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CLINICAL UTILITY OF MOBILE AND AUTOMATED HEARING HEALTH TECHNOLOGY IN AN INFECTIOUS DISEASE CLINIC SETTING

By

Marize Brittz

(13028589)

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SUPERVISOR: Dr. Barbara Heinze

Dr. Faheema Mahomed-Asmail, Prof. Anton Stoltz

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LIST OF ABBREVIATIONS

AIDS – Acquired Immunodeficiency Syndrome

ARV – Antiretroviral Therapies

DIN – Digits-In-Noise

hfPTA – high-frequency Pure Tone Average

HIV – Human Immunodeficiency Virus

ID – Infectious Disease

ISO – International Standards Organization

mHealth – Mobile Health

OS – Operating System

SA Eng DIN – South African English Digits-In-Noise

SD – Standard Deviation

SNR – Signal to Noise Ratio

SPL – Sound Pressure Level

FORMATTING

APA referencing style was used in this dissertation.

ABSTRACT

Decentralised detection and monitoring of hearing loss can be supported by new mHealth technologies using automated testing, which can be facilitated by minimally trained persons. These technologies may prove particularly useful in an infectious disease (ID) clinic setting where patients are at high risk for hearing loss. The current study aimed to evaluate the clinical utility of mobile and automated audiometry hearing health technology in an ID clinic setting.

The current study was exploratory as it aimed to determine whether smartphone automated audiometry and South African English Digits-In-Noise (SA Eng DIN) smartphone applications could be utilised in an infectious disease clinic setting to monitor an HIV-related hearing loss in a feasible and time efficient way. Smartphone automated audiometry (hearTest™) and speech-in-noise testing (SA English Digits-In-Noise (DIN) test) were compared with manual audiometry at 2, 4, and 8 kHz. Smartphone automated audiometry and the DIN test were repeated to determine the test re-test reliability. Two hundred subjects (73% female and 27% male) were enrolled. Fifty participants were re-tested with the smartphone applications. Participants' ages ranged from 18 to 55 years with a mean age of 44.4 (8.7 SD).

Threshold comparisons were made between smartphone audiometry testing and manual audiometry. Smartphone automated audiometry, manual audiometry, and test re-test measures were compared to determine the statistical significance of any differences observed using the Wilcoxon signed-ranked test. Spearman rank correlation test was used to determine the relationship between the smartphone applications and manual audiometry, as well as for test re-test measurements.

For all participants, 88.2% of thresholds corresponded within 10 dB or less between smartphone audiometry and manual audiometry. There was a significant difference (p>0.05) between smartphone and manual audiometry for the right ear at 4 and 8 kHz and the left ear at 2 and 4 kHz respectively. No significant difference was noted (p>0.05) between test and re-test measures of smartphone technology except at 4kHz in the right ear in smartphone automated audiometry. The absolute average difference between the initial and re-test of DIN testing was 1.2 dB (1.5 SD). No significant difference was noted in the test re-test measures of the DIN test (p <

0.05). A correlation coefficient of 0.56 was present in the DIN test re-test measures when the Spearman rank correlation test was administered.

Smartphone audiometry with calibrated headphones provides reliable results and can be used as a baseline and monitoring tool at ID clinics.

Keywords: automated audiometry, Digits-In-Noise, HIV-related hearing loss, Human-Immunodeficiency Virus, Infectious Disease clinic setting, mHealth, smartphone, ototoxicity

CHAPTER 1: INTRODUCTION

1.1 HIV/AIDS

The human immunodeficiency virus (HIV) and resultant acquired immune deficiency syndrome (AIDS) affect millions of people worldwide. The virus slowly attacks and damages the body's immune system, causing a decrease in CD4 T-lymphocytes (CD4+ cell), which may lead to an inability to fight off infections. The body becomes more prone to opportunistic infections, which occur more frequently and are more severe in individuals with a suppressed immune system (Bakhshaee, Sarvghad, Khazaeni, Movahed, and Hoseinpour, 2014; Prasad, Bhojwani, Shenoy, and Prasad, 2006). HIV/AIDS is at present a non-curable disease and for that reason it constitutes a long-term health problem.

Infection with HIV can be described as a global pandemic as it affects millions of people worldwide. The Joint United Nations Programme on HIV/AIDS (2015) estimated that in 2005 there were 32.0 million (29.9-34.5 million) individuals infected with HIV, and the number has increased to 36.9 million (34.3-41.4 million) people in 2015 globally. The highest prevalence rate of HIV/AIDS-infected children and adults occurs in the Sub-Saharan African region where 25.8 million (24.0-28.7 million) people are HIV-positive. In 2015, the Joint United Nations Programme on HIV/AIDS declared that around 38.1 million people had become infected with HIV since 2000 (UNAIDS, 2015).

Despite the fact that HIV/AIDS has infected millions of people and is a non-curable disease, antiretroviral therapy (ARV) has guaranteed a longer life expectancy for Individuals with HIV (Jolles, Kinlich de Loes, Johnson, and Janossy, 1996). Longer life expectancy has shifted the focus from HIV's life-threatening effects and placed the emphasis on quality of life and managing the disease (Marin et al., 2009; Peters et al., 2013).

1.2. HIV/AIDS effects on the auditory system

Manifestations in the head and neck area are among the first signs of HIV infection and include auditory and otological symptoms (Bakhshaee et al., 2014; Khoza-Shangase and Ross, 2002; Prasad et al., 2006). Auditory and otological symptoms

comprise tinnitus, vertigo, otalgia, ear canal pruritus, and hearing difficulties (Khoza-Shangase and Ross, 2002; van der Westhuizen, Swanepoel, Heinze, and Hofmeyr, 2013). These symptoms arise more often in Individuals with HIV than in those not infected (Fokouo et al., 2015). Van der Westhuizen et al. (2013) found that one in every three to four Individuals with HIV presents with auditory and otological symptoms. Otological symptoms appear to increase as the progression of the disease intensifies (Iacovou, Vlastarakos, Papacharalampous, Kampessis, and Nikolopoulos, 2012). From early 1985, numerous studies have reported otological manifestations related to HIV/AIDS with accounts of sensorineural hearing loss in this population ranging from 14% (Khoza-Shangase and Ross, 2002) to 76.32% (Araújo et al., 2012).

Individuals with HIV have a high risk of developing a hearing loss due to various causes (Ongulo and Oburra, 2010; van der Westhuizen et al., 2013). Various researchers report hearing loss as result of the virus directly affecting the auditory structures (Matas, Samelli, Angrisani, Magliaro, and Segurado, 2015; Reyes-Contreras et al., 2002). Neuropathological changes and harm to the central nervous system can be a result of demyelination of subcortical areas of the brain caused by the virus (Iacovou et al., 2012). Iacovou et al. (2012) stated that Individuals with HIV have a higher rate of altered brainstem auditory evoked potentials compared to noninfected individuals. These alterations suggest central auditory pathway impairment and can result in a sensorineural hearing loss. Most HIV-infected individuals present with a sensorineural hearing loss that gradually worsens in the higher frequencies, leading to a moderate hearing loss (Prasad et al., 2006). A sensorineural hearing loss occurs as a result of damage to the inner ear, vestibulo-cochlear (eighth cranial) nerve, or the brain (Khoza-Shangase and Ross, 2002; Modongo et al., 2014; van der Westhuizen et al., 2013).

Indirectly, opportunistic infections can cause a hearing loss by compromising the sensory and neural structures of the auditory system. As Individuals with HIV have a suppressed immune system, they are more prone to various infections, some of which may result in a sensorineural hearing loss. Opportunistic infections include cytomegalovirus (CMV), otoshyphilis, herpes zoster virus, meningitis, and toxoplasmosis (Shaw, 2012; Stearn and Swanepoel, 2010). Furthermore, opportunistic infections such as recurrent acute otitis media or serous otitis media

due to Eustachian tube dysfunction can also result in a conductive hearing loss (CHL) (Chandrasekhar et al., 2000; Prasad et al., 2006).

Studies have shown that ARVs and medication prescribed for opportunistic infection can be ototoxic (A. Bankaitis and Schountz, 1998; Stearn and Swanepoel, 2010). Drugs prescribed for opportunistic infections include antibiotic, antifungal, and antiviral agents that are ototoxic (Shaw, 2012). Among opportunistic infections, Tuberculosis (TB) has the highest prevalence in HIV patients (WHO, 2016). Tuberculosis affects up to a third of HIV-infected individuals and physicians often prescribe antibiotics such as aminoglycosides, which include streptomycin and amikacin, both found to be toxic to the auditory system (Modongo et al., 2014; Sinxadi and Blockman, 2005). Moreover, particular ARV medication could worsen the ageing effect on hearing due to mitochondrial toxicity (A. Bankaitis and Schountz, 1998; Luque et al., 2014; Thein, Kalinec, Park, and Kalinec, 2014). According to Assuiti, Lanzoni, dos Santos, Erdmann, and Meirelles, (2013), a group of HIV-infected adults between the ages of 18 and 58 who were exposed to ARV treatment showed indicative changes in the peripheral auditory pathway compared to the untreated group. A recent study also found that some frequently used anti-HIV agents are toxic to certain auditory cells (not cochlear hair cells), either causing cell death or damaging cell proliferation (Thein et al., 2014), thereby causing a decrease in hearing ability.

Hearing loss caused by HIV/AIDS can decrease quality of life by resulting in inability to function independently and to contribute to society in daily living (Chia et al., 2007; Gopinath et al., 2012; Mick, Kawachi, and Lin, 2014). Moreover, South Africans living in rural areas have to contend with issues such as poverty that results in inadequate access to medical services (Swanepoel, Olusanya, and Mars, 2010c). This can add even more difficulty and hardship to the consequences of the disease (Majumdar and Mazaleni, 2010). A study by Bakhshee et al. (2014) showed that 40% of HIV-positive participants were unemployed or had a low income, which put these individuals at higher risk for social problems, for instance social isolation and mental health issues. Therefore, audiologists and healthcare workers should be aware of the effects of HIV on hearing and HIV-infected individuals' social existence.

Regular monitoring of hearing in HIV-positive patients has been recommended (Assuiti, Lanzoni, dos Santos, Erdmann, and Meirelles, 2013; Eloff, 2010). Early detection or monitoring of an HIV-related hearing loss can minimise further diminishing of people's daily lives. To obtain hearing health services, HIV/AIDS infected adults can visit an audiologist for a full diagnostic audiometric assessment, but these services can be lengthy and costly, and may not be easily accessible. Patients from underserved and rural areas often have many financial expenses and have to travel long distances to hospitals or clinics, which may also have long waiting lists (Swanepoel and Hall, 2010). It has been reported that there is less than one audiologist available per million people in the African region (WHO, 2013). Audiologists are often not available, indicating a shortage of audiologists and poor access to ear health services in underserved areas (Visagie, Swanepoel, and Eikelboom, 2015). Through decentralisation, audiological services may more readily reach these individuals by using mobile health (mHealth) screening tools using cellular phones and networks (Louw, Swanepoel, Eikelboom, and Myburgh, 2017).

1.3. Smartphone automated hearing health technology

The use of telehealth approaches such as mHealth has become more popular in recent years (Swanepoel et al., 2010a; Clark and Swanepoel, 2014). Mobile health is a subcategory area of telehealth services that make use of mobile devices and technology to promote, deliver, and monitor health care services (Clark and Swanepoel, 2014). The use of cell phones and cellular networks has increased rapidly worldwide (Internet World Stats, 2016). There has been a growing demand for the use of tele-audiology, which has led to the development of audiological applications (Clark and Swanepoel, 2014; Swanepoel, Clark et al., 2010a). Mobile health services do not require health professionals or audiologists and can ensure that more people will receive audiological services (Yousuf Hussein et al., 2015). The use of mHealth solutions for hearing testing has been demonstrated to be mobile and affordable at a primary health care level (Margolis and Morgan, 2008; Swanepoel, Mngemane, and Tutshini, 2010b; Van Der Aerschot et al., 2016)

The combination of tele-audiology and smartphone technology may be an efficient and useful tool to implement in an ID clinic setting (Margolis and Morgan, 2008).

Such an mHealth tool should be cost-effective, user-friendly, portable, and an alternative to conventional audiometry (Swanepoel et al., 2014).

An inexpensive example of an mHealth screening tool is the hearScreen™ smartphone application that was recently validated in school children (Mahomed-Asmail, Swanepoel, Eikelboom, Myburgh, and Hall, 2016c). The hearScreen™ smartphone application is a hearing screening procedure which indicates a pass or a fail utilising a specific screening threshold across selected frequencies. An extension of the screening test is the validated hearTest™ smartphone application (Sandström, Swanepoel, Carel Myburgh, and Laurent, 2016; van Tonder, Swanepoel, Mahomed-Asmail, Myburgh, and Eikelboom, 2017). This smartphone application automatically seeks thresholds by recording a patient's responses. The application presents pure tones and the patient simply needs to respond by pressing a button on the screen when he/she heard the tone through claibrated headphones. This smartphone application demonstrated hearing thresholds similar to conventional manual air-conduction audiometry and can be self-administered (Sandström et al., 2016; van Tonder et al., 2017). It uses a low-cost smartphone (Android Operating System) and can be calibrated (Van Der Aerschot et al., 2016; van der Westhuizen et al., 2013). The application allows for monitoring hearing as it has a data storage feature to securely upload results to a cloud-based server (van Tonder et al., 2017). Patients' results can be monitored automatically over time from the server to flag cases where there may be a drop in hearing sensitivity. The application also permits for real-time environmental noise monitoring that allows for quality control to be conducted both onsite and remotely using a cloud-based management platform (Swanepoel et al., 2014). This type of technology offers potential advantages for use in an ID clinic setting and may expand and improve hearing services to Individuals with HIV.

Another example of an mHealth screening tool is a simple speech-in-noise test known as the South African English DIN (SA Eng DIN) test. The DIN test is a screening tool and uses a "closed-set" design with low linguistic demands (Potgieter, Swanepoel, Myburgh, Hopper, and Smits, 2016; Potgieter, Swanepoel, Myburgh, and Smits, 2017). The test is representative of everyday speech-in-noise environments. It is ecologically valid and sensitive to detect the presence of a hearing loss and does not require calibrated headphones (Potgieter et al., 2016; Smits, Kapteyn, and Houtgast, 2004; Smits, Theo Goverts, and Festen, 2013). The

SA Eng DIN mobile application is self-administered, fully automated, and only takes a few minutes to complete. The DIN test generates a digital signal that covers a bandwidth of 30 to 20 000 Hz, which includes the human voice (Potgieter et al., 2016; Potgieter et al., 2017). The test requires the patient to respond to triplet digits presented in English in the presence of noise, by entering what they heard onto the application (Potgieter et al., 2016), which is mostly understood and familiar with other speaking languages (Banford and Claughton, 2002). In a multilingual environment, understanding speech in noise is considerably diminished by a SNHL (Smits and Houtgast, 2005). However, CHL does not cause as much deterioration of the ability to understand speech in noise and the DIN is therefore insensitive to a conductive component (Smits and Houtgast, 2005). Nonetheless, the DIN gives results in SNR dB that can be utilised as a baseline for future surveillance.

1.4. Rationale

Smartphone automated hearing technology has not been used extensively for diagnostic audiometry. Integrating mHealth screening tools such as smartphones in an ID clinic could increase cost-effective decentralised hearing testing (Keidser and Convery, 2016a; Louw et al., 2017). mHealth screening tools may both improve the quality of life in individuals with HIV and allow clinicians more time to determine the need for appropriate referrals (Margolis and Morgan, 2008). Audiologists can, therefore, spend less time on initial diagnostic assessments and increase the time spent on more difficult and challenging conditions. This approach can also decrease costs of test administration for both the patient and the audiologist (Margolis and Morgan, 2008). Both mHealth screening tools described above are examples of inexpensive and portable technology that can decrease the workload of hearing professionals in an ID clinic setting in an affordable and mobile way.

Monitoring hearing in individuals with HIV in an ID clinic with smartphone hearing technology has not been investigated previously. Mobile health, together with an automated protocol, may lessen the burden on limited material and human resources. Implementing an mHealth screening tool such as hearTest™ or SA Eng DIN test could allow decentralised service delivery to a population at risk for hearing loss, such as people infected with HIV who visit the ID clinic (Keidser and Convery,

2016a; Louw et al., 2016). As higher frequencies tend to worsen first in individuals with HIV due to ototoxicity, it may be beneficial to select a protocol that includes high frequencies (Chandrasekhar et al., 2000; Fausti et al., 1994; Khoza-Shangase, 2010; van der Westhuizen et al., 2013). Also, lower frequencies are more sensitive to environmental noise, and including these frequencies in a clinic setting may negatively impact results (Mahomed-Asmail, Swanepoel, Eikelboom, Myburgh, and Hall, 2016c). Given that both hearTest™ and the SA Eng DIN test can detect the presence of a hearing loss, the current study will determine the validity the two smartphone applications in an ID clinic setting for monitoring purposes. The smartphone applications could be used as a rapid baseline and monitoring screening tools for patients attending the ID clinic settings. Therefore, the aim may be stated as follows: to determine the clinical utility of smartphone automated audiometry with calibrated headphones and smartphone-based DIN test in an ID clinic.

CHAPTER 2: METHODOLOGY

2.1 Research aim

To evaluate the clinical utility of mobile and automated hearing health technology in an infectious disease (ID) clinic setting when compared to manual audiometry in a feasible and time efficient way.

Research objectives

- To compare smartphone automated audiometry with the golden standard manual audiometry.
- To compare the Digits-In-Noise test with the golden standard manual audiometry high frequency pure tone average (hfPTA).
- To evaluate the test re-test reliability of each smartphone application
- To evaluate the time efficiency of each smartphone application

2.2 Research design

This study employed a quantitative exploratory research design. An exploratory design is conducted when there are few or no earlier studies to refer to and the focus is usually on gaining insights with a view to further investigation (Leedy and Ormrod, 2010; Maxwell and Satake, 2006). The current study is exploratory as it aimed to determine whether hearTest and South African English DIN (SA Eng DIN) smartphone applications could be utilised in an infectious disease clinic setting to monitor an HIV-related hearing loss in a feasible and time efficient way.

2.3 Ethical considerations

Permission

Before data collection commenced, permission was obtained from the Infectious Disease Clinic at Steve Biko Academic Hospital (SBAH) and from the Antiretro Viral (ARV) clinic at Tshwane District Hospital (TDH) (Appendix A and B). Ethical clearance was obtained from the Faculty of Health Science (Appendix C), and from the Faculty of Humanities (Appendix D).

Confidentiality

A researcher should respect participants' HIV status and treat it at the highest level of secrecy (HPCSA, 2002). Each participant who was tested was provided with an alpha-numerical number (e.g. 001A) during data collection and statistical analysis. In order to ensure confidentiality, no identifying information of the participants was used. The only information retrieved from participants' files was their HIV status and medication. This was explained to each participant in the informed consent letter (Appendix E and F), as well as verbally.

Protection from harm

The risks involved in participating in a study should not be greater than the normal risks of one's everyday living (Leedy and Ormrod, 2010). Participants were informed what the tests consisted of in the informed consent letter (Appendix E and F), as well as verbally before testing started. By providing the information, the researcher ensured understanding by the participants that the current study did not entail any medical risks or discomfort. Participants were also informed that withdrawing from the study would not influence their visits and they would be able to continue as normal at the clinic.

Informed consent

According to Leedy and Ormrod (2010), participants should be informed about the nature of the study as well as their level of performance in the study. An informed consent letter (Appendix E and F) was given to each participant before testing started. Participants were informed in the letter as well as verbally that medications listed in their files were documented. Permission from SBAH and TDH were acquired to obtain this information from their records (Appendix A and B).

2.4 Participants

A nonprobability convenience sampling technique was used in the current study since identified populations were available at the ID clinic and ARV clinic (Brewerton and Millward, 2001). HIV positive patients that visited the clinic were asked to participate in the current study. Participants were diagnosed with HIV through an antibody test, Enzyme-Linked-Immunosorbent-Assay. A power analysis indicated that a minimum of 150 subjects should be tested. Therefore the sample consisted of

200 participants with a mean age of 41.5 years old (8.7 SD). A percentage of 73% were female and 27% were male participants. All participants were recruited from the ID clinic at SBAH and ARV clinic from TDH. Medications were retracted from patients' files to document TB ototoxic medications, as well as ARV medications. However, none were seen as these patients received a standard hearing test through the clinic. These data can be used for future research in a monitoring programme. On average, 83 HIV-positive individuals visit the ARV clinic every day, while five HIV-positive people visit the ID clinic per day. Data collection took place between February and May of 2017.

2.5 Test environment and testing personnel

All tests were conducted by the researcher, who is the primary author of the current study. Testing was conducted in a quiet room provided by the ID clinic of SBAH and the ARV clinic of TDH, Pretoria. No noise concerns were present while testing.

2.6 Equipment

Table 1 provides a detailed summary of the equipment that was used for the current study's data collection

Table 1. Summary of equipment

Equipment	Description of use
WelchAllyn 719 Series Lithium Ion Handle otoscope with reusable specula	Visually inspect the external ear canal for foreign objects or impacted or excessive cerumen.
226-Hz probe tone (GSI Tympstar, Grason-Stadler) tympanometer	This tympanometer was used to determine participants' middle ear status by placing a probe in the ear. The tympanometer was calibrated on 10 January 2017 according to the ANSI (9S3.39, 1987) regulations.
Smartphone automated threshold audiometry (hearTest smartphone application) Android OS (v4.3) application with supra-aural Sennheiser HD 280 Pro headphones (Sennheiser, Wedemark, Germany) running on a Samsung Galaxy A3 (GT-19300)	This mobile application was used for smartphone automated threshold audiometry. A threshold prototype developed from recently validated hearScreen™ application software was employed in this application (Swanepoel et al., 2014). Equivalent threshold sound pressure levels (ETSPLs) determined according to Madsen and Margolis (2014) were applied for the supra-aural headphones. The hearScreen™ calibration function was performed on the hearTest™ application according to ISO 389-8. The application monitored and recorded noise levels during data collection for each participant. Results from the data collection were uploaded to a database (hearData) at the end of each session using a connection to a 3G cellular network. The application determined thresholds across higher frequencies 2, 4, and 8 kHz.
DIN testing (SA Eng DIN smartphone Application) on an Android-compatible Samsung Galaxy S6 device with Samsung S6 insert earphones.	This mobile application measured the participant's speech reception threshold (SRT), through changing levels of long-term average speech spectrum noise (LTASS) by a 2 dB up and down adaptive procedure (Potgieter et al., 2016). The test included a series of digits being presented to the participant binaurally.
Diagnostic Audiometry (KUDUwave Type 2 Clinical Audiometer) (MoyoDotNet, Johannesburg, South Africa) (IEC 60645-1/2)	The program is run through a notebook computer (Acer Aspire E1-532, running Microsoft 8) with the audiometer hardware covered in each circumaural earcup and insert earphones. The headphones were power-driven by a USB cable plugged into the notebook. The insert earphones were calibrated under ISO 389-2. Background noise was consistently monitored by a microphone on the outside of the headphones.

2.7 Procedures

Hearing testing was conducted during participants' monthly visits at the ID Clinic at SBAH and the ARV clinic at TDH, Pretoria, Gauteng. Otological examinations (otoscopy and tympanometry) were performed first, followed by smartphone testing and manual audiometry if no conductive pathology was present. Participants with a hfPTA higher than 15 dB HL in either ear were defined to have a hearing loss (ISO, 1998). Fifity participants were retested with automated audiometry and the DIN test. The process for data collection compromised the following:

2.7.1 Otoscopy

Otoscopy was performed to examine the external ear canal and the tympanic membrane to identify any external ear canal pathologies. Participants who presented with a conductive component were excluded from the study as the DIN test is insensitive to (does not detect) a conductive hearing loss (Smits and Houtgast, 2005). Participants who presented with an atypical result were referred to the relevant department (Appendix G and H).

2.7.2 Tympanometry

Tympanometry was conducted to identify any middle ear pathologies. Jerger (1970) tympanometry norms were used (Table 2).

Table 2. Jerger (1970) tympanometry norms

Variables	Measurement
Middle ear pressure	-50 daPa -→ +50daPa
Ear canal volume	0,8 ml → 2,0 ml
Compliance	0,3 ml → 1,7 ml

Tympanograms were recorded on the data collection sheet (Appendix H). Participants presenting with tympanograms other than type A tympanogram were not included in the study, as the DIN test is insensitive to conductive pathologies (Smits

and Houtgast, 2005). Participants who presented with an atypical tympanogram were referred to the ENT department at SBAH and TD (Appendix G and H).

2.7.3 hearTest™ smartphone application

The participant was seated (Figure 1) and the tester gave the participant clear instructions, verbally, to press the button on the screen whenever he/she heard the tone presented via the smartphone application (Figure 2). The participant's demographic information was entered into the device, and the tester placed the headphones on the participant's ears. The application was run in the default test mode that required the patient to self-administer the test. An automatic test protocol was used, utilising the ISO shortened ascending method (ISO, 2010). The participant pushed the "START" button, and testing commenced in the left ear unless the participant indicated the right ear was the better hearing ear at 40 dB HL at 2 kHz. If a participant was responded reliably in the initial testing sequences, subsequent frequency testing commenced at 30 dB HL. A tone sequence consisted of the following: a) a random waiting interval between 750ms – 4000ms; b) a tone presentation 1200ms and c) a grace waiting interval 1200ms. A reliable response was recorded when a participant pressed the button in either the tone presentation or grace periods. If a patient responds in the random waiting interval period, this is considered a false response and is logged as such by the application. If the false response rate exceeds 20% in a test, a pop-up is displayed in the test to provide the option to restart the test.

Figure 1 Participant seating arrangement during testing

If a participant pressed the button on the screen in response to the tone being heard (positive response), the application automatically decreased its threshold with 10 dB HL. In the event a participant did not respond to the sound presented by the application (negative response), the application automatically increased with 5 dB. A positive response was recorded as a threshold when two of three responses occurred at the same intensity with three ascents. A negative response was recorded when a maximum intensity was reached without a reaction of the participant. Testing was only conducted until a minimum of 10 dB HL, as smartphone testing is primarily intended for a primary health care setting where noise levels can make testing below 10 dB HL almost impossible (van Tonder, Mahomed-Asmail et al., 2017).

If a patient did not respond at the starting level of 40 dB HL, the intensity was automatically increased with 20 dB HL until a response occurred, in order to fast-track severe to profound thresholds. To avoid the test tone being heard in the non-test ear, the application applied masking automatically. The contralateral noise was initiated with intensities above 40 dB HL as specified in ISO 8253:1.

The tone sequence consisted of the following: a) a random waiting interval of 2000ms followed by b) a sound presentation of 1200ms and subsequently c) a grace waiting interval of 1200ms. The participant should respond either during the tone presentation or during the grace period. If a participant reacted during the random waiting interval period, it was logged onto the hearTest™ application as a false response. If a false response rate exceeded 20% in one test, a pop-up was displayed and provided the option to restart the test.

The application utilised a noise-monitoring algorithm and measured noise levels in the test room (Mahomed-Asmail, Swanepoel, and Eikelboom, 2016b). Before testing, noise could be measured and altered, for example windows were closed for incoming noise from outside. During testing, the noise was also monitored and logged into the test data.

Once testing was completed for a participant, the screen displayed the results in four tabs (threshold, audiogram, reliable, re-test) (Figure 2.). The initial display indicated the participant's audiometric results in dB HL at 2, 4, and 8 kHz in each ear along with a pure tone average which was averaged from the three frequencies tested in

each ear. The audiogram screen displayed the results on an audiogram, and the reliable display indicated the reliability of the test, noise concerns, and threshold concerns. The re-test screen allowed the tester to select frequencies needed to be re-tested.

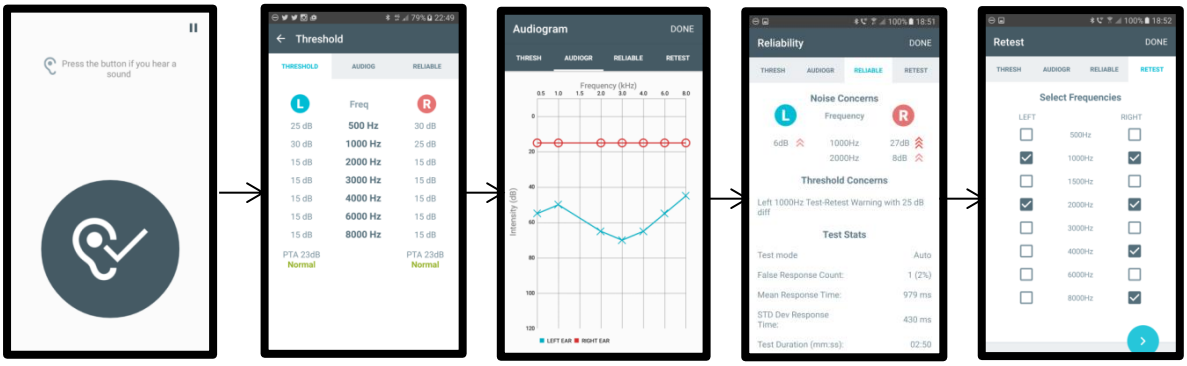

Figure 2 hearTest™ sequence of screens

2.7.4 SA Eng DIN smartphone application

The following information was required to be inserted into the application before testing commenced: name and surname, gender, and date of birth. The participant also adjusted the noise on the application to a comfortable hearing level. The participant then had to press the "Start Test" button to begin the test. Triplet digits were presented in both ears simultaneously, and a pop-up keyboard appeared that allowed the participant to enter the numbers heard. Consecutive triplet-digits were presented binaurally, with a gradual increase of signal-to-noise-ratio (SNR).

When the participant inserted the triplet-digit correctly, the next triplet was presented at 2 dB lower SNR. When a participant entered the triplet presented incorrectly, the next triplet was introduced at a 2 dB higher SNR. A triplet-digit was judged to be correct when all three numbers were inserted appropriately. The SRT was calculated as the average SNR from the forth to the last of the triplets presented. When participant presented with an SNR of more than -9.4 dB SNR, it was considered abnormal (Potgieter et al., 2017).

A list of triplets is stored in the Android application containing 120 unique digit-triplets (Smits et al., 2013). When the test started, the application randomly selected a triplet-digit from the list. The DIN application collected the triplet-digits by merging the

suitable digits with intervals of 500ms at the beginning of each triplet being presented. Following numbers were tailed by 200ms silences with a 100ms of jitter in between. The DIN test operated at a fixed noise level and varying speech level when triplet-digits with negative SNR were presented. When positive triplet-digits were presented, the speech level became fixed and the noise level varied. These levels assured that the signal was kept constant overall, and provided a comfortable listening experience for the participant. Results were recorded in SNR after the test was initiated.

2.7.5 Manual Diagnostic Audiometry

The KUDUwave utilised circumaural ear cups which were placed over insert earphones to provide sufficient attenuation (Storey, Munoz, Nelson, Larsen, and White, 2014). The researcher, who is a qualified audiologist, performed manual diagnostic audiometry. The researcher sat behind the participant with the headphones connected to the notebook computer and performed the test manually. The KUDUwave used multiple external and internal sound pressure level (SPL) sound meters, which continuously measured the ambient noise level, and indicated to the tester when noise was too loud to allow testing. Each participant received clear instructions to press the button whenever they heard the tone. The response button was connected to the KUDUwave device and notebook via USB cable to record the participant's response to the sound presented. Participants were tested diagnostically at 2, 4 and 8 kHz. Air-conduction thresholds were obtained using the modified Hughson-Westlake method, starting at 30 dB HL at 2 kHz in the left ear. The same procedure was followed for the right ear. If a participant failed to respond to the stimulus the intensity was increased by 5 dB HL. If a participant responded to the stimulus, the intensity was decreased in 10 dB HL steps. A threshold was recorded when the participant responded three consecutive times at the lowest threshold. Appropriate masking for air-conduction was applied when the threshold in the non-test ear exceeded the interaural attenuation (ASHA, 2005).

All data were recorded on a data collection sheet (Appendix I). Participants who presented with a moderate sensorineural hearing loss or a more severe loss (above 35 dB HL) were referred to the Audiology department at SBAH and TD (Appendix G

and H). Participants who presented with normal hearing were given a pass letter (Appendix J and K). Participants who presented with abnormal findings relating to the ear canal and atypical tympanogram together with a hearing loss were referred to the ENT department for investigation of the conductive pathology, and were excluded from the study.

2.8 Data analysis

A comparative analysis was conducted between thresholds obtained from the smartphone application and conventional audiometry using MS Excel and SPSS v.22 (Armonk, New York). Data were not normally distributed. Therefore a nonparametric analysis (Wilcoxon signed-rank test) was used to determine if there were significant differences between smartphone audiometry and manual audiometry ($p < 0.05$). A total of 1200 thresholds were obtained across 2, 4, and 8 kHz. Testing was only conducted down to a minimum of 10 dB HL. Thus, all results were analysed to account for the possible influence of a floor effect.

Threshold data for smartphone audiometry and manual audiometry were analysed descriptively for average differences, average absolute differences, and respective distributions. High-frequency pure tone average (hfPTA) (2, 4 and 8 kHz) of the better ear in each participant was calculated for comparison with the DIN test. Corresponding thresholds between smartphone audiometry and manual audiometry were determined and expressed as a percentage of cases within 5 dB, within 10 dB, and differing by 15 dB or more. The same analysis was done for the test re-test measures in smartphone automated audiometry. The Spearman rank correlation test ($p<0.05$) for nonparametric data was used to determine the test re-test reliability and of both smartphone audiometry and DIN testing. The same analysis was done for the relationship between DIN test, manual audiometry and smartphone automated audiometry.

CHAPTER 3: RESEARCH ARTICLE

Monitoring hearing in an infectious disease clinic with mHealth technologies

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Marize Brittz[1], Barbara Heinze[1], Faheema Mahomed-Asmail[1], De Wet Swanepoel[123], Anton Stoltz [4]

1. Department of Speech-Language Pathology and Audiology, University of Pretoria, Pretoria, South Africa

2. Ear Science Institute Australia, Subiaco, Australia

3. Ear Sciences Centre, The University of Western Australia, Nedlands, Australia

4. Department of Infectious Diseases, Steve Biko Academic Hospital, Pretoria, South Africa

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3.1 Abstract

Background: Decentralised detection and monitoring of hearing loss can be supported by new mHealth technologies using automated testing that can be facilitated by minimally trained persons. These may prove particularly useful in an infectious disease (ID) clinic setting where the risk of hearing loss is high.

Purpose: To evaluate the clinical utility of mobile and automated audiometry hearing health technology in an ID clinic setting.

Research Design: Smartphone automated audiometry (hearTest™) and speech-in-noise testing (SA English DIN (Digits-In-Noise) test) were compared with manual audiometry (2, 4, and 8 kHz). Smartphone automated audiometry and the DIN test were repeated to determine the test re-test reliability.

Study Sample: Two hundred subjects (73% female and 27% male) were enrolled. Fifty participants were retested with the smartphone applications. Participants' ranged from 18 to 55 years of age with a mean age of 44.4 (8.7 SD).

Data Analysis: Threshold comparisons were made between smartphone audiometry testing and manual audiometry. Smartphone automated audiometry, manual audiometry and test re-test measures were compared (Wilcoxon signed-ranked test). Spearman rank correlation test was used to determine the relationship between the smartphone applications and manual audiometry, as well as for test re-test reliability.

Results: Within all participants, 88.2% of thresholds corresponded within 10 dB or less between smartphone audiometry and manual audiometry. There was a significant difference ($p>0.05$) between the right ear at 4 and 8 kHz and in the left ear at 2 and 4 kHz between smartphone and manual audiometry respectively. No significant difference was noted ($p>0.05$) between test and retest measures of smartphone technology.

Conclusions: Smartphone audiometry with calibrated headphones provides reliable results in an ID clinic setting and can be used as a baseline and monitoring tool at ID clinics.

Keywords: Human Immunodeficiency Virus, hearing loss, Mobile Health, audiometry

Abbreviations: AIDS = Acquired Immune Deficiency Syndrome; ARV = Antiretroviral Therapies; DIN = Digits In Noise; high-frequency pure tone average = hfPTA, HIV = Human Immunodeficiency Virus; ISO = International Standards Organization; mHealth = mobile health; OS = operating system; SNR = Signal to noise ratio; SD = standard deviation, TB = Tuberculosis

3.2 Introduction

Hearing loss is closely associated with various infectious diseases due to intrinsic causes related to the infection and extrinsic causes related to the medications (Cohen et al., 2014). Human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS) and Tuberculosis (TB) are examples of infectious diseases.

The use of antiretroviral therapies (ARVs) has improved life expectancy (Jolles et al., 1996) which shifted the paradigm of HIV/AIDS from life-threatening to the quality of life (Eloff, 2010). With increased life expectancy, individuals with HIV/AIDS are now at higher risk for developing comorbid diseases (Marin et al., 2009; Peters et al., 2013). Head and neck diseases are of the first to arise, such as manifestations of the ear that result in auditory and otologic symptoms (Bankaitis and Keith, 1995; Khoza-Shangase and Ross, 2002; Matas et al., 2014; van der Westhuizen et al., 2013). Symptoms can include otorrhea, tinnitus, otalgia and hearing loss (Khoza-Shangase and Ross, 2002; Prasad et al., 2006). Hearing loss can develop due to the direct effect of the virus on the auditory nerve, through opportunistic infections or ototoxicity (Chandrasekhar et al., 2000; Stearn and Swanepoel, 2010). Ototoxicity can be a result of combinations of ARVs as well as the effect of medications prescribed for opportunistic infection (Bankaitis and Schountz, 1998), and among opportunistic infections, TB has the highest prevalence among HIV patients (WHO, 2016). Aminoglycosides are core ingredients for TB medication but also are considered toxic, and can potentially cause an irreversible hearing loss (Modongo et al., 2014).

Hearing loss can decrease one's quality of life by the inability to function independently and to contribute to society in daily living (Olusanya et al., 2006; Chia et al., 2007; Gopinath et al., 2012; Mick et al., 2014). From early 1985, numerous studies have reported otological manifestations related to HIV/AIDS with a sensorineural hearing loss present in from 14% (Khoza-Shangase and Ross, 2002) to 76% (Araújo et al., 2012) of this population. As a result, identifying and regular monitoring of hearing has been recommended (Assuiti et al., 2013; Eloff, 2010). To detect a hearing loss, HIV-positive individuals can visit an audiologist for a diagnostic audiometric assessment, but these services can be lengthy, costly and may not be easily accessible. Furthermore, it has been reported that there is less than one audiologist available per million people in the African region (WHO, 2013). Also,

those from underserved and rural areas often have many financial expenses and have to travel long distances to get to hospitals for health care services (Swanepoel and Hall, 2010). In low- and middle- income countries where health-care services are unavailable or unaffordable, hearing loss can lead to an economic burden on the resources of communities and countries (Olusanya et al., 2006; Swanepoel, Clark et al., 2010a). With the increased use of technology and access to global connectivity, hearing health access can move beyond the reliance on expensive audiometric booths and equipment (Clark and Swanepoel, 2014). Through decentralisation, audiological services may more readily reach these individuals by using mobile health (mHealth) screening tools using cellular phones and networks (Louw et al., 2017). The use of cell phones and cellular networks have rapidly increased worldwide, making access to hearing health services possible in rural areas (Internet World Stats, 2016; Potgieter et al., 2015). There has been a growing demand for the use of tele-audiology, which led to the development of audiological applications (Clark and Swanepoel, 2014; Swanepoel, Clark et al., 2010a). The use of mHealth solutions for hearing testing has been demonstrated to be mobile and affordable at a primary health care level (Margolis and Morgan, 2008; Swanepoel, Mngemane et al., 2010b; Van Der Aerschot et al., 2016). Such technologies could improve access to hearing health services in an infectious disease (ID) clinic setting by providing an inexpensive alternative to a conventional screening of diagnostic audiometry (Margolis and Morgan, 2008; Swanepoel et al., 2014).

An example of an inexpensive mHealth audiometry tool is the validated hearTest™ smartphone application (Sandström et al., 2016; van Tonder et al., 2017). The smartphone application can be self-administered and demonstrates hearing thresholds similar to conventional manual air-conduction audiometry by using a low-cost smartphone (Android Operating System) and calibrated headphones (Van Der Aerschot et al., 2016; van Tonder et al., 2017). The application has a data storage feature, where results can be uploaded to a cloud-based server (van Tonder et al., 2017). This allows for monitoring or surveillance of patients' results over time that can be done automatically from the server to flag cases where there may be a drop in hearing sensitivity. The application also has real-time environmental noise monitoring that allows for quality control to be conducted onsite and remotely using a cloud-based management platform (Swanepoel et al., 2014). This type of technology

offers potential advantage for use in ID clinic settings that could increase access to hearing detection and surveillance services in these clinics (Margolis and Morgan, 2008; van Tonder et al., 2017).

Another inexpensive mHealth hearing screening tool which can be used to detect a hearing loss is a simple speech-in-noise test known as the South African English Digits-In-Noise (DIN) test. This smartphone application is a screening tool which makes use of digits and uses a “closed-set” design with low linguistic demands (Potgieter et al., 2016, 2017). The test is representative of everyday speech-in-noise environments and is ecologically valid to detect the presence of a sensorineural hearing loss, and it does not require calibrated headphones (Potgieter et al., 2016; Smits et al., 2004; Smits and Houtgast, 2005; Smits et al., 2013). The digits are presented in English which is mostly understood and familiar with other speaking languages (Banford and Claughton, 2002). The DIN test gives results in signal-to-noise ratio (SNR), which can be used as a baseline for surveillance of hearing in an ID clinic setting.

Both mHealth screening tools are examples of inexpensive and portable technology that can decrease the need for hearing services in an ID clinic setting in an affordable and mobile way. By implementing an mHealth tool such as hearTest™ or South African English DIN test could allow decentralised service delivery to a population at-risk for hearing loss, such as those infected with HIV and TB attending the ID clinic (Keidser and Convery, 2016a; Louw et al., 2016). As higher frequencies tend to worsen first in HIV-positive individuals due to ototoxicity, it may be beneficial to select a screening protocol that includes high frequencies (Chandrasekhar et al., 2000; Fausti et al., 1994; Khoza-Shangase, 2010; van der Westhuizen et al., 2013). Also, lower frequencies are more sensitive to environmental noise which may affect results if it was included in a clinic setting (Mahomed-Asmail et al., 2016a). Given that both hearTest™ and the South African English DIN test can detect the presence of a hearing loss, the study will determine the validity and clinical utility of these two smartphone applications in an ID clinic setting for monitoring purposes. The study aimed to determine the current clinical utility of smartphone automated audiometry with calibrated headphones and smartphone-based DIN test in an ID clinic when compared to manual audiometry in a feasible and time efficient way.

3.3 Material and Methods

Institutional review board clearance was obtained before any data collection commenced. All participants provided written informed consent. Data collection took place at ID clinics present two tertiary hospitals in Gauteng, South Africa.

Participants

A nonprobability convenience sampling technique was used in the current study since identified populations were available at the ID clinic and ARV clinic (Brewerton and Millward, 2001). All participants who visited these ID clinics were diagnosed with HIV, and were asked to participate in the current study. A power analysis was conducted indicating a minimum of 150 subjects should be tested therefore the sample consisted of 200 HIV-positive individuals with a mean age of 41.5 years (8.69 SD). Seventy-three percent of participants were female, and 27% were male. Data was collected at two ID clinics for sampling purposes. An average of 83 HIV-positive individuals visits the first ID clinic, and an average of five HIV-positive individuals visit the second ID clinic per day. Participants that presented with a conductive pathology were excluded from the study. Data collection took place between February – May 2017.

Equipment

Otoscopy was conducted using a Welch Allyn 719 Series Lithium Ion Handle otoscope, and tympanometry was performed using a 226-Hz probe tone GSI Tympstar, Grason-Stadler tympanometer.

Smartphone audiometry data were collected with a Samsung Galaxy A3 smartphone running the hearTest™ Android OS (v4.3) application. Supra-aural Sennheiser HD 280 Pro headphones (Sennheiser, Wedemark, Germany) were used, calibrated according to RETSPL's, adhering to equivalent threshold sound pressure levels identified for this headphones according to Madsen and Margolis, (2014). Only high frequencies were selected for the protocol which included 2, 4, and 8 kHz. Pure tones were limited up to 90 dB HL at 2 and 4 kHz and up to 80 dB HL at 8 kHz. The lowest stimulus level that was presented was 10 dB HL at all selected frequencies.

DIN testing (South African English DIN test smartphone Application) was conducted on a Samsung Galaxy S6 device with Samsung S6 insert earphones. This mobile application measures the participant's speech recognition threshold (SRT) with a

measurement error of 0.7 dB, through changing levels of long-term average speech-spectrum noise (LTASS) by a 2 dB up and down adaptive procedure (Potgieter et al., 2016, 2017). The test included a series of three numbers from zero to nine, known as triplet-digits being presented to the participant binaurally, for example 4-7-1.

The smartphone applications were compared to manual threshold audiometry. This was performed using the KUDUwave (MoyoDotNet, Johannesburg, South Africa) Type 2 Clinical Audiometer (IEC 60645-1/2). This tool has been validated to use outside a sound-treated room and was used as opposed to the gold standard as a practical validated audiometric test in the clinics (Maclennan-Smith et al., 2013; Storey et al., 2014). The KUDUwave software was operated from a notebook computer (Acer Aspire E1-532, running Microsoft Windows 8). The audiometer hardware was encased in the circumaural earcups and was powered by a USB cable plugged into the notebook. The audiometer was calibrated according to ISO 389-5:2006 before data collection. The circumaural cups covered the transducer earphones after insertion. The insert earphones were calibrated according to ISO 389-2. A response button was connected to the KUDUwave device, which recorded the participants' response. The circumaural earcups have incorporated microphones which measured ambient noise levels during testing. The same frequencies as for smartphone automated audiometry were tested with manual audiometry.

Procedures

Testing was conducted in a quiet room provided by the clinics. The hearTest™ application integrates noise monitoring referenced to maximum permissible ambient noise levels during the assessment. Noise levels did not exceed the maximum permissible ambient noise levels, as noise concerns would be expected more at 0.5 and 1 kHz. If noise levels were too high for testing, environmental changes were made, for example turn of the ventilator. Otological examinations (otoscopy and tympanometry) were done first, followed by smartphone automated audiometry, DIN test and manual audiometry, in this given order. Fifty participants were retested with smartphone automated audiometry and DIN testing.

The otologic examination was performed by the first author who is a qualified audiologist to identify participants that presented with any abnormal ear canal or tympanic membrane findings. Participants that presented with an atypical finding in

otoscopy and tympanometry were excluded from the study as the DIN test is insensitive to detect a conductive hearing loss (Smits and Houtgast, 2005). Participants that presented with a conductive component were referred for necessary intervention.

Instructions were provided verbally, and the participant was seated with their back facing the tester. Headphones were placed on the participants' ears, and the test started at 2 kHz at 40 dB HL. Testing automatically began in the left ear, unless a participant indicated the right ear is the better hearing ear. If a patient was responding reliably in the initial testing sequences, subsequent frequency testing commenced at 30 dB HL. This was to decrease test time for patients with normal hearing. Reliability of the responses was determined automatically via the application. This was to decrease test time for patients with normal hearing. If a participant pressed the ‘on-screen button’ after the tone was heard, it was recorded as a positive response and the tone would automatically decrease by 10 dB. If a participant did not respond when a stimulus was presented, it was registered as a negative response and the tone would automatically increase by 5 dB. A positive response was recorded as the lowest threshold on the application when two of three responses occurred at the same intensity with three ascents. When test intensities exceeded 40 dB HL, contralateral masking was presented in the opposite ear as specified in ISO 8253:1. Testing was conducted until a minimum of 10 dB HL as noise levels in the healthcare setting can make testing below 10 dB HL almost impossible (van Tonder et al., 2016).

For the DIN test the participant was required to adjust the noise on the application to a comfortable hearing level. The participant then had to press the "Start Test" button to begin the test. Triplet digits were presented and a pop-up keyboard appeared to allow the participant to enter the numbers heard. The triplet-digits were presented and the participant entered the triplet heard correct, the next triplet was introduced at a 2 dB lower SNR and for an incorrect response at a 2 dB higher SNR. The SRT was calculated as the average SNR from the forth to the last of the triplets presented. Results were recorded in SNR after the test was performed.

Manual threshold audiometry was performed to compare thresholds of smartphone audiometry and manual audiometry. Insert earphones were placed into the ear

canal, and headphones were put on the participants' ears. Only air conduction thresholds were measured. The test began at 2 kHz, 30 dB HL. Testing was done according to the modified Hughson-Westlake method at 2, 4, and 8 kHz by increasing in steps of 5 dB and decreasing in steps of 10 dB to find a true threshold. Appropriate masking was used for air-conduction when the threshold in the non-test ear obtained exceeds the interaural attenuation (ASHA, 2005).

Data analysis

A comparative analysis was performed between thresholds obtained from the smartphone application and conventional audiometry using SPSS v.22 (Armonk, New York) and MS Excel. Data were not normally distributed. Therefore a nonparametric analysis (Wilcoxon signed-rank test) was used to determine if there were significant differences between smartphone audiometry and manual audiometry ($p < 0.05$). A total of 1200 thresholds were obtained across 2, 4, and 8 kHz. Testing was only conducted down to a minimum of 10 dB HL. Thus, all results were analysed to account for the possible influence of a floor effect. These results are visible in all the tables except Figure 3 and 4. Threshold data for smartphone audiometry and manual audiometry were analysed descriptively for average differences, average absolute differences, and respective distributions. High-frequency pure tone average (hfPTA) (2, 4 and 8 kHz) of the better ear in each participant was calculated for comparison with the DIN test. Corresponding thresholds between smartphone audiometry and manual audiometry were determined and expressed as a percentage of cases within 5 dB, within 10 dB, and differing by 15 dB or more. The same analysis was done for the test re-test measures in smartphone automated audiometry. The Spearman rank correlation test ($p<0.05$) for nonparametric data was used to determine the test re-test reliability and of both smartphone audiometry and DIN testing. The same analysis was done for the relationship between DIN test, manual audiometry and smartphone automated audiometry.

3.4 Results

Participants with a hfPTA higher than 15 dB HL in either ear were defined to have a hearing loss (ISO, 1998). Among participants, 106 subjects (53%) presented with a

sensorineural hearing loss when smartphone audiometry was used and 96 (48%) when manual audiometry was used.

A strong positive correlation between smartphone automated audiometry and manual audiometry was evident ranging from 0.76 to 0.79 across frequencies (Figure 3). Analysis of the smartphone automated audiometry was conducted, which indicated that 37.5% of thresholds were not affected by the floor effect (Table 3) at a minimum response level at 10 dB HL. Means and standard deviations for both smartphone audiometry and manual audiometry ranged from 26.1 (12.0 SD) to 33.1 (15.7 SD) (Table 4). A statistically significant difference was evident between the right ear of 4 and 8 kHz for smartphone compared to manual audiometry ($p<0.05$). A statistical difference was also seen in the left ear at 4 kHz between smartphone and manual audiometry (Table 5). However, the majority (88.2%) of thresholds differed by 10 dB or less (Table 5). Threshold differences between smartphone audiometry and manual audiometry ranged between -1.7 (9.3 SD) and 4.4 (SD=11.0). Absolute average differences (Table 5), excluding the floor effect, varied between 4.2 (4.1 SD) to 8.6 (10.3 SD). The mean false positive rate for smartphone automated PTA was 3,1% (4.9 SD)), which indicated that participants responded consistently. If a patient responded when no stimulus was presented, it is considered as a false response and is logged as such by the application. A moderate positive correlation (r= 0.42) was present between manual audiometry and the DIN SRT (Figure 4).

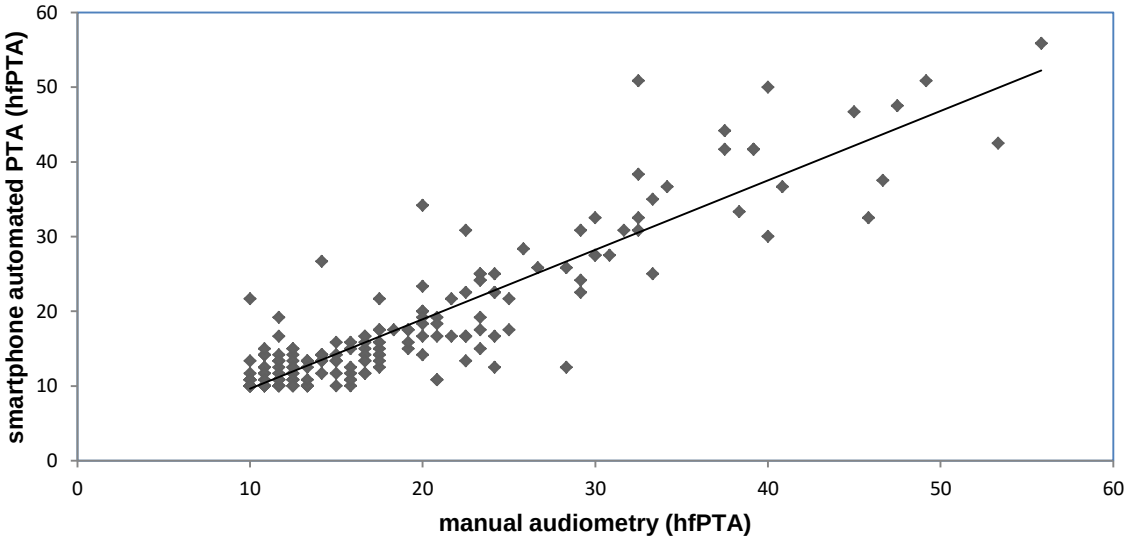

Figure 3 Scatter plot of the hfPTA of smartphone automated audiometry vs manual audiometry. hfPTA indicates high-frequency pure tone average.

Table 3 Distribution of thresholds for smartphone automated audiometry and manual audiometry.

		Frequencies (kHz)		
		% (n)		
		2	4	8
Right	Automated and conventional =10 dB	39.5 (79)	41.5 (83)	38.5 (77)
	Automated > 10 dB and conventional = 10 dB	12 (24)	23.5 (47)	4 (8)
	Automated = 10 dB and conventional > 10 dB	12.5 (25)	5.5 (11)	12.5 (25)
	Automated > 10 dB and conventional > 10 dB	36 (72)	29.5 (59)	45 (90)
Left	Automated and conventional =10 dB	24.5 (49)	41.5 (83)	37 (74)
	Automated > 10 dB and conventional = 10 dB	31 (62)	25.5 (51)	9 (18)
	Automated = 10 dB and conventional > 10dB	4 (8)	1.5 (3)	11.5 (23)
	Automated > 10 dB and conventional > 10 dB	40.5 (81)	31.5 (63)	42.5 (85)
Total	Automated and conventional =10dB	32 (128)	41.5 (166)	37.75 (151)
	Automated > 10 dB and conventional = 10 dB	21.5 (86)	24.5 (98)	6.5 (26)
	Automated = 10 dB and conventional > 10dB	8.25 (33)	3.5 (14)	12 (48)
	Automated > 10 dB and conventional > 10 dB	38.25 (153)	30.5 (122)	43.75 (175)

Table 4 Means (SD) for smartphone automated audiometry and manual audiometry thresholds unaffected by the floor effect in dB HL.

		Frequency (kHz)		
		2	4	8
Right	Smartphone automated audiometry	26.4 (13.4)	29.7 (13.0)	28.8 (13.5)
	Manual audiometry	26.9 (15.4)	27.3 (16.1)	31.7 (15.9)
Left	Smartphone automated audiometry	26.1 (12.0)	33.1 (15.7)	31.9 (17.7)
	Manual audiometry	25.4 (14.5)	26.9 (16.5)	32.3 (17.6)
Total	Smartphone automated audiometry	26.2 (12.7)	31.5 (14.5)	30.3 (15.7)
	Manual audiometry	26.1 (14.9)	27.1 (16.3)	32.0 (16.7)

Table 5 Average Differences* and Correspondence between Automated and Manual Audiometry per frequency excluding the floor effect

			Frequency (kHz)		
			2	4	8
Right ear	Threshold comparison excluding the floor effect (n)		72	59	90
	Average difference (dB)	Mean	-0.5	2.5**	-3.0**
		SD	5.9	9.6	9.3
	Correspodence(%)	0-5 dB	84.7	62.7	70
		± 10 dB	9.7	20.3	18.9
		≥ 15 dB	5.6	16.9	11.1
Left ear	Threshold comparison excluding the floor effect (n)		81	63	85
	Average difference (dB)	Mean	0.7	6.2**	-0.4
		SD	7.3	11.9	9.1
	Correspodence(%)	0-5 dB	86.4	58.7	76.5
		± 10 dB	7.4	17.5	14.1
		≥ 15 dB	6.2	23.8	9.4
Total	Threshold comparison excluding the floor effect (n)		153	122	175
	Average difference (dB)	Mean	0.1	4.4**	-1.7**
		SD	6.6	11.0	9.3
	Correspodence(%)	0-5 dB	85.6	60.7	72.6
		± 10 dB	8.5	18.9	16.6
		≥ 15 dB	5.9	20.5	10.9

* Manual subtracted from automated audiometry thresholds

** Significant difference (p>0.05)

Table 6 Average absolute differences for thresholds unaffected by the floor effect in dB HL.

		Frequency (kHz)		
		2	4	8
Right	Number	72	59	90
	Absolute average difference	4.3	6.5	6.6
	SD	4.1	7.4	7.3
Left	Number	81	63	85
	Absolute average difference	4.4	8.6	5.8
	SD	5.8	10.3	7.0
Total	Number	153	122	175
	Absolute average difference	4.3	7.6	6.2
	SD	5.0	9.1	7.1

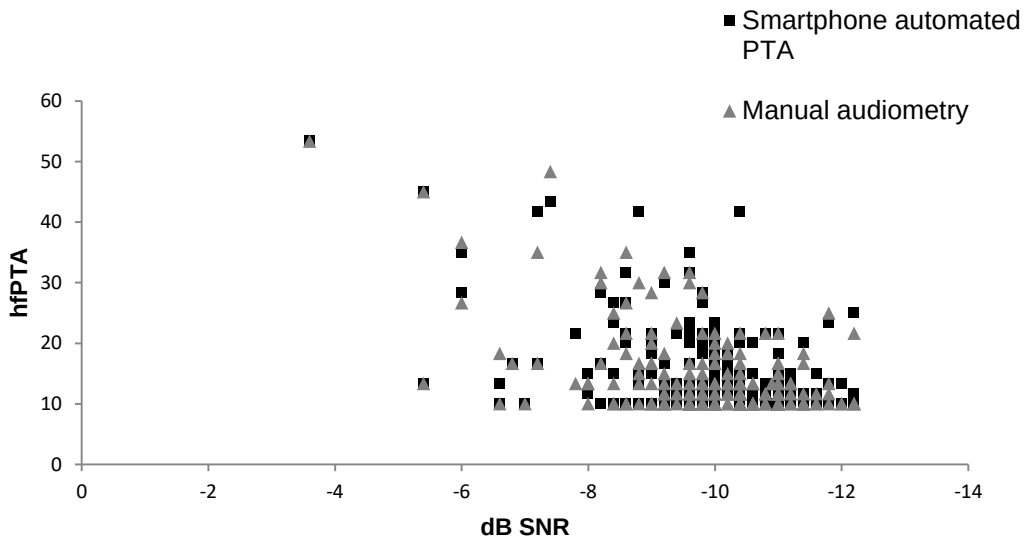

Figure 4 Scatter plot of the SRT vs the hfPTA of both smartphone automated audiometry and manual audiometry. Squares represent smartphone automated audiometry; triangles, manual audiometry. SNR indicates signal-to-noise-ration; hfPTA, high-frequency pure tone average.

No significant difference was noted ($p<0.05$) between test and retest thresholds of smartphone audiometry. A moderate to strong positive correlation was evident across all frequencies between test re-test thresholds of smartphone audiometry ranging from 0.44 to 0.88 (Table 7). Eighty five point eight percent (103/120) of thresholds corresponded within 0 to 5 dB between the initial test and retest with smartphone audiometry. The absolute average difference between the test and re-test measures of DIN testing was 1.2 dB SNR (1.5 SD). No significant difference was noted in the test re-test measures of the DIN test ($p < 0.05$). A correlation coefficient of 0.56 was present in the DIN test re-test measures when the Spearman rank correlation test was administered. Smartphone automated PTA took an average 247 seconds (11 SD) to complete and the DIN test an average of 234 seconds (26 SD) (Table 8).

Table 7 Test-re-test reliability of automated audiometry

		Frequency (kHz)		
		2	4	8
Right ear	n	18	15	13
	Mean diff (test minus re-test)	1.4	2.7	0.0
	SD	7.4	7.3	7.9
	Absolute difference	4.2	4.0	5.4
	SD	6.2	6.6	5.6
	Correlation coefficient (r)	0.70	0.76	0.68
	0-5 dB difference (%)	83.3	87	77
	10 dB difference (%)	11.1	7	15
	>15 dB difference (%)	5.6	7	8
Left ear	n	30	25	19
	Mean diff (test minus re-test)	1.7	2.8	3.2
	SD	6.1	13.2	8.5
	Absolute difference	2.7	7.6	4.2
	SD	5.7	11.1	8.0
	Correlation coefficient (r)	0.88	0.44	0.83
	0-5 dB difference (%)	96.7	76	89
	10 dB difference (%)	0.0	8	5
	>15 dB difference (%)	3.3	16	6
Total	n	48	40	32
	Mean diff (test minus re-test)	1.6	2.8	1.9
	SD	6.5	11.3	8.3
	Absolute difference	3.2	6.3	4.7
	SD	5.9	9.7	7.1
	Correlation coefficient (r)	0.83	0.55	0.80
	0-5 dB difference (%)	91.7	80.0	84.4
	10 dB difference (%)	4.2	7.5	9.4
	>15 dB difference (%)	4.2	12.5	6.3

* Significant difference (p<0.05)

Table 8 Mean test durations and average time for automated audiometry and DIN test

	Automated	Automated (re-test)	DIN test
Mean (seconds)	273	247	234
SD	49	11	26
Min – Max (seconds)	108 - 794	99 - 675	142 - 444

3.5 Discussion

Mobile health technology may provide affordable, mobile access to hearing test services that can improve clinical efficiency in settings where the risk of hearing loss may be high, like an ID clinic. We aimed to evaluate the clinical utility of smartphone automated audiometry and DIN test in an ID clinic. The current study indicated good reliability for the use of smartphone applications in an ID clinic. By evaluating the clinical utility of any novel tool, the mobile applications should be compared to the gold standard conventional audiometry (Bland and Altman, 1999). In this case, a clinical audiometer (KUDUwave) was used as the reference test since it has been validated for use in controlled environments outside a sound booth (Maclennan-Smith et al., 2013). This comparative reference test, while validated for use outside a sound booth, is limited by the fact that it was not conducted in a typical sound booth adhering to required maximum permissible ambient noise levels.

Hearing threshold variation between two methods of hearing assessment is accepted as subclinical within context when compared with conventional audiometry if hearing thresholds vary by 10 dB or less (McDaniel et al., 2013; OSHA, 1983). A significant statistical difference was seen at 4 and 8 kHz ($p<0.05$), however, the majority of thresholds (88.2%) of those unaffected by the floor effect corresponded within 10 dB or less between smartphone automated audiometry and manual audiometry. This is in line with a study done by Mahomed et al., (2016b) which showed a correspondence of 87.7% between automated audiometry and conventional audiometry. There are some possible reasons for the significant differences in thresholds between the smartphone and conventional audiometry. These may include slight calibration differences between the circumaural headphones (smartphone) and insert earphones (conventional), smartphone testing was a self-operated automated procedure while manual audiometry was conducted

by an audiologist. Furthermore, the insert earphone covered by circumaural earcup for the manual audiometry offers more attenuation to environmental noise, which may also have influenced threshold differences in this context outside a sound booth.

Several studies have compared automated or smartphone audiometry with conventional or manual audiometry in various settings. Although none have been conducted in an ID clinic environment (Margolis et al., 2011; Mahomed-Asmail et al., 2013; Peer and Fagan, 2015; Sandström et al., 2016; van Tonder et al., 2017). Threshold differences between automated and manual audiometry reported in a meta-analysis ranged between -5.0 dB (8.7 SD) and -0.1 dB (5.5 SD) across frequencies 2, 4 and 8 kHz, on the validity of automated and manual audiometry (Mahomed-Asmail et al., 2013). Mean differences in the current study were in line with the meta-analysis as well as for results reported by van Tonder et al., (2017) that ranged from -3.3 dB (6.2 SD) to 1.6 dB (6.6 SD). As well as for Margolis et al., (2011) and Sandström et al., (2011). However, variability (SD's) is seen to be higher at 4 and 8 kHz compared to these studies.

Mean differences for test re-test measures of smartphone automated audiometry were comparable to mean differences between smartphone and manual audiometry thresholds in the current study. Mahomed et al., (2013) reported mean differences from 0.0 dB (6.4 SD) to 0.7 (7.1 SD) in test re-test reliability differences between 2 and 4 kHz in automated audiometry. Similar variability (SD's) were reported in the current study. Swanepoel and Biagio (2011) compared computer-based audiometry with conventional audiometry and found similar absolute average differences that ranged from 3.0 to 3.3. However, higher variability was observed in this study at 4 and 8 kHz. In contrast, test re-test thresholds have a strong positive correlation, and test re-test differences fell within the 0-5 dB range 88% of the time. Also, mean test re-test differences were less than 2 dB, and absolute average differences were less than 4 dB. Therefore, smartphone automated audiometry is a reliable mHealth screening tool to monitor hearing in an ID clinic setting.

A moderate positive relationship for test re-test reliability was observed in DIN testing (r=0.56). In contrast, Rashid et al., (2017) found higher correlation coefficients (r=0.74) between DIN SNR and pure tone average in an occupational setting using a

speech-in-noise test in high-frequency hearing losses. The differences between the studies may suggest that the DIN test has a possible learning effect which was also reported by Smits et al., (2013). Rashid et al., (2017) showed a mean difference between test re-test measures of 0.3 dB SNR (1 SD), which is in line with the current study. Strong correlations between SRT's and pure tone averages in high frequencies were observed in various studies (Jansen et al., 2013; Leensen and Dreschler, 2013; Rashid et al., 2017). In these studies, DIN or speech-in-noise tests were implemented in occupational settings to screen for a noise-induced hearing loss. A lower correlation coefficient that was observed in the current study may be due to the procedures of the other studies that were adapted to screen for higher frequency hearing losses. These studies also had different language and speech material, for example, Dutch consonant-vowel-consonant combinations containing high-frequency consonants (Jansen et al., 2013; Leensen and Dreschler, 2013; Rashid et al., 2017). Test frequencies in the current study also differed from these previous studies that included frequencies from 2, 3, 4, and 6 kHz.

The total time for smartphone automated audiometry and DIN test only differed by 39 seconds. By taking the time and coverage rate into consideration, an ID clinic could test more than 80 individuals per day with these smartphone applications, depending on the working hours of an ID clinic. Health care workers or nurses available in the clinic can be minimally trained to facilitate the test in a quiet environment (Yousuf Hussein et al., 2015). As both tests were self-administered, trained staff can also test patients for monitoring purposes during patients' monthly visits.

A limitation of the current study is the order of the tests that were not randomised and may have influenced the results. As smartphone automated audiometry was administered first, it is expected for the thresholds to be higher than those of manual audiometry. Therefore, it is recommended that future research should implement a counterbalanced order in their method of testing. In DIN testing, results were binaural and not ear specific. This may be a clinical implication for the future if a unilateral hearing loss is present. Future research can adapt the test procedure to get ear specific results and may prevent missing a one-sided hearing loss. For future research in test re-test measures for DIN testing, participants should receive a training list before the evaluation; as it was not done in the current study.

In the HIV-population, higher frequencies appear to be affected first, with hearing loss spreading to the conventional-frequency range through the progression of the disease and the course of treatment of ototoxic medications (Fausti et al., 1994). In the current study, it is evident that participants did not show typical high-frequency hearing losses. This may be due to the relatively young sample that was present as the mean age is 44.4 years. Moreover, the majority of patients may have recently started with ARV medication. Furthermore, these patients are required to visit the clinic monthly, which improves their immune system due to the use of ARV's. Ototoxicity might also be more prevalent in patients that concurrently use a combination of ARV's together with medications prescribed for opportunistic infections. However, the current study aimed to determine the feasibility of the mobile hearing applications for future monitoring purposes. Recommendations for future research in the clinical utility of smartphone hearing applications in an ID clinic setting could implement a protocol that extends testing of audiometry in higher frequencies (16 kHz and higher). Early detection of ototoxicity in assessing higher frequencies can lessen communication deficit and reduce the risk of ototoxicity, as higher frequencies are essential for verbal communication (Fausti et al., 1994). Clinical health workers can manage an ototoxicity monitoring programme to implement in an ID clinic setting along with an audiologist for necessary intervention.

3.6 Conclusion

The use of smartphone automated audiometry could be a portable, inexpensive, practical and accessible alternative to manual audiometry in ID clinic settings (Clark and Swanepoel, 2014; Foulad et al., 2013; Swanepoel, Olusanya et al., 2010c). Based on the results, smartphone automated audiometry demonstrates better reliability than the DIN test to implement in an ID clinic setting. The smartphone application could be used as a rapid baseline and monitoring screening tool for ototoxicity for patients' attending an ID clinic.

3.7 Acknowledgments

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Declaration of interest: The hearTest™ application is intellectual property owned and trademarked by the University of Pretoria. The third author is a co-inventor of the hearTest™ application.

CHAPTER 4: DISCUSSION AND CONCLUSION

4.1 Discussion of results

Monitoring of Immunodeficiency Virus (HIV) related hearing loss has been recommended in Individuals living with HIV (Assuiti et al., 2013; Harris, Peer, and Fagan, 2012; Maro et al., 2014; van der Westhuizen et al., 2013). Implementing mobile technology that can improve clinical efficiency in settings where individuals are typically at high risk for hearing loss, like in an Infectious Disease (ID) clinic, may provide affordable, mobile access to hearing services (Convery et al., 2013; Louw et al., 2017). However, there is a lack of research regarding the clinical utility of hearing mHealth technologies in a specialised health centre such as the ID clinic setting, where the prevalence of hearing loss is rising. This study determined the clinical utility of smartphone automated audiometry and Digits-In-Noise (DIN) test in an ID clinic setting.

For the clinical utility of a novel mHealth screening tool to be assessed, it should be compared to the golden standard pure tone audiometry testing (Bland and Altman, 1999). In this case, a clinical audiometer (KUDUwave) was used as the reference test as it has been validated for use in controlled environments outside a sound booth (Maclennan-Smith, Swanepoel, and Hall, 2013).

4.1.1 Clinical utility of smartphone automated audiometry

All participants who had no conductive pathology were tested with the smartphone automated audiometry application, hearTest™. A hearing loss was deemed to be present when participants presented with a high-frequency pure tone average (hfPTA) greater than 15 dB HL (ISO, 1998). A total of 106 (53%) participants presented with a hearing loss in smartphone automated audiometry and 96 (48%) participants in manual audiometry.

Thresholds were compared in order to evaluate the clinical utility of the automated test. Hearing threshold variation between two methods of hearing assessment is accepted as subclinical within context when compared with conventional audiometry if hearing thresholds vary by 10 dB or less (OSHA, 1983; McDaniel et al., 2013). Analysis of minimum response levels on the smartphone automated audiometry

indicated that 37.5% of thresholds were not affected by the floor effect. A statistical difference was evident between the right ear at 4 kHz and 8 kHz for smartphone compared to manual audiometry. This was also the case for the left ear at 4 kHz when smartphone and manual audiometry were compared. However, the majority of thresholds (88.2%) of those unaffected by the floor effect corresponded within 10 dB or less between smartphone automated audiometry and manual audiometry. This is in line with a study by Mahomed-Asmail, Swanepoel, and Eikelboom (2016a), which showed a correspondence of 87.7% between automated audiometry and conventional audiometry. There is no clear-cut reason for the differences in thresholds between smartphone and manual audiometry, but there are a number of possible reasons. These may include: a) smartphone testing was a self-operated automated procedure whilst manual audiometry was conducted by an audiologist, b) calibration differences between the supra-aural headphones of smartphone and inserts earphones of conventional audiometry, and c) the insert earphones covered by circumaural earcups for manual audiometry testing has more attenuation to environmental noise, which also influences thresholds in this context outside a sound booth.

A strong positive correlation was found between smartphone automated audiometry and manual audiometry, that ranged from 0.76 to 0.79 across frequencies. Peer and Fagan (2015) found similar correlations that ranged from 0.73 to 0.79 in a high-risk population for ototoxicity (including HIV patients) using an iOS-based application called uHear. However, the uHear application is only set for iOS-based software and can become more expensive to implement in an ID clinic setting than an Android operating smartphone.

Several other studies have compared automated audiometry with conventional audiometry in various settings (Mahomed-Asmail, Swanepoel, Eikelboom, and Soer, 2013; Margolis, Frisina, and Walton, 2011; Peer and Fagan, 2015; Sandström et al., 2016; van Tonder et al., 2017). However, the current study purports to be the first to conduct smartphone automated audiometry in an ID clinic. The current study reported average absolute differences varied from 4.2 (4.1 SD) to 8.6 (10.3 SD) and mean differences from -1.7 (9.3 SD) to 4.4 (11.0 SD). Thresholds differences between automated and manual audiometry reported in a meta-analysis (Mahomed-Asmail et al., 2013) ranged between -5.9 dB (8.7 SD) and -0.1 dB (5.5 SD) across

frequencies 2, 4, and 8 kHz. Mean differences in the current study were in line with the meta-analysis, as well as with results obtained in studies that compared smartphone audiometry with conventional audiometry (Margolis et al., 2011; Sandström et al., 2016; van Tonder et al., 2017). However, higher variability (SDs) was seen in the current study.

Mean differences for test re-test measures of smartphone automated audiometry were comparable to mean differences between smartphone and manual audiometry thresholds in the current study. No significant difference was noted ($p>0.05$) between test and re-test measures of smartphone automated audiometry. Test re-test measures of smartphone automated audiometry resulted in absolute average differences ranging between 1.6 (6.5 SD) and 2.8 (11.3 SD). Mahomed et al. (2013) reported mean differences from 0.0 dB (6.4 SD) to 0.7 (7.1 SD) in test re-test reliability differences between 2 and 4 kHz. There are no definite reasons for the differences between the current study and those of Mahomed et al., (2013). A possible reason may be due to a learning affect. Similar variability (SDs) were reported in the current study. Swanepoel and Biagio (2011) compared computer-based audiometry with conventional audiometry and found similar absolute average differences that ranged from 3.0 to 3.3 dB HL. Higher variability was observed in this study at 4 and 8 kHz. In contrast, test re-test thresholds demonstrated with a strong positive correlation ranging from 0.44 to 0.88, and test re-test differences fall within the 0-5 dB range 85.8% of the time. In addition, mean test re-test differences were less than 2 dB, and absolute average differences were less than 4 dB. Therefore, smartphone automated audiometry may be a reliable screening tool for monitoring hearing in an ID clinic setting.

4.1.2 Clinical utility of Digits-In-Noise testing

All participants who presented with normal middle ear functioning were tested with the DIN test smartphone application, as it is insensitive to (does not detect) a conductive hearing loss (Smits and Houtgast, 2005). A total of 27% (n=54) of participants presented with abnormal results when tested with the DIN test. There is no definite reason for the hearing losses differences between the hearTest™ and the DIN test. However, it may be due to the sensitivity of the two tests that may differ.

A moderate positive correlation (r=0.42) was present between manual audiometry and the DIN SRT. Strong linear correlations have been reported by various studies between DIN SNR and conventional audiometry (Jansen, Luts, Dejonckere, van Wieringen, and Wouters, 2013; Leensen and Dreschler, 2013; Rashid, Leensen, de Laat, and Dreschler, 2017). In these studies, DIN or speech-in-noise tests were implemented in an occupational setting to screen for a noise-induced hearing loss. Other studies may have shown a higher correlation than in the results from the current study due to procedures that were adapted to screen for higher frequency hearing losses. These studies also measured the relaibility in different lanuage and speech material, for example, Dutch consonant-vowel-consonant combinations contaning high-frequency consonants (Jansen et al., 2013; Leensen and Dreschler, 2013; Rashid et al., 2017). Frequencies of above mentiond studies differed from the current study that included frequencies from 2, 3, 4, and 6 kHz. The DIN test in the present study was intended to get an SNR as a baseline for future monitoring.

A moderate positive relationship for test re-test reliability was observed in DIN testing (r=0.56). Rashid et al. (2017), in contrast, found higher correlation coefficients (r=0.74) in an occupational setting using a speech-in-noise test in high-frequency hearing losses. This may suggest that the DIN test has a possible learning effect which was also reported by Smits et al. (2013). The absolute average difference between the initial and re-test SNR of the DIN test was 1.2 dB (1.5 SD). This is in line with results reported by Rashid et al. (2017). No significant difference was noted in the test re-test measures of the DIN test (p>0.05).

4.1.3 Time efficiency and coverage rate

Total time of smartphone automated audiometry (247 seconds, 11 SD) and DIN testing (234 seconds, 26 SD) differed by only 39 seconds.

An average of 83 patients visit the ID clinic at Tshwane District Hospital daily, and an average of five HIV patients per day visit the ID clinic at Steve Biko Academic Hospital. The coverage rate for the ID clinic at Steve Biko Academic Hospital is low as it does not serve only HIV-positive patients. The ID clinic treats various types of infectious diseases, for example tuberculosis and drug-resistant tuberculosis; sepsis; acute, viral, and bacterial meningitis; malaria, and so forth.

Taking the time and coverage rate into consideration, such a clinic can test an average of 84 patients per day, depending on the working hours of the clinic. Health care workers or nurses available in the clinic can be minimally trained to facilitate the test in a quiet environment (Yousuf Hussein et al., 2015). As both tests were self-administered, trained staff can also test patients for monitoring purposes during their monthly visits.

4.2 Clinical implications and recommendations

- Results of this study indicate that the hearTest™ can be clinically utilised in an ID clinic. Certain aspects of the current study can be improved to optimise further research regarding the clinical utility of automated and mobile hearing health technology. Tests were not randomised and this may have influenced results. As smartphone automated audiometry was administered first, it is to be expected that the thresholds would be higher than those of manual audiometry. Therefore, it is recommended that testing be conducted in a counterbalanced order when validating novel screening tools in future research (Mahomed-Asmail et al., 2013).
- Smartphone automated audiometry was self-administered in the current study, but can also be done through test-operator mode. It is recommended that the test should be conducted through test-operator mode in future research projects so that a participant does not have control over the procedure. Clinical health workers or staff available at the clinic can be minimally trained to administer the smartphone application at patients' monthly visits (Yousuf Hussein et al., 2015)
- Only three frequencies were assessed with smartphone automated audiometry. Higher frequencies appear to be affected first in the HIV-positive population (Fausti et al., 1994). The hearing loss then spreads to conventional frequencies through the course of treatment with ototoxic medications (Fausti et al., 1994). A further factor that may have influenced results is the fact that lower frequencies are more sensitive to environmental noise (Mahomed-Asmail et al., 2016a). It is recommended that in future frequencies throughout the complete audiogram (0.25 to 8 kHz) and also higher frequencies (16 kHz and higher) be assessed for monitoring purposes.

4.3 Critical evaluation

It is crucial to evaluate the research project critically, to interpret the findings in order to determine whether there are appropriate applications to practice, and to provide pointers for improvement in future studies. A critical evaluation typically involves examination of the strengths and limitations of a study,

Strengths of the study

- The study consisted out of 200 participants, which were a larger number than detected in the power analysis.
- The analysing of the data was relatively easy
- The results present to be reliable
- Necessary recommendations could be made directly to the physician or ENT when a conductive component is detected
- Participants who presented with a hearing loss were referred directly to the Audiology department in the same hospital for further diagnostic testing and necessary intervention.

Limitations of the study

- It was observed that the majority of the participants' first language was not English, while instructions could only be provided in English or Afrikaans. An available translator at the clinic assisted in cases where the participant did not understand Afrikaans or English
- The hearTest™ application only tested to a minimum of 10 dB. Thresholds equal to 10 dB in both smartphone automated audiometry and manual audiometry were required to be excluded for a part of the analysis, to eliminate the possible influence of the floor effect.
- As testing was not done in a counterbalanced method, the order effect may have an influence on the results
- Data of the current study are not robust enough to explain the significant differences.
- There are results lacking to describe the validity on the DIN test.
- The influence of any pre-existing hearing loss was not explored.

4.4 Future research

Based on the critical evaluation of the current research project, recommendations for future research could be established. Recommendations are discussed below.

- As smartphone automated audiometry was only administered to a minimum of 10 dB, testing should be investigated down to a minimum of 0 dB in a clinical setting.
- All conductive pathologies were excluded from this research project. Future research should include these pathologies in using both smartphone applications.
- ARV's are known to have ototoxic agents that can cause a possible irreversible hearing loss (Khoza-Shangase, 2011; Shaw, 2012). Furthermore, throughout the progression of the disease, otological symptoms such as hearing loss intensifies (Iacovou et al., 2012). In future; the hearTest™ application can be carried out in a monitoring programme for the surveillance of the disease of ototoxicity. Testing of PTA can extend frequencies higher than 8 kHz for ototoxicity purposes (Fausti et al., 1994).
- A monitoring programme can be carried out in this type of clinic (Figure 5.). The audiologist at the same/nearest hospital can train clinical health workers to administer the tests (Yousuf Hussein et al., 2015). Furthermore, he/she will educate the physicians in the clinic about the effect the HIV-virus can have on patients' hearing abilities. HIV-positive individuals should receive a pre-treatment assessment as a baseline for follow-up surveillance. Patients visit the clinic monthly and should, therefore, be tested again prior their appointment with the clinic physician. If a shift is observed in their thresholds or SNR, it should be documented, and the cause of the shift should be established regarding if a conductive pathology or sensorineural hearing loss is present. The newly developed hearScope™ can identify conductive pathologies to rule out a conductive hearing loss. Thenceforth, the necessary intervention can take place. This proposed conceptual model for a future monitoring program is illustrated in figure 5.
- A monitoring programme can be carried out in an ID clinic setting (Figure 5.). The audiologist at the same/nearest hospital can train clinical health workers to administer the tests (Yousuf Hussein et al., 2015).

- A qualitative research component can derive from the current study on the views of health care workers or nurses on the smartphone applications.

4.5 Monitoring programme in an ID clinic

A proposed model for a monitoring programme in ID clinic settings is provided in Figure 5.

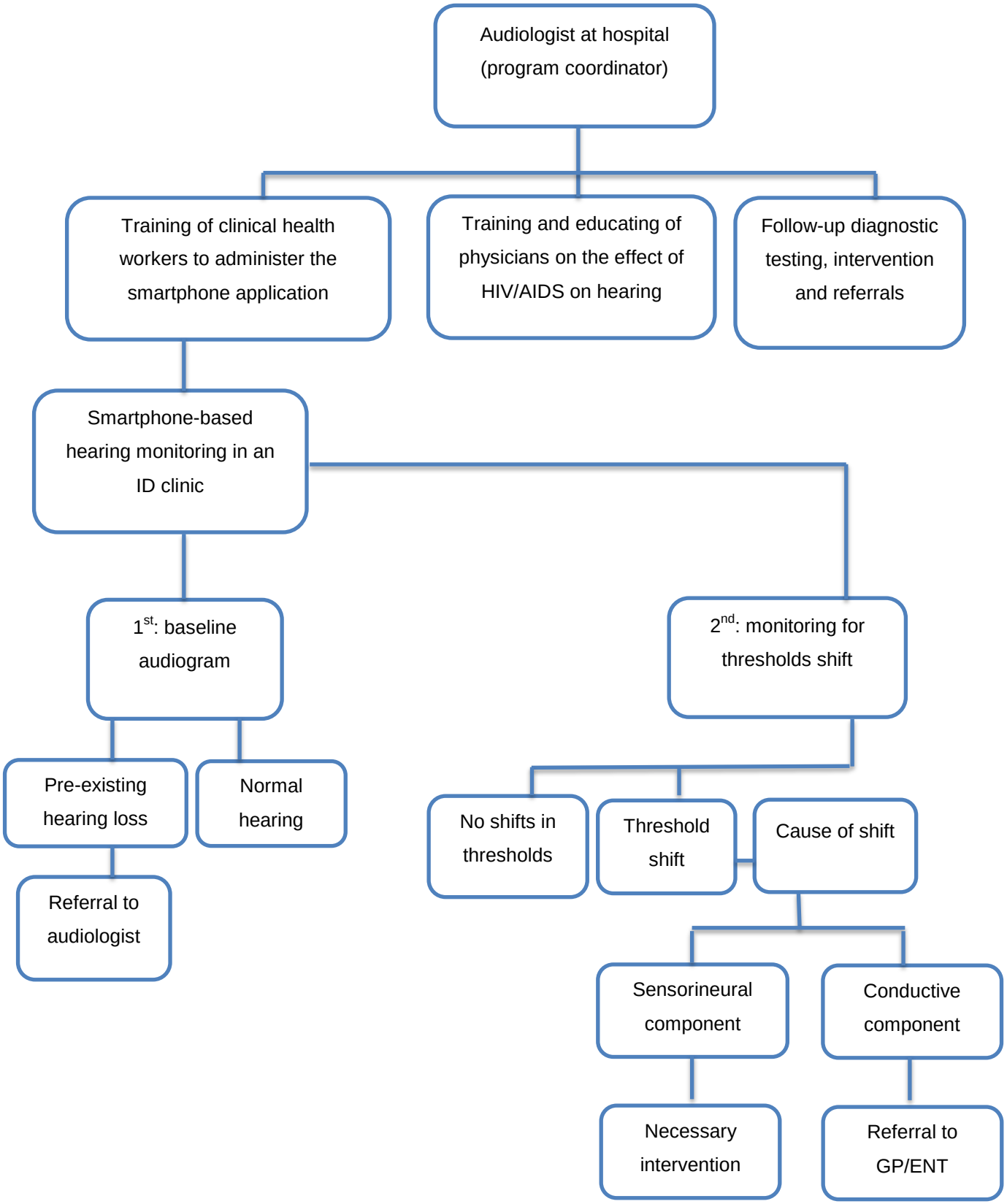

Figure 5. Conceptual model for a hearing monitoring programme

The model depicted in Figure 5 was designed to expand the current study's aim to include a monitoring programme. It has been recommended that the hearing of

Individuals with HIV should be monitored (Assuiti et al., 2013). In view of the shortage of audiologists (WHO, 2013), clinical health workers can be trained to administer these smartphone applications (Yousuf Hussein et al., 2015). The hearing monitoring protocol for Individuals with HIV can be implemented in the clinic where these patients receive medical attention.

Since the number of audiologists in clinic settings is limited, an audiologist can serve as a program coordinator. The audiologist's main duties will be to train clinical health care workers in facilitating the smartphone applications, to ensure ongoing monitoring, to educate health care workers on the effects of HIV/AIDS on hearing, and to provide intervention and referrals when needed. Monthly meetings with the audiologist should ensure an effective monitoring program.

The hearing test can be conducted while the nurse is checking each patients' vital signs in a quiet room provided by the clinic. A patient's first test will serve as a baseline. Any shift in hearing sensitivity can then be detected in the patient's next visit to the clinic. If a hearing loss was present at the patient's first test, referral should be made to the audiologist for further investigation. If a shift in hearing sensitivity is present after the initial test, it should be investigated to determine whether it is due to a conductive pathology or a sign of a sensorineural hearing loss. This can be done by establishing the presence or absence of a conductive pathology through using the newly developed hearScope™, or by using a Tympanometer to detect the presence of a middle ear pathology. If a conductive pathology is present, referrals can be made to the Ear, Nose and Throat specialist or the General Practitioner. If a sensorineural hearing loss is present, the shift in hearing sensitivity may be directly or indirectly caused by HIV/AIDS. Therefore, appropriate referrals should take place after determining the possible cause, e.g. ototoxicity or a comorbid infection. Thereafter, necessary intervention can take place.

4.6 Conclusion

The implementation of smartphone automated audiometry in an ID disease clinic setting can increase access hearing services for Individuals living with HIV. The current research project highlighted that further research is needed into the possibility of monitoring programmes in ID clinics through use of an mHealth tool.

The use of smartphone automated audiometry could be a portable, inexpensive, practical and accessible alternative screening tool to manual audiometry in ID clinic settings (Clark and Swanepoel, 2014; Foulad, Bui, and Djalilian, 2013; Swanepoel, Mngemane, et al., 2010b). Smartphone automated audiometry offers data capturing, automated protocols, and integrated noise monitoring, thus allowing detection of an HIV-related hearing loss and management thereof at patients' monthly visits. Based on the results, the hearTest™ smartphone application demonstrated better reliability than the DIN test to implement in an ID clinic setting. The smartphone application could be used as a rapid baseline and monitoring screening tools for ototoxicity for patients' attending an ID clinic.

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APPENDICES

Appendix A – Permission from CEO of Steve Biko Academic Hospital

To: Chief Executive Officer/Information Officer
Seve Biko Academic Hospital

Dear Miss/Mr

From: Masters Student,
Supervisors

Marize Brittz, Dr Heinze & Dr Mahomed-Asmail

Re: Permission to do research at Steve Biko Academic Hospital

Drs Faheema Mahomed-Asmail, Barbara Heinze and I are researchers from the Department of Speech Language Pathology and Audiology at the University of Pretoria. I am requesting permission on our behalf to conduct a study at the Infectious Disease clinic at the Steve Biko Academic Hospital which may involve access to patient records. The request is lodged with you in terms of the requirements of the Promotion of Access to Information Act. No. 2 of 2000.

The title of the study is: Validity of automated threshold audiometry and Digits-In-Noise testing in a HIV clinic

The researchers request access to the following information:

- Access to the clinical files and records of patients at the Infectious Disease Clinic.

We intend to publish the findings of the study in a professional journal and/ or at professional meeting like symposia, congresses, or other meetings of such a nature.

We intend to protect the personal identity of the patients by assigning each patient an alpha-numeric code.

We undertake not to proceed with the study until we have received approval from the Faculty of Health Sciences Research Ethics Committee, University of Pretoria.

Yours sincerely

Permission to do the research study at this hospital and to access the information as requested, is hereby approved.

Chief Executive Officer

_____ Hospital

Dr _____

21/10/2016

DR ME KENOSI
CHIEF EXECUTIVE OFFICER
STEVE BIKO
ACADEMIC HOSPITAL

Signature of the CEO

Hospital Official

Appendix B - Permission from CEO of Tshwane District Hospital

To: Chief Executive Officer/Information Officer
Tshwane District Hospital

Dear Miss/Mr

From: Masters Student, Supervisors

Marize Brittz, Dr Heinze & Dr Mahomed-Asmail

Re: Permission to do research at Tshwane District Hospital

Drs Faheema Mahomed-Asmail, Barbara Heinze and I are researchers from the Department of Speech Language Pathology and Audiology at the University of Pretoria. I am requesting permission on our behalf to conduct a study at the ARV clinic at the Tshwane District Hospital which may involve access to patient records.

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

The title of the study is: Clinical utility of mobile and automated hearing health technology in an infectious disease clinic setting

The researchers request access to the following information:

- Access to the clinical files and records of patients at the Infectious Disease Clinic.

We intend to publish the findings of the study in a professional journal and/ or at professional meeting like symposia, congresses, or other meetings of such a nature.

We intend to protect the personal identity of the patients by assigning each patient an alpha-numeric code.

We undertake not to proceed with the study until we have received approval from the Faculty of Health Sciences Research Ethics Committee, University of Pretoria.

Yours sincerely

Permission to do the research study at this hospital and to access the information as requested, is hereby approved.

Chief Executive Officer

TDH Hospital

Dr NKVSI

Signature of the CEO

Tshwane District Hospital
Private Bag X179
PRETORIA 0001
2017 -01- 30
Tshwane Distrik Hospitaal
Privaatsak X179
PRETORIA 0001

Hospital Official Stamp

Appendix C – Ethical clearance form: Faculty of Health Science

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 28 August 2018.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

26/01/2017

Approval Certificate
New Application

Ethics Reference No.: 42/2017

Title: Clinical utility of mobile and automated hearing health technology in an infectious disease clinic setting

Dear Miss Marize Brittz

The **New Application** as supported by documents specified in your cover letter dated 20/01/2017 for your research received on the 23/01/2017, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 25/01/2017.

Please note the following about your ethics approval:
- Ethics Approval is valid for 1 year
- Please remember to use your protocol number (**42/2017**) 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 approval is conditional on the receipt of **6 monthly written Progress Reports**, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

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

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

☎ 012 356 3084 deepeka.behari@up.ac.za / fhsethics@up.ac.za http://www.up.ac.za/healthethics
✉ Private Bag X323, Arcadia, 0007 - Tswelopele Building, Level 4, Room 60, Gezina, Pretoria

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 28 August 2018.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

23/02/2017

Approval Certificate
Amendment
(to be read in conjunction with the main approval certificate)

Ethics Reference No.: 42/2017

Title: Clinical utility of mobile and automated hearing health technology in an infectious disease clinic setting

Dear Miss Marize Brittz

The **Amendment** as described in your documents specified in your cover letter dated 6/02/2017 received on 6/02/2017 was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 22/02/2017.

Please note the following about your ethics amendment:
- Please remember to use your protocol number (**42/2017**) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committe may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics amendment is subject to the following:
- The ethics approval is conditional on the receipt of **6 monthly written Progress Reports**, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

We wish you the best with your research.

Yours sincerely

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

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

☎ 012 356 3084 deepeka.behari@up.ac.za http://www.up.ac.za/healthethics
✉ Private Bag X323, Arcadia, 0007 - Tswelopele Building, Level 4, Room 60, Gezina, Pretoria

Appendix D – Ethical clearance form: Faculty of Humanities

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

8 June 2017

Dear Mr Brittz

Project:	**Clinical utility of mobile and automated hearing health technology in an infectious disease clinic setting**
Researcher:	**M Brittz**
Supervisor:	**Prof A Stoltz, Ms B Heinze and Ms F Mahomed**
Department:	**Speech-Language Pathology and Audiology**
Reference number:	**13028589 (42/2017)**

Thank you for the application that was submitted for ethical consideration.

The Research Ethics Committee of the Faculty of Humanities acknowledges that your ethics application was reviewed and approved by Faculty of Health Science Ethics Committee on **25 January 2017.** We therefore give fully ethical clearance. Data collection may commence

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

We wish you success with the project.

Sincerely

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

CC: Prof B Vinck (HoD)
Prof A Stoltz, (Supervisor)
Ms B Heinze (Supervisor)
Ms F Mahomed (Supervisor)

Appendix E – Informed consent letter: Steve Biko Academic Hospital

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Participant information Form

Dear Participant,

Thank you for considering participating in the research project entitled ***Clinical utility of mobile and automated hearing health technology in an infectious disease clinic setting.*** We are conducting a study regarding the hearing status of patients present at the Infectious Disease Clinic at Steve Biko Academic Hosptial. Before you agree to take part in this study you should fully understand what is involved. We ask that you read this form and ask questions should you have any before agreeing to participate in the study.

Volunteers

If you want to participate in this study you can be either male or female and should be between the age of 18 and 55 years with positive HIV blood tests.

Procedures

Participation in the study will involve a single assessment period lasting 10-15 minutes. **Testing will occur on the day of your appointment at the Infectious Disease Clinic at Steve Biko Academic Hospital.** If you agree to participate in this study, the assessment will include the following tests

1. Otoscopy

For this test, you are required to be seated while I will inspect your ear canal and eardrum, using an ear-light.

2. Middle ear test

For this test, you are required to be seated while I measure you eardrum movement and middle ear presure by inserting a soft probe into your ear canal.

3. hearTest screening test

For this test you will have earphones on your ears. You are requested to respond to a soft tone presented in both ears pushing a button on the screen. The soft tone will be presented via the smartphone application.

4. HearZA screening test

For this test, you will also have on earphones. You are required to repeat three consecutive numbers by pressing the numbers on the smartphone screen. The numbers will be presented by the smartphone application in the presence of noise.

5. Hearing test

For this test you will wear earphones on your ears. You are required to respond to a soft tone by pushing a button. This will test your hearing sensitivity.

Rights as a Volunteer

Your participation in this research is entirely voluntary. You have the right of withdrawing from the study at any time. Withdrawing from the study will not affect your medical treatment plan at the clinic and you can continue as normal.

Confidentiality

All personal or sensitive information will be kept confidential. You will be allocated an alpha-numeric code, e.g. A001. The code will be used during data analysis in order to ensure the anonymity of your participation. The code will only be known to the researcher and supervisors. In the event of publication of this research project, no personally identifying or sensitive information will be disclosed.

Risks and Benefits

There are minimal risks involved during this study and you will not be negatively influenced in any way. You will benefit from this study by obtaining a free hearing screening and a diagnostic hearing evaluation. If necessary, you will be referred for further medical or audiological intervention.

Data storage

Data will be stored at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for 15 years for research and archiving purposes.

Should you require any additional information, or clarification on the information stated above, please feel free to contact Marize Brittz at 0825990525.

Should you wish to make use of these services and participate in this research project, kindly complete the informed consent form.

Thank you for exhibiting interest in this research project.
Thank you for your participation and assistance in this research project.

Researchers

Marize Brittz

Research supervisors:
Dr. Barbara Heinze, Dr Faheema Mohamed-Asmail, Prof Anton Stoltz

Consent to participate in this study

Participant information number	

Informed consent

The research has been explained to me. I, _____(name and surname) voluntarily consent to participate in the study titled ***Clinical utility of mobile and automated hearing health technology in an infectious disease clinic setting***. I know that I may refuse to participate or stop my participation in the research at any time.

_____	_____
Participant	Date
_____	_____
Investigator	Date
_____	_____
Witness	Date

Appendix F – Informed consent letter: Tshwane District Hospital

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Participant information Form

Dear Participant,

Thank you for considering participating in the research project entitled ***Clinical utility of mobile and automated hearing health technology in an infectious disease clinic setting.*** We are conducting a study regarding the hearing status of patients present at the ARV Clinic at Tshwane District Hospital. Before you agree to take part in this study you should fully understand what is involved. We ask that you read this form and ask questions should you have any before agreeing to participate in the study.

Volunteers

If you want to participate in this study you can be either male or female and should be between the age of 18 and 55 years with positive HIV blood tests.

Procedures

Participation in the study will involve a single assessment period lasting 10-15 minutes. **Testing will occur on the day of your appointment at the ARV Clinic at Tshwane District Hospital.** If you agree to participate in this study, the assessment will include the following tests

1. Otoscopy

For this test, you are required to be seated while I will inspect your ear canal and eardrum, using an ear-light.

2. Middle ear test

For this test, you are required to be seated while I measure you eardrum movement and middle ear presure by inserting a soft probe into your ear canal.

3. hearTest screening test

For this test you will have earphones on your ears. You are requested to respond to a soft tone presented in both ears pushing a button on the screen. The soft tone will be presented via the smartphone application.

4. HearZA screening test

For this test, you will also have on earphones. You are required to repeat three consecutive numbers by pressing the numbers on the smartphone screen. The numbers will be presented by the smartphone application in the presence of noise.

5. Hearing test

For this test you will wear earphones on your ears. You are required to respond to a soft tone by pushing a button. This will test your hearing sensitivity.

Rights as a Volunteer

Your participation in this research is entirely voluntary. You have the right of withdrawing from the study at any time. Withdrawing from the study will not affect your medical treatment plan at the clinic and you can continue as normal.

Confidentiality

All personal or sensitive information will be kept confidential. You will be allocated an alpha-numeric code, e.g. A001. The code will be used during data analysis in order to ensure the anonymity of your participation. The code will only be known to the researcher and supervisors. In the event of publication of this research project, no personally identifying or sensitive information will be disclosed.

Risks and Benefits

There are minimal risks involved during this study and you will not be negatively influenced in any way. You will benefit from this study by obtaining a free hearing screening and a diagnostic hearing evaluation. If necessary, you will be referred for further medical or audiological intervention.

Data storage

Data will be stored at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for 15 years for research and archiving purposes.

Should you require any additional information, or clarification on the information stated above, please feel free to contact Marize Brittz at 0825990525.

Should you wish to make use of these services and participate in this research project, kindly complete the informed consent form.

Thank you for exhibiting interest in this research project.
Thank you for your participation and assistance in this research project.

Researchers

Marize Brittz

Research supervisors:

Dr. Barbara Heinze, Dr Faheema Mohamed-Asmail, Prof Anton Stoltz

Consent to participate in this study

Participant information number	

Informed consent

The research has been explained to me. I, _____(name and surname) voluntarily consent to participate in the study titled ***Clinical utility of mobile and automated hearing health technology in an infectious disease clinic setting***. I know that I may refuse to participate or stop my participation in the research at any time.

_____	_____
Participant	Date
_____	_____
Investigator	Date
_____	_____
Witness	Date

Appendix G – Referral letter: Steve Biko Academic Hosptial

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Research Participant Referral Letter

Date: d d / m m / y y y y

To: _____

D.O.B: d d / m m / y y y y

_____ participated in a research study called **Clinical utility of mobile and automated hearing health technology in an infectious disease clinic setting,** on the d d / m m / y y y y at the Infectious Disease Clinic at Steve Biko Academic Hospital. The test battery included:

- Otoscopy
- Tympanometry
- hearTest
- HearZA
- Diagnostic pure tone assessment

The following conclusion was drawn from the results obtained:

_____

Our recommendations include:

- A full diagnostic audiological assessment at the Speech Therapy and Audiology department.
- 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 our study. Should you require further information kindly contact the researcher (Marize Brittz) at 0825990525.

Barbara Heinze (PhD)

Faheema Mahomed-Asmail(PhD)

Marize Brittz

Communication Pathology Building
Dept of Speech-Language Pathology and Audiology
Corner of Lynnwood Road and Roper Street, Hatfield
Private Bag X20, Hatfield, 0028
University of Pretoria
PRETORIA
Republic of South Africa

Tel: 012 420 5358
Fax: 012 420 3517
www.up.ac.za

barbara.heinze@up.ac.za

Appendix H – Referral letter: Tshwane District Hospital

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Research Participant Referral Letter

Date: d d / m m / y y y y

To: _____

D.O.B: d d / m m / y y y y

_____ participated in a research study called **Clinical utility of mobile and automated hearing health technology in an infectious disease clinic setting,** on the d d / m m / y y y y at the ARV Clinic at Tshwane District Hospital. The test battery included:

- Otoscopy
- Tympanometry
- hearTest
- HearZA
- Diagnostic pure tone assessment

The following conclusion was drawn from the results obtained:

_____

Our recommendations include:

- A full diagnostic audiological assessment at the Speech Therapy and Audiology department.
- 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 our study. Should you require further information kindly contact the researcher (Marize Brittz) at 0825990525.

Barbara Heinze (PhD)

Faheema Mahomed-Asmail(PhD)

Marize Brittz

Communication Pathology Building
Dept of Speech-Language Pathology and Audiology
Corner of Lynnwood Road and Roper Street, Hatfield
Private Bag X20, Hatfield, 0028
University of Pretoria
PRETORIA
Republic of South Africa

Tel: 012 420 5358
Fax: 012 420 3517
www.up.ac.za

barbara.heinze@up.ac.za

Appendix I – Data collection sheet

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities
Department of Communication Pathology

Participant worksheet

Date of visit: ____/__/__

Participant Information Number:	**File number:**
Age:	**DOB:**
Gender:	**HIV status:**
Medications:	

Otoscopic Examination:

Right ear	Normal	>75% wax in canal	Perforation	Discharge	Other
Left ear	Normal	>75% wax in canal	Perforation	Discharge	Other

Tympanograms:

	Type	**Volume**	**Pressure**	**Compliance**
Right ear				
Left ear				

Automated threshold audiometry

	2 kHz	**4 kHz**	**8 kHz**
Right			
Left			
Overall results			

DIN test (HearZA)

SNR:

Diagnostic Audiometry

	2 kHz	**4 kHz**	**8 kHz**
Right			
Left			
Diagnostic interpretations			

Overall results:

University of Pretoria
PRETORIA 0002
Republic of South Africa

Tel: 012 420 2355
Fax: 012 420 3517

bart.vinck@up.ac.za
www.up.ac.za

Appendix J – Pass letter: Steve Biko Academic Hospital

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

Research Participant Pass Letter

Date: d d / m m / y y y y

To: _____ D.O.B: d d / m m / y y y y

Thank you for participating in the research study, **Clinical utility of mobile and automated hearing health technology in an infectious disease clinic setting,** on the d d / m m / y y y y at the Infectious Disease Clinic at Steve Biko Academic Hospital. Your test battery included:

- Otoscopy
- Tympanometry
- hearTest
- HearZA
- Diagnostic pure tone assessment

According to the test results, your hearing is normal. It is recommended that you have your hearing evaluated annually. Should you require further information kindly contact the researcher (Marize Brittz) at 0825990525.

Barbara Heinze (PhD)

Faheema Mahomed-Asmail (PhD)

Marize Brittz

Communication Pathology Building
Dept of Speech-Language Pathology and Audiology
Corner of Lynnwood Road and Roper Street, Hatfield
Private Bag X20, Hatfield, 0028
University of Pretoria
PRETORIA
Republic of South Africa

Tel: 012 420 5358
Fax: 012 420 3517

barbara.heinze@up.ac.za
www.up.ac.za

Appendix K – Pass letter: Tshwane District Hospital

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

Research Participant Pass Letter

Date: d d / m m / y y y y

To: _____ D.O.B: d d / m m / y y y y

Thank you for participating in the research study, **Clinical utility of mobile and automated hearing health technology in an infectious disease clinic setting,** on the d d / m m / y y y y at the ARV Clinic at Tshwane District Hospital. Your test battery included:

- Otoscopy
- Tympanometry
- hearTest
- HearZA
- Diagnostic pure tone assessment

According to the test results, your hearing is normal. It is recommended that you have your hearing evaluated annually. Should you require further information kindly contact the researcher (Marize Brittz) at 0825990525.

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University of Pretoria
PRETORIA
Republic of South Africa

Tel: 012 420 5358
Fax: 012 420 3517

barbara.heinze@up.ac.za
www.up.ac.za

Appendix L – Proof of submission of manuscript

11-Oct-2017

Dear Ms. Brittz:

Your manuscript entitled "Monitoring hearing in an infectious disease clinic with mHealth technologies" has been successfully submitted online and is presently being given full consideration for publication in the Journal of the American Academy of Audiology.

Your manuscript ID is 17-120.

Please mention the above manuscript ID in all future correspondence or when calling the office for questions. If there are any changes in your street address or e-mail address, please log in to ScholarOne Manuscripts at https://mc.manuscriptcentral.com/jaaa and edit your user information as appropriate.

You can also view the status of your manuscript at any time by checking your Author Center after logging in to https://mc.manuscriptcentral.com/jaaa.

Thank you for submitting your manuscript to the Journal of the American Academy of Audiology.

Sincerely,

Journal of the American Academy of Audiology Editorial Office