ya Poleks-Malerne le So kwa

Appendix G



CHENDRERSTOLT WAR PREIDELA UNIVERSITY OF PREIDELA YUNIBESITE: (NA PREIDELA Faculty of Humanities Department of Speech-Language Pathology and Audiology

Participant Informed Consent Document

Appendix E

Dear Participant

Temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds.

Supervisor: Dr. L Pottas and Dr. M Soer Interviewers: Lizelle Ehlers Tel: 012 347 8849 or 074 581 4903 E-mail: ehlers.lizelle0915@gmail.com

As a final year student in B. Communication Pathology (Audiology) at the University of Pretoria, it is required from me to conduct a research study and submit a research report in partial fulfillment of my degree. In my study, I will determine the temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds.

Thank you for considering participating in this study. The University of Pretoria's Research Proposal and Ethics Committees requires that a researcher should ensure informed consent from a respondent before commencing with the research. Informed consent entails the following:

- Purpose of the study: The purpose of the study is to determine the temporal resolution abilities in individuals with and without diabetes mellitus type II with normal pure tone thresholds, using the Gaps-In-Noise (GIN) test and the Random Gap Detection Test (RGDT).
- 2. Procedures:
 - Participation in the study will require that I meet you at Steve Biko Academic Hospitals' Diabetes Clinic.
 - I will use a self-administrated questionnaire form that will be given to you. The purpose of this questionnaire is to exclude the participants that do not adhere to the selection criteria of the study.

- A set of tests will be administered to ensure that your middle ear. functioning, hearing and processing of sound is normal.
- The Gaps-In-Noise (GIN) test will then be administered. Headphones will be placed over your ears and you will then be requested to listen to noise that has gaps or silent periods of varying duration within the noise. You need to press the button provided every time a gap is heard.
- Thereafter, the Random Gap Detection Test (RGDT) will be performed. You
 will be requested to count the number of clicks that is presented to both
 ears, while simultaneously gaps are present between the clicks presented
 to you. You will have to respond verbally or non-verbally by raising one
 finger (if one gap is heard) or two fingers (if two gaps are heard).
 - The entire evaluation will take approximately one hour to complete.
- Risks and discomforts: Should you experience any discomfort, fatigue or emotional distress as a result of the research, please inform the interviewer.
- Benefits: Please note that no benefits or gains are tied to participation in the research study.
- Participant's rights: You are free to withdraw from the study at any stage. As participation in voluntary, no negative consequences will arise from withdrawal. Should you withdraw, participation; all data that you provide will be destroyed immediately.
- 6. Confidentiality: The information obtained will be used for research purposes only and your name, surname or any private information which could identify will not be recorded on the questionnaire as a participant number will be used. Therefore, no identifying information will be revealed in the research report. The data collected will be available to the research supervisors, Dr. L Pottas, Dr. M Soer, the Acting Head of the Department of Speech-Language Pathology and Audiology, Dr. J. van der Linde and the entire scientific community.
- Rights of access to the researcher: Should any questions or concerns arise; the supervisors, Dr. L Pottas can be contacted at telephone: 012 420 2815 or e-mail: <u>Idia pottas@up.ac.za</u> and Dr. M Soer at 012 420 2815 or <u>maggi.soer@up.ac.za</u>.
- Storage of research data: The data will be stored for archiving and research purposes in the Department of Speech-Language Pathology and Audiology for 15 years before being destroyed.
- Ethical approval: Ethical approval was granted by the Research Ethics Committee of the Faculty of Health Science. Should you require any further information please contact Mrs Manda Smith from the Research Ethics office at 012 356 3085.

Please indicate your consent to participate in the study by signing a copy of this letter.

I____have read this letter and understand what is requested. I hereby consent to participate in the study. Research participant

Witness

Date

Date

Lizelle Ehlers (Student)

28/03/2018 Date

Dr. L Pottas (Supervisor)

28/3/2018 Date

Dr. M Soer (Supervisor)

28/03/18

Date

Dr. J van der Linde

28 -03 - 2018

Date

(ACTING HEAD: Department of Speech-Language Pathology and Audiology)

Falculteit Geesterwetenskappe Departement Spreak-Tealpatelogie en Ouclokogie

Lefapha la Bomotho Kgoro ya Phatholotili ya Polelo-Maleme in Go iwa

Appendix H



Appendix G

Diabetes Questionnaire

Student researcher: Lizelle Ehlers Supervisors: Dr L Bottas & Dr M Soer, Email address: ehlers.lizelle0915@gmail.com Phone number: 074 581 4903

Please complete the following questionnaire by providing information as accurate as possible.

1. Personal Information

Participant number: _____

D.O.B:

____ Date: _____ Gender: Male ____ Female

2. Medical Information

I. How long ago was your diabetes diagnosis made?

1-5 years 6-10 yea	rs 11-15 years	16-20 years
--------------------	----------------	-------------

II. Are you using any medications? If yes state, the specific medication used.

Diabetes medication	Pills.
	Injections
	Other:
High blood pressure	Pilis
medication	Other:
Cholesterol medication	Pilis
	Other:

 If you answered yes to the previous question, please state how often you take the medication.

Hourly	Dally	Weekly	Monthly
--------	-------	--------	---------

Iv. Have you experienced any of the following health complications since diagnosis? Please mark those applicable

1	Kidney problems/disease
2	Eye problems (e.g. retinopathy)
3	Foot problems (e.g. ulcers)
4	Heart disease
5	Stroke

3. Otologic information

v. Have you ever had your hearing tested before?

1	Yes	2	No

vi. If yes, what was the result of the hearing test?

1	Normal
2	Abnormal; hearing loss
3	Not applicable

vil. If you said yes to the above-mentioned question when was the test done?

1-5 years ago	6-10 years ago	11-15 years ago	16-20 years or
			more ago

vill. Have you been experiencing any problems with your hearing, since the diagnosis of diabetes?

1 Yes 2 No	
------------	--

Ix. Do you have a history of hearing loss in your family?

	r i i i i i i i i i i i i i i i i i i i	ef.		a) (1)		
1	Yes	2	No		3	Don't know

x. Did you ever have middle ear infections?

		=	
1	Yes	2	NO

xl. If you said yes to the above-mentioned question, how often did you have the infection?

Less than 3 t	mes in a year
More than 31	mes in a year
Not applicabl	2

xii. If you had middle ear infections previously, how was the infection treated?

1	Sweet oll
2	Antibiotics
3	Surgery
4	The infection was not treated

xill. Have you ever been exposed to excessive loud sounds/noises? If yes, please specify

1	Airplanes	4	Gunfire
2	Construction machinery	5	Mining Industry
3	Loud music	6	Other:

xiv. The diabetes diagnosis effected your quality of life.

Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	2	60	4	5

Appendix I



Appendix H

Data capturing sheets for participants with and without diabetes mellitus type II.

1) <u>Otoscopy</u>

Right ear: _____

Left ear: _____

2) Acoustic Immittance measurements

Tympanometry

Right ear:

- Ear canal volume: ______
- Middle ear pressure: ______
- Static compliance:
- Tympanogram type: ______

Left ear:

- Ear canal volume:
- Middle ear pressure: ______
- Static compliance: ______
- Tympanogram type: ______

Acoustic reflexes

Right ear:

٠	500 Hz: (pg);	Contra;
•	1000 Hz: [gs];	Contra;
٠	2000 Hz: (RSK	Contra;

4000 Hz: [ps]; ______Contra; ______

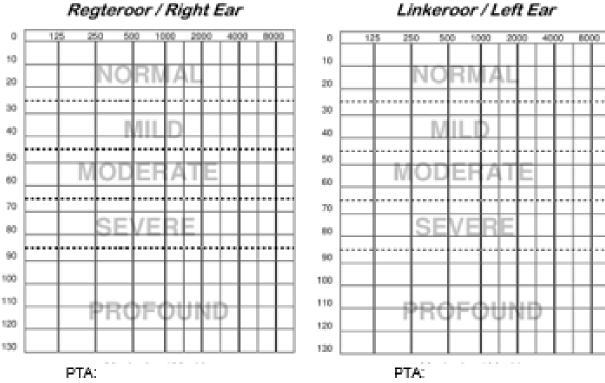
Left ear:

•	500 Hz: (pg);	Contra:
٠	1000 Hz: (ps);	Contra;
•	2000 Hz: [ps];	Contra;

4000 Hz: [gs];

Contra;

3) Pure tone audiometry



Regteroor / Right Ear

4) Gaps-In-Noise (GIN) test

Duration Threshold	2 0066	3 0086	4 0066	5 0066	6 0066	8 0006	10 0005	12 0005	15maec	20msec	Total
List 2	6	6	6	6	6	6	6	6	6	6	60
LDUZ	96	×	96	je.	*	%	%	*	%	95	%

Duration Threshold	2 0006	3 (7086	4 0066	5 0066	6 0066	8 0006	10 0005	12 (1965)	15maec	20msec	Total
List 3)°	6	6	6	6	6	6	6	6	6	60
LDCD	8	%	2	2	*	%	%	2	2	2	%

Duration Threshold	2 0066	3 0066	4 0066	5 0066	6 0066	8 0006	10 (1965	12 0005	15maec	20maec	Total*
TOTAL	22	12	12	12	12	12	12	12	12	12	120
TOTAL	96	96	96	26	2	ž	*	*	95	95	96

False Positives Right Ear:

False Positives Left Ear: _____

Gap detection threshold Right ear:

Gap detection threshold Left ear: _____

Total Score in % = Total # correct - False Positives <u>L Total</u> # of Trials X 100

5) Random Gap Detection Test (RGDT)

<u>Tones</u>

Subset 1 (practice subset): Smallest / lowest gap in mac.-

Subset 2 (tonal/click subset):

- 500 Hz GDTh:
- 1000 Hz GDTh:
- 2000 Hz GDTh:
- 4000 Hz <u>GRUN</u>

<u>Clicks</u>

Subset 3 (practice subset): Smallest / lowest gap in mass.-

Subset 4 (tonal/click subset): Smallest / lowest gap in msec -

6) Reason for referral

- Audiologist
- Ear Nose and Throat
 Specialist

Appendix J



VERSENTLY ON PERCENT VERSENTY OF PERCENT VERSENTS IN PRODUCTS Faculty of Humanities Department of Speech-Linguage Pathology and Audiology

Appendix J: Referral letter Steve Biko Academic Hospital

Research Participant Referral Letter

Tev		
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Date:		

D.O.B:

Temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds at the Speech Therapy and Audiology department at Steve Biko Academic Hospital. The test battery included:

- Otoscopy
- Tympanometry
- Acoustic reflexes
- Diagnostic pure tone assessment
- Gaps-in-noise (GIN) test
- Random Gap Detection Test (RGDT)

The following conclusion was drawn from the results obtained:

Our recommendations are as follows:

- A full diagnostic audiological assessment at the Speech Therapy and Audiology department.
- A complete auditory processing evaluation at the Department of Speech-Language Pathology and Audiology at the University of Pretoria.
- Cerumen management at the Ear Nose and Throat department.
- Further investigation of middle ear pathology at the Ear Nose and Throat department.

Thank you for your participation in this research study. Should you require any additional information please contact the researcher (Lizelle Ehlers) at 074 581 4903.

-

Lizelle Ehlers LEiles 2

Dr L Pottas

Dr M Soer AllSov .

Falurheit Goosteswetenskappe Departement Spraak-Taalpatologie en Oudiologie Laftights la Borrocho Kgoro yn Phetholotii yn Poleio-Maleme le Golwin

Appendix K



UNIVERSITY OF PRETORIA VIVIDED TO JA PRETORIA Faculty of Humanities Department of Speech-Language Pathology and Audiology

Appendix K: Referral letter Department of Speech-Language Pathology and Audiology (University of Pretoria)

Research Participant Referral Letter

To:

Date:		

D.O.B:

Temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds at the Department of Speech-Language -Pathology and Audiology at the University of Pretoria. The test battery included;

- Otoscopy
- Tympanometry
- Acoustic reflexes
- Diagnostic pure tone assessment
- Gaps-in-noise (GIN) test
- Random Gap Detection Test (RGDT)

The following conclusion was drawn from the results obtained:

Our recommendations are as follows:

- A full diagnostic audiological assessment at the Department of Speech-Language Pathology and Audiology at the University of Pretoria.
- A complete auditory processing evaluation at the Department of Speech-Language Pathology and Audiology at the University of Pretoria.
- Cerumen management at an Ear Nose and Throat Specialist
- Further investigation of middle ear pathology at an Ear Nose and Throat Specialist.

Appendix L



UNIVERSITY OF PRICE

Faculty of Humanities Department of Speech-Language Pathology and Audiology

Appendix L: Pass letter Steve Biko Academic Hospital

Research Participant Pass Letter

To:

Date:	
D.O.B:	

Thank you for participating in this research study namely; Temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds at the Speech Therapy and Audiology department at Steve Biko Academic Hospital. The test battery included;

- Otoscopy
- Tympanometry
- Acoustic reflexes
- Diagnostic pure tone assessment
- Gaps-in-noise (GIN) test
- Random Gap Detection Test (RGDT)

According to the test results, your hearing and temporal resolution abilities are normal. It is recommended that you evaluate your hearing annually. Should you require further information please contact the researcher (Lizelle Ehlers) at 074 581 4903.

Lizelle Ehlers

Dr L Pottas

Dr M Soe

Fakultelt Gesteswetenskappe Departement Spraak-Tualpetologie en Oudiologie Lefapha la Bomotho

Kgoro ya Phatholoth ya Polela Malerne te Golivia

Appendix M



UNIVERSITE TAN PRIMINA UNIVERSITE OF PRETORIA PROVERSITE TA PRETORIA Faculty of Humanities Department of Speech-Language Pathology and Audiology

Appendix M: Pass Letter Department of Speech-Language Pathology and Audiology (University of Pretoria)

Research Participant Pass Letter

To:

Date: _		 		_
D.O.B:				

Thank you for participating in this research study namely; Temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds at the Department of Speech-Language Pathology and Audiology at the University of Pretoria. The test battery included;

- Otoscopy
- Tympanometry
- Acoustic reflexes
- Diagnostic pure tone assessment
- Gaps-in-noise (GIN) test
- Random Gap Detection Test (RGDT)

According to the test results, your hearing and temporal resolution abilities are normal. It is recommended that you evaluate your hearing annually. Should you require further information please contact the researcher (Lizelle Ehlers) at 074 581 4903.

Lizelle Ehlers

LENA

Dr L Pottas

Dr M Soer 1445

Fakulteit Geosteswetenskappe Departement Sprask-Taalpaiclogie en Oudiologie Lefaphe la Domotho Kgoro ya Phatholosti ya Polek-Malerse le Go kwa

Appendix N

Appendix N

UNIVERSITY OF PRETORIA

FACULTY OF HUMANITIES

RESEARCH PROPOSAL & ETHICS

DECLARATION

Full name: Lizelle Sanet Ehlers

Student number: 14207932

Degree/Qualification: MA (Audiology)

Title of this thesis/dissertation/mini-dissertation:

Temporal resolution abilities of individuals with and without diabetes mellitus type II with normal pure tone thresholds.

I declare that this thesis / dissertation / mini-dissertation is my own original work. Where secondary resources is used, this has been carefully acknowledged and referenced in accordance with university requirements.

I understand what plagiarism is and am aware of university policy and implications in this regard.

All

Signature

10/04/2018

Date

Appendix O

The article will be submitted to Diabetes Research and Clinical Practice for review. The article is therefore in accordance with the journal's specifications and therefore differs from the format of the dissertation.

The article is submitted as a separate document to the dissertation.