

AUTOMATED SMARTPHONE THRESHOLD AUDIOMETRY: VALIDITY AND TIME- EFFICIENCY

By

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

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LIST OF ABBREVIATIONS

dB: Decibel

HL: Hearing Level

Hz: Hertz

SD: Standard Deviation

MPANL: Maximum Permissible Ambient Noise Levels

OS: Operating System

iOS: Apple Operating System

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ABSTRACT

Automated smartphone-based threshold audiometry has the potential to provide affordable audiometric services in underserved contexts where adequate resources and infrastructure are lacking. This study investigated the validity of the threshold version (hearTest) of the hearScreen™ smartphone-based application using inexpensive smartphones (Android OS) and calibrated supra-aural headphones.

A repeated-measures, within-subject, study design was employed, comparing automated smartphone audiometry air conduction thresholds (0.5 to 8 kHz) to conventional audiometry thresholds. A total of 95 participants, with varying degrees of hearing sensitivity, were included in the study. 30 participants were adults, with known bilateral hearing losses of varying degrees (mean age of 59 years, 21.8 SD; 56.7% female). 65 participants were adolescents (mean age of 16.5 years, 1.2 SD; 70.8% female), of which 61 had normal hearing and 4 had mild hearing losses.

Within the adult sample, 70.6% of thresholds obtained through smartphone and conventional audiometry corresponded within 5 dB. There was no significant difference between smartphone (6.75 min average, 1.5 SD) and conventional audiometry test duration (6.65 min average, 2.5 SD). Within the adolescent sample, 84.7% of audiometry thresholds obtained at 0.5, 2 and 4 kHz corresponded within 5 dB. At 1 kHz 79.3% of the thresholds differed by 10 dB or less. There was a significant difference ($p < .01$) between smartphone (7.09 min, 1.2 SD) and conventional audiometry test duration (3.23 min, 0.6 SD).

The hearTest application using calibrated supra-aural headphones provided valid air conduction hearing thresholds. Therefore, it is evident that using inexpensive smartphones with calibrated headphones provides a cost-effective way to provide access to threshold air conduction audiometry.

Keywords: Automated audiometry, diagnostic audiometry, threshold audiometry, air conduction, validation, cost-effective, mHealth, smartphone.

1. INTRODUCTION

It is estimated that 5.3% of the world population suffer from disabling hearing loss (WHO, 2013), which is a global cause for concern within the healthcare sector (WHO, 2008). The majority of individuals suffering from hearing loss reside in low and middle income countries (WHO, 2014). Many of these hearing losses remain untreated (WHO, 2014) due to the shortage of hearing healthcare professionals worldwide (Goulios & Patuzzi, 2008; Windmill & Freeman, 2013). Untreated hearing loss leads to communication difficulties and social isolation (WHO, 2014). As a result, many hearing loss sufferers are at an economic and vocational disadvantage (WHO, 2014). Therefore, hearing loss is considered to be one of the largest contributors to the global burden of disease (WHO, 2008). A survey, conducted by Fagan and Jacobs (2009), concluded that there is less than one hearing healthcare professional for every one million people in developing countries. The shortage of professionals combined with a lack of infrastructure and resources, as well as too few training facilities, impedes the provision of adequate hearing healthcare services (Clark & Swanepoel, 2014; Fagan & Jacobs, 2009; Swanepoel, Olusanya & Mars, 2010a).

Fortunately, with reducing mortality rates and an increase in life expectancy worldwide, global healthcare systems are focusing more intently on reducing disabilities such as hearing loss (WHO, 2008). Currently, the World Health Organization is providing assistance to low and middle income countries to develop hearing healthcare programmes that can be incorporated into primary healthcare systems (WHO, 2014).

Evidence suggests that individuals who suffer from hearing loss can benefit from early identification, intervention and appropriate management (Clark & Swanepoel, 2014; WHO, 2014). Therefore, there is an increasing need to implement cost effective assessment and intervention techniques (Fagan & Jacobs, 2009). In order to reduce the mismatch between demand and availability of hearing healthcare services, several solutions have been suggested. Some of these solutions include automated audiometry, portable audiometers (Swanepoel et al., 2010a) and teleaudiology (Khoza-Shangase & Kassner, 2013). Automated audiology encompasses the use of automated audiological

test procedures to assess hearing sensitivity (Margolis & Morgan, 2008). The Otogram, a computer assisted audiometer, is an example of automated audiometry (Ho, Hildreth & Lindsey, 2009). With the Otogram, patients are able to self-administer audiometric assessments with results that are comparable to conventional audiometry (Ho et al., 2009). Similarly, the Automated Method for Testing Auditory Sensitivity (AMTAS) allows for automated testing without the need for testing to be conducted by trained hearing healthcare professionals and yields results that are comparable to conventional audiometry (Margolis, Glasberg, Creeke, & Moore, 2010). Automated audiometry such as the Otogram and AMTAS have the potential to increase hearing healthcare service delivery because they do not require trained professionals to conduct the assessment procedures (Margolis et al., 2010; Ho et al., 2009). As such, paraprofessionals can be trained to facilitate audiological assessments, because automation greatly reduces the complexity of these services (Clark & Swanepoel, 2014; Swanepoel, Clark, Koekemoer, Hall, Krumm, Ferrari, McPhearson, Olusanya, Mars, Russo & Barajas, 2010b). As a result, hearing healthcare professionals are able to focus their attention on management, counselling and intervention (Swanepoel et al., 2010b).

The KUDUwave audiometer is an example of a computer based audiometer that can be used for manual or automated diagnostic hearing assessments (Swanepoel et al., 2010a; Swanepoel & Biagio, 2011) and allows hearing assessments outside of conventional audiometric booths in certain environments (Maclennan-Smith, Swanepoel & Hall, 2013; Swanepoel, Maclennan-Smith & Hall, 2013). The KUDUwave is also portable, which allows for the provision of hearing healthcare services in areas where the lack of sound proof booths limits the services provided (Swanepoel et al., 2010a; Swanepoel et al., 2010b). Although devices such as the Otogram, AMTAS and KUDUwave eliminate the need for soundproof booths and hearing healthcare professional supervision during assessments, cost-effectiveness remains an issue in combatting the shortage of financial resources.

Telehealth, and mobile health (mHealth) in particular, are promising to provide resource-efficient methods of hearing assessment due to availability and low costs of mobile

devices throughout developed and developing countries (Clark & Swanepoel, 2014; Kelly & Minges, 2012; Margolis & Morgan, 2008; Swanepoel et al., 2010a; Swanepoel, Myburgh, Howe, Mahomed & Eikelboom, 2014). mHealth denotes the use of mobile communication technologies to assist healthcare professionals in delivering appropriate services (WHO, 2011). Innovative technology in the form of smartphones, as well as an increase in global connectivity, allows hearing healthcare professionals to provide services without the need for costly audiometric equipment (Clark & Swanepoel, 2014). mHealth is a particularly attractive avenue, as smartphone devices have the ability to provide assessment and management by combining automation and portability as well as cloud based data storage and real-time noise monitoring (Mahomed-Asmail, Swanepoel, Eikelboom, Myburgh & Hall, 2016b).

Over the past few years, several mHealth applications, have been developed (Foulad, Bui & Djalilian, 2013; Swanepoel et al., 2014; Abu-Ghanem, Handzel, Ness, Ben-Artzi-Blima, Fait-Ghelbendorf, Himmelfarb, 2015; Thompson, Sladen, Hughes Borst & Still, 2015; Yeung, Heley, Beauregard, Champagne & Bromwich, 2015) in an effort to create low-cost solutions for providing hearing healthcare services such as screening, assessments and intervention (Mosa, Yoo & Sheets, 2012; Swanepoel et al., 2014). Apple iOS has been utilized, on a number of occasions, in the development of mHealth applications due to the standardization of hardware and software components across devices, allowing for universally shared applications across iOS models (Foulad et al., 2013). The uHear, for example, is a smartphone-based application for Apple iOS and is a self-administered air conduction threshold test (Peer & Fagan, 2015). Studies conducted on this application have yielded mixed outcomes. In some studies, the uHear™ was said to accurately identify disabling hearing loss, detect early high frequency threshold changes (Peer & Fagan, 2015), rule out moderate hearing losses and determine the degree of hearing loss (Szudek, Ostevik, Dziegielewski, Robinson-Anagor, Gomaa, Hodgetts & Ho, 2012; Abu-Ghanem et al., 2015). However, in other studies, the uHear™ was found to produce elevated thresholds when compared to manual audiometry (Szudek et al., 2012; Khoza-Shangase & Kassner, 2013). Similar to the uHear™, the EarTrumpet is also a self-administered, smartphone-based, Apple iOS air

conduction threshold test that yields results comparable to conventional audiometry (Foulad et al., 2013). A study conducted by Derin, Cam, Beydilli, Acar, Elicora and Sahan (2016) concluded that the EarTrumpet can be used to accurately assess the hearing sensitivity of individuals with sudden hearing loss who have been referred to emergency services. Furthermore, the Shoebox audiometer is another iOS device made up of an Apple iPad coupled with audiometric headphones, and much like the uHear and EarTrumpet, yields results that are comparable to conventional audiometry (Yeung, Javidnia, Heley, Beauregard, Champagne & Bromwich, 2013; Thompson et al., 2015). Although these applications make audiological services more readily available, Apple iOS devices are considered premium mobile devices, with an average cost of \$813 in comparison to Android devices, with an average cost of \$216 (Jana, 2015). As such, Apple iOS devices are associated with significant cost and therefore have poor penetration in emerging economies such as Africa (Sanchez, 2013).

hearScreen™, is the first Android OS hearing test application that uses calibrated headphones and can be operated on an entry level smartphone (Swanepoel et al., 2014; Mahomed-Asmail et al., 2016b). hearScreen™ is a low-cost solution that is able to accurately screen hearing on a “pass/fail” criteria (Mahomed-Asmail et al., 2016b). The application integrates several additional features during testing, to ensure accurate test results. Real-time noise monitoring, running during the testing procedure, ensures that maximum permissible ambient noise levels (MPANL) are not exceeded (Mahomed-Asmail et al., 2016b). This feature allows frequencies in which the noise levels were in excess to be retested (Swanepoel et al., 2014). A study, conducted by Mahomed-Asmail et al. (2016b), utilized real-time noise monitoring on the hearScreen™ to determine if noise levels could have influenced responses. Findings of the study indicated that, of the 5 children who failed the screening due to noise, 3 of these children did in fact have a hearing loss (Mahomed-Asmail et al., 2016b). Furthermore, a study conducted by Yousuf Hussein, Swanepoel, Biagio de Jager, Myburgh, Eikelboom & Hugo (2015) found that, in children, exceeded MPANLs had a significant impact on passing or failing the hearing screening. However, in adults, exceeded MPANLs did not impact the outcome of the hearing screening (Yousuf Hussein et al., 2015). In addition to real-time noise monitoring,

cloud-based data storage allows the test administrator to upload the test results on to a cloud-based server for remote monitoring and management, (Mahomed-Asmail et al., 2016b) eliminating the need for an onsite hearing healthcare professional (Clark & Swanepoel, 2014). These additional hearScreen™ features can allow the hearing healthcare professional to implement quality control into hearing assessments as well as simplify data management services (Swanepoel et al., 2014; Mahomed-Asmail et al., 2016b).

Extending the capabilities of the hearScreen™ from a “pass/fail” criteria into a full threshold determination application could increase the reach of hearing healthcare services in developing regions. In these areas, where audiological equipment is not readily available, hearTest could be used as a baseline and monitoring tool to provide hearing healthcare professionals with much needed diagnostic information, in terms of air conduction threshold audiometry. The current study therefore aimed to investigate the validity of a threshold version of the hearScreen™ smartphone-based application (hearTest) using inexpensive smartphones (Android OS) and calibrated supra-aural headphones.

The research question was therefore: *Can a threshold version of the hearScreen App provide valid hearing thresholds using low-cost Android smartphones?*

2. METHODOLOGY

2.1 Research Aims

Main aim

To validate a threshold version of the hearScreen™ smartphone-based application (hearTest) using inexpensive smartphones (Android OS) and calibrated supra-aural headphones.

2.2 Research Design

This study employed a repeated-measures, within-subject, study design (Leedy & Ormrod, 2014) to compare smartphone audiometry to conventional audiometry. Each study participant underwent audiometric threshold determination by means of smartphone audiometry as well as conventional audiometry. In an effort to reduce any possible order effects on the test outcomes, counterbalancing was employed. As such, participants were subjected to the threshold determination methods in a randomized order. Furthermore, blinding procedures were employed. Audiologists conducting the second threshold determination method were blind to results of the first test.

2.3 Ethical Considerations

Ethical clearance to conduct the study was granted by the University of Pretoria's Faculty of Humanities Ethics Committee prior to data collection (Appendix A)

Ethical considerations in research where human participants are concerned can be categorised into three important groups, namely: protection from harm, voluntary and informed participation and the right to privacy (Leedy & Ormrod, 2014). These three aspects were kept in mind by the researcher, throughout the data collection procedure, to ensure that no participants experienced physical or psychological distress (Leedy & Ormrod, 2014).

2.3.1 Protection from Harm

Researchers should endeavour not to cause unnecessary psychological or physical harm to participants (Mouton & Babbie, 2007; Leedy & Ormrod, 2014). Therefore, the risk of participation in any given study should not surpass the risks of daily living (Leedy & Ormrod, 2014). In an effort to achieve this goal, the researcher treated all participants in a courteous and respectful manner. All participants were provided with the opportunity to learn more about the goals of the study without being misled. Furthermore, before the commencement of the study, each participant was reminded that if at any point he/she should feel physical or emotional discomfort he/she had the option to withdraw from the study immediately without any negative consequences.

2.3.2 Voluntary and Informed Participation

When individuals are specifically recruited to contribute in a research study, they should be informed about the nature of the study and be given a choice to participate or not to participate in the study (Mouton & Babbie, 2007; Leedy & Ormrod, 2014). Furthermore, they should also be given the right to withdraw from the study at any time (Leedy & Ormrod, 2014). In an effort to achieve this goal in the current study, participants were required to complete an informed consent form before testing commenced (Appendix C). In the case of adolescent participants (< 18 years old), the informed consent was obtained from the participant's parents/guardian's prior to recruitment as a participant (Appendix D). Moreover, each adolescent with parental informed consent was asked to complete an assent form before their data was utilised (Appendix E).

2.3.3 Right to Privacy

Research involving human participants must respect each participant's right to privacy (Leedy & Ormrod, 2014). As such, the researcher must be able to guarantee the participant's anonymity and endeavour to keep all findings confidential (Mouton & Babbie, 2007). Therefore, the research report should not be presented in a way that will allow others to become aware of a participant's identity or their responses and behaviours during the study (Leedy & Ormrod, 2014). In an effort to achieve this goal in the current study, each participant was given a unique coded number which replaced the participant's

name. Moreover, no identifying information such as addresses, or telephone numbers were requested during the study.

2.4 Data Collection Structure

2.4.1 Participants

95 individuals were recruited as participants for the study. 30 adult participants were identified from the University of Pretoria's Department of Speech Therapy and Audiology's hearing assessment and hearing aid fitting clinics as well as from a private audiology practice in the West Rand of Johannesburg. These participants all had known bilateral sensorineural hearing losses of varying degrees. Participant ages ranged between 24 and 92 years. The mean age was 59 years (21.8 years SD) of which 56.7% were female.

Furthermore, 65 adolescents were identified from the University of Pretoria's prospective students' programme. Within the adolescent sample, 61 of the participants had normal hearing sensitivity with a pure tone average ≤ 20 dB HL. The remaining 4 participants had mild hearing losses, ranging between 21 and 40 dB HL. Participant ages ranged between 16 and 21 years. The mean age was 16.5 (1.2 years SD) of which 70.8% were female.

2.4.2 Research Equipment

The table below provides a summary of the equipment used in the current study:

Table 1. Summary of Equipment

Equipment	Description
Heine mini 3000 otoscope with reusable specula	An otoscope was used to visually inspect the ear canal and eardrum.
GSI Tymstar - Comprehensive Middle Ear Tympanometer	This device determines middle ear functioning. Tympanometry was measured to determine ear canal volume, middle ear pressure and compliance. Reflexes

	<p>were measured to determine the integrity of the auditory nerve pathway.</p>
<p>GSI 61 - Two Channel Clinical Audiometer coupled with TDH 39 audiometric headphones and GN Otometrics Otosuite loaded onto a Lenovo z50 Notebook coupled with 10-Ohm Otometrics insert earphones</p>	<p>Both audiometers were calibrated according to ISO 389-1 (2013) and 389-2 (2014) standards and used in conjunction with an ISO 825-1 (2010) compliant soundproof booth.</p> <p>Participants from both study samples underwent conventional pure tone air conduction audiometry on one of these two audiometers. Thresholds were determined at 0.5kHz, 1kHz, 2kHz, 4kHz and 8kHz.</p>
<p>Samsung SM-G313H Trend Neo smartphone run by Android OS version 4.4 coupled with Sennheiser HD 202 II supra-aural headphones</p>	<p>The hearTest application was loaded onto the Samsung SM-G313H Trend Neo smartphone coupled with Sennheiser HD 202 II headphones, calibrated according to ISO 389-1 (2013) and 389-9 (2014) standards used in conjunction with an ISO 825-1 (2010) compliant soundproof booth.</p> <p>Participants from both study samples underwent automated smartphone pure tone air conduction audiometry. Thresholds were determined at 0.5kHz, 1kHz, 2kHz and 4kHz through an automated pre-specified protocol.</p>

2.4.3 Research Procedures

Informed Consent

Permission was obtained from the clinic coordinators at the Department of Speech Therapy and Audiology, as well as from the private practice staff to use their patients as participants in the adult sample of the study (Appendix B). At the department of Speech Therapy and Audiology, coordinators involved in the clinics were trained in using the

hearTest application. For the purpose of student training, students carried out the conventional test procedures. However, they were under the constant supervision of the coordinators and the researcher (author J.v.T.). At the beginning of each student rotation, students were trained in using the hearTest before the participant arrived. At the private practice the researcher (author J.v.T.) and the practice's audiologist carried out the test procedures.

Furthermore, permission was obtained from all the parents of all the students in the University's prospective students' programme to use their children as participants in the adolescent sample of the study (Appendix D)

In all instances, participants were given an informed consent letter (Appendix C for adults and E for adolescents) to sign if they were willing to participate in the study. The nature of the study was explained to each participant. Only once the participant understood the process of the testing protocol and had signed the informed consent form willingly, did data collection commence.

Conventional Audiometry Test Battery

Once informed consent was given, the student and/or audiologist started with the full diagnostic test battery. Otoscopy and diagnostic immittance measures were conducted first to determine the functioning of the middle ear and the integrity of the auditory nerve. Thereafter, diagnostic air conduction testing, using the the ISO shortened ascending method (ISO 8253-1, 2010), was completed to determine the participants hearing sensitivity. Air conduction pure tone testing was performed at frequencies of 0.5kHz, 1kHz, 2kHz, 4kHz and 8kHz bilaterally. In instances where a hearing loss was identified the student and/or audiologist went on to conduct bone conduction and appropriate masking to ensure appropriate intervention. However, for the purpose of the study, only the air conduction thresholds were utilised. It should be noted that some participants received conventional audiometry first, whereas others received smartphone audiometry first.

Smartphone Threshold Determination

hearTest was conducted at the frequencies of 0.5, 1, 2, 4 and 8 kHz bilaterally. The test procedure started at 40dB HL and followed the ISO 8253-1 (2010) shortened ascending method, based on responses provided by the participant. Responses were recorded as positive responses when the patient pushed the button on the screen of the smartphone. Negative responses were recorded when the participant did not press the button. It should be noted that some participants received conventional audiometry first, whereas others received smartphone audiometry first.

2.5 Data Processing Procedure

Data processing can be defined as the integration of the collected data and presenting it in a logical manner (Mouton & Babbie, 2007). For the purpose of this study, the raw data was first converted into a numerical format (Mouton & Babbie, 2007). Thereafter, the raw data was stored on a Microsoft Excel sheet and imported for analysis by the statistics programme 'Statistical Package for the Social Sciences' (SPSS v22., Chicago, Illinois).

2.6 Data Analysis Procedure

Statistical analyses, on the collected data, were performed using SPSS (SPSS v22., Chicago, Illinois) and Microsoft Excel (Microsoft Inc, Redmond, Washington) to determine if smartphone threshold determination was as accurate and time efficient as conventional audiometry.

The data were not normally distributed (Shapiro-Wilk Test of Normality) necessitating non-parametric analyses (Wilcoxon Signed Ranks Test) to determine if there were significant differences between conventional audiometry and smartphone testing ($p < .01$). As such, descriptive statistics were employed to synthesise the quantitative data that was collected (Irwin, Pannbacker, & Lass, 2008). Measures of central tendency (mean, median) and variability (standard deviation, range) were used to describe statistically significant differences between conventional and smartphone audiometry as well as test duration. Data was represented by means of tables and figures to ensure all results were clearly defined and did not misrepresent the findings of the study (Leedy & Ormrod, 2014).

2.7 Reliability and Validity

Reliability can be defined as the consistency and the accuracy that a measuring instrument yields (Leedy & Ormrod, 2014). For the purpose of this study, equivalent forms of reliability were employed. This can be defined as the extent to which two different versions of the same instrument (e.g. smartphone threshold determination and conventional threshold determination) yield similar results (Leedy & Ormrod, 2014).

Validity can be defined as the extent to which the instrument measures what it is intended to measure (Leedy & Ormrod, 2014). For the purpose of this study, criterion validity was employed. This can be defined as the extent to which the results of an assessment instrument correlate with another, related measure (e.g. the results of the automated threshold determination in comparison to the results of the conventional audiometry) (Leedy & Ormrod, 2014).

As such, the reliability and validity of this research project were ensured by the following measures:

- All equipment was calibrated in accordance with ISO & SANS prescribed standards.
- All students and/or audiologists were trained adequately, prior to conducting test procedures on participants, and were always under the supervision of a departmental staff member and the researcher.
- Blinding procedures were employed to eliminate the possibility of the testers influencing the results
- Counterbalancing procedures were employed to eliminate the possibility of test order affecting the results

3. AUTOMATED SMARTPHONE THRESHOLD AUDIOMETRY: VALIDITY AND TIME-EFFICIENCY

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3.1 ABSTRACT

Background: Smartphone-based threshold audiometry with automated testing has the potential to provide affordable access to audiometry in underserved contexts.

Purpose: To validate the threshold version (hearTest) of the validated hearScreen™ smartphone-based application using inexpensive smartphones (Android OS) and calibrated supra-aural headphones.

Research Design: A repeated-measures within-subject study design was employed to compare air conduction thresholds (0.5 to 8 kHz) obtained through automated smartphone audiometry to thresholds obtained through conventional audiometry.

Study Sample: 95 participants were included in the study. 30 adults, who had known bilateral hearing losses of varying degrees (mean age of 59 years, 21.8 SD; 56.7% female). 65 adolescents (mean age of 16.5 years, 1.2 SD; 70.8% female), of which 61 had normal hearing and the remaining 4 had mild hearing losses.

Data Analysis: Threshold comparisons were made between the two test procedures. The Wilcoxon signed ranked test was utilised for comparison of threshold correspondence between manual and smartphone thresholds and the paired samples t-test was used to compare test time.

Results: Within the adult sample, 94.4% of thresholds obtained through smartphone and conventional audiometry corresponded within 10 dB or less. There was no significant difference between smartphone (6.75 min Average, 1.5 SD) and conventional audiometry test duration (6.65 min Average, 2.5 SD). Within the adolescent sample, 84.7% of thresholds obtained at 0.5, 2 and 4 kHz with hearTest and conventional audiometry corresponded within 5 dB or less. At 1 kHz 79.3% of the thresholds differed by 10 dB or less. There was a significant difference ($p < .01$) between smartphone (7.09 min, 1.2 SD) and conventional audiometry test duration (3.23 min, 0.6 SD).

Conclusions: The hearTest application with calibrated supra-aural headphones provides a cost effective option to determine valid air conduction hearing thresholds.

3.2 INTRODUCTION

The World Health Organisation reports that, globally, 360 million individuals suffer from a disabling hearing loss (WHO, 2013). The vast majority of these individuals have an unidentified hearing loss and reside in low income and middle income countries (WHO, 2014). Availability of hearing healthcare professionals in developing countries is limited (Goulios and Patuzzi, 2008; Windmill and Freeman, 2013) and is unable to meet the demand (Fagan & Jacobs, 2009). It is estimated that there is less than one audiologist for every one million people in developing countries (Fagan and Jacobs, 2009). Additionally, the high cost of audiometric equipment and sound proof booths, in combination with a lack of infrastructure and resources impedes the provision of adequate hearing healthcare services (Fagan and Jacobs, 2009; Swanepoel et al., 2010a; Clark & Swanepoel, 2014; Peer and Fagan, 2015).

The increase in innovative technology and global connectivity has resulted in tele-audiology being widely proposed as an affordable and resource-efficient option to combat the lack of skilled hearing healthcare professionals and hearing healthcare services in some areas (Margolis and Morgan, 2008; Swanepoel et al., 2010a; Swanepoel, Mngemane, Molemong, Mkwanazi & Tutshini, 2010c; Swanepoel et al, 2014; Foulad et al., 2013). Tele-audiology may be able to bridge the gap between service providers and

patients created by geographic and economic barriers (Swanepoel et al., 2010a; Foulad et al., 2013).

The growth in the demand for tele-audiology has led to increased development of audiological software and applications (Mosa et al., 2012; Clark and Swanepoel, 2014). Additionally, portable audiometers (Ho et al., 2009; Swanepoel et al., 2010a; Swanepoel et al., 2010b; Mosa et al., 2012) and smartphone based hearing tests such as uHear™, EarTrumpet and the Shoebox Audiometer (Foulad et al., 2013; Abu-Ghanem et al., 2015; Thompson et al., 2015; Yeung et al., 2015), are allowing provision of hearing healthcare services in areas where the absence of sound booths and audiological equipment restricts access to care (Ho et al., 2009; Swanepoel et al., 2010a; Swanepoel et al., 2010b; Mosa et al., 2012; Abu-Ghanem et al., 2015).

Increasing cellular network coverage across the world allows hearing healthcare professionals to make use of applications such as videoconferencing and cloud-based data storage to assess and manage patients from more places in the world than ever before (Swanepoel et al., 2010b; Swanepoel and Biagio, 2011; Mosa et al., 2012; Clark and Swanepoel, 2014). Automated audiometry can be used to conduct screening and full diagnostic audiometry, with results comparable to manual audiometry (Margolis and Morgan, 2008; Swanepoel and Biagio, 2011; Mahomed et al., 2013). Automated diagnostic audiometry effectively reduces the complexity of audiological protocols, allowing for the use of paraprofessionals to facilitate automated hearing assessments (Swanepoel et al., 2010; Clark and Swanepoel, 2014; Abu-Ghanem et al., 2015). With the option of having paraprofessionals conduct the test battery, hearing healthcare professionals may be able to spend more time on patient management, counselling and intervention (Mosa et al., 2012; Swanepoel et al., 2013). Mobile health (mHealth), as a branch of tele-audiology, is seeing tremendous growth as a means of health promotion and provision because of the widespread penetration of mobile devices throughout developed and developing countries (Kelly and Minges, 2012; Clark and Swanepoel, 2014).

mHealth denotes the use of mobile communication technologies such as cell phones and tablets to assist healthcare professionals to deliver appropriate services (WHO, 2011). Research indicates that mHealth, in the form of commercially available smartphones, is able to create low-cost solutions for providing hearing healthcare services such as screening, assessments and intervention, (Mosa et al., 2012; Swanepoel et al., 2014) even in environments with lack of resources and poor infrastructure. mHealth enables improved communication between healthcare professionals as well as access to assessment tools and patient information (Burdette, Herchline & Oehler, 2008). Additionally, mHealth, in conjunction with emerging technology, allows implementation of quality control during testing by utilizing features such as real time environmental noise monitoring to ensure results that are comparable to conventional audiometry (Mosa et al., 2012; Swanepoel et al., 2014; Mahomed-Asmail et al., 2016b). As such, smartphones could enable healthcare professionals to provide efficient and effective services to their patients (Burdette et al., 2008).

To date, several smartphone applications have been developed to test hearing (Foulad et al., 2013; Swanepoel et al., 2014; Abu-Ghanem et al., 2015; Thompson et al., 2015; Yeung et al., 2015). For example, uHear™ (Unitron, Commack, New York), a smartphone-based application for Apple iOS (Apple Inc., Cupertino, California), which is a self-administered air conduction threshold test (Peer and Fagan, 2015). Several studies have been conducted to compare the uHear™ to conventional audiometry and have yielded mixed outcomes. In a study conducted by Peer and Fagan (2015), uHear™ was able to accurately identify disabling hearing loss as well as detect early high frequency threshold changes. In a study conducted by Szudek et al. (2012), uHear™ was able to accurately rule out a moderate hearing loss as well as determine the degree of hearing loss in individuals with hearing loss. However, in this study, uHear™ was found to overestimate the hearing thresholds of normal hearing individuals (Szudek et al., 2012). As a result, normal hearing individuals often presented with hearing loss (Szudek et al., 2012). Similarly, in a study conducted by Khoza-Shangase and Kassner (2013), uHear™ produced elevated thresholds when compared to thresholds obtained through manual audiometry. In contrast to the uHear™, the EarTrumpet, (Praxis Biosciences, Irvine,

California) which is also a self-administered Apple iOS smartphone application, yields results that are comparable to conventional audiometry (Foulad et al., 2013). The mixed outcomes of Apple iOS application studies could be attributed to limitations such as the lack of calibrated headphones that adhere to calibration standards (e.g. ISO and ANSI). Some applications, such as Shoebox Audiometry, have attempted to solve this problem by coupling audiometric headphones to the Apple iPad (Yeung et al., 2013). The Shoebox Audiometer is a self-administered, automated, air conduction threshold test that is able to determine hearing thresholds between 15-90 dB HL, that are comparable to conventional audiometry (Yeung et al., 2013; Thompson et al., 2015). This solution may be prohibitively costly in developing countries considering that many Apple iOS devices are high-end products with poor penetration in developing world regions (Kochi, 2012) with applications that can only be purchased through the Apple App Store (Kelly and Mingos, 2012).

A low-cost smartphone application, using Android OS (Google Inc., Santa Clara, California) smartphones, has also been reported for hearing testing (Swanepoel et al., 2014). The hearScreen™ application has provided the first inexpensive Android smartphone solution coupled with calibrated headphones (Swanepoel et al., 2014). hearScreen™ is able to accurately screen hearing on a “pass/fail” criteria (Mahomed-Asmail et al., 2016b). Extending the hearScreen™ application for automated threshold audiometry could increase the reach of cost effective hearing testing, through smartphones operated by trained laypersons or paraprofessionals in primary healthcare settings. The current study investigated the validity of a threshold version of the validated hearScreen™ smartphone-based application (hearTest), using inexpensive smartphones (Android OS) and calibrated supra-aural headphones.

The purpose of this study was to determine the concurrent validity of the smartphone application when compared to conventional audiometry. Concurrent validity is utilised when a new test method is proposed as a substitute for the gold standard method (Chin & Lee, 2008). This validation technique requires both methods to be evaluated at the same time to determine the correlation between them (Chin & Lee, 2008).

3.3 METHOD

Human subjects approval to conduct this study was granted by the appropriate institutional review board before data collection commenced. Adults and adolescents, with hearing sensitivity, ranging from normal to profound were chosen as participants in order to obtain results for a wide range of hearing sensitivity. Participants for the adult sample were patients recruited from two audiological clinics at a South African University, the hearing assessment and hearing aid fitting clinic and a private audiology practice in the West Rand of Johannesburg, South Africa. Participants for the adolescent sample were recruited from a prospective students' programme at the above mentioned university. All participants provided written informed consent. In instances where the participants were younger than 18 years, written consent was obtained by the parents, as legal guardians of the participants, as well as written assent from each participant prior to data collection.

3.3.1 Subjects

There were 95 participants included in the study: 30 adults and 65 adolescents. For the adult participants, ages ranged between 24 and 92 years. The mean age was 59 years (21.8 years SD), of which 56.7% were female. Adult participants were evaluated by means of a full diagnostic test battery, in the respective clinics, to determine the type, magnitude and configuration of their hearing loss. However, for the purpose of this study, only the results of the air conduction thresholds were used for comparison with the smartphone application. All adult participants presented with sensorineural hearing losses ranging from mild to profound, as classified by ASHA (2011).

For the adolescent participants, ages ranged between 16 and 21 years. The mean age was 16.5 years (1.2 years SD), of which 70.8% were female. The majority (n=61) had normal hearing sensitivity, with a pure tone average (PTA) ≤ 20 dB HL. The remaining four participants had mild hearing losses, with PTA between 21 and 40 dB HL, which were identified using air and bone conduction audiometry. However, for the purpose of this study, only the results of the air conduction thresholds were used for comparison with the smartphone application.

3.3.2 Equipment

Two methods of air conduction threshold estimation were conducted: conventional air conduction audiometry and automated smartphone-based air conduction audiometry, utilizing hearTest.

Conventional audiometry

When conventional audiometry was administered, one of two audiometers was used. Participants obtained from the University were tested with the GSI 61 Two Channel Audiometer (Grason-Stadler Inc., Eden Prairie, Minnesota) coupled with TDH 39 audiometric headphones (Telephonics Corporation, Farmingdale, New York). Participants at the private audiological practice were tested with the GN Otometrics Otosuite (GN Otometrics, Taastrup, Denmark) loaded onto a Lenovo (Lenovo, Morrisville, North Carolina) z50 Notebook couple with 10-Ohm Otometrics insert earphones (GN Otometrics, Taastrup, Denmark). In both instances, participants were tested by either a qualified audiologist (author J.v.T.) or a final year audiology student of the University under the supervision of a qualified audiologist. Testing was conducted in an ISO 6189 (1983) compliant sound proof booth and all apparatus was calibrated to meet the current ISO 389-1 (1998) and 389-2 (1994) standards.

Automated smartphone audiometry

In the case of automated diagnostic audiometry, the hearTest application was loaded onto a Samsung SM-G313H Trend Neo Smartphone (Samsung, Suwon, South Korea) and run by Android OS version 4.4 coupled with Sennheiser HD 202 II supra-aural headphones (Sennheiser, Wedemark, Germany). The hearTest application is a smartphone-based, self-administered, automated hearing assessment. The hearScreen™ calibration function (Swanepoel et al., 2014) was used to calibrate the Sennheiser HD 202 II headphones according to prescribed standards (ISO 389-1, 1998) adhering to equivalent threshold sound pressure levels determined for this headphone according to ISO 389-9 (2009), as described by Van Der Aerschot, Swanepoel, Mahomed-Asmail, Eikelboom & Myburgh (Submitted). Calibration was performed using an IEC 60318-1 G.R.A.S. Ear stimulator (G.R.A.A Sound & Vibration, Holte, Denmark) connected

to a Type 1 SLM (Rion NL-52) (Rion Science & Technology Shanghai LTD, Shanghai, China). Testing was conducted in an ISO 6189 (1983) compliant sound proof booth.

The absolute maximum intensity differed across frequencies according to the output capability of the Sennheiser HD 202 II headphones. From 0.5 to 4kHz the intensity limit was 90 dB HL and at 8 kHz the intensity limit was 80 dB HL. The hearTest output level was restricted to 10 dB HL. Therefore, hearing thresholds below 10 dB HL at 0.5 to 8kHz were not established in order to account for the minimum output level of hearTest.

3.3.3 Procedures

A repeated-measures, within-subject, study design (Leedy and Ormrod, 2014) was employed to compare smartphone audiometry to conventional audiometry. As such, each participant underwent testing for both threshold seeking methods. Counterbalancing methods were employed, in the adult sample, to reduce the likelihood of test order adversely affecting test outcomes. Therefore, test order started with conventional audiometry in 53% of cases for the adult sample. However, participants in the adolescent sample were sourced from a busy hearing screening clinic. Due to strict time constraints, and the numbers of individuals who needed to be screened, counterbalancing could not be enforced. As a result, test order started with conventional audiometry in 34% of the cases. Blinding procedures were employed for both samples. Audiologists conducting the second threshold determination method blind to results of the first test.

Conventional audiometry threshold determination commenced in the best ear as reported by the participant. Test frequencies included 0.5, 1, 2, 4 and 8 kHz. Hearing thresholds were determined using the ISO shortened ascending method (ISO 8253-1, 2010). Threshold determination started at 40 dB HL at 1 kHz, followed by 0.5 kHz and then 2 to 8 kHz. Participants were instructed to press a hand-held response button every time a tone was heard. Thresholds below 10 dB HL were not determined, due to the minimum output level of the hearTest. Test duration was timed using a stopwatch.

The automated self-administered smartphone testing determined thresholds across the frequencies 0.5, 1, 2, 4 and 8 kHz. An automatic test protocol utilising the ISO shortened ascending method (ISO 8253-1, 2010) was implemented. Participants were instructed to touch a response button on the smartphone screen every time a tone was heard (Figure 1). In the event that the participant touched the response button (positive response) the tone was automatically decreased by 10 dB. In the event that the participant did not push the response button (negative response) the tone was automatically increased by 5 dB. A positive response was recorded as a threshold when two out of three responses occurred at the same level with three ascents. A negative response was recorded when the maximum intensity was reached without a response from the participant. A blinding procedure was employed for both samples. In the adult sample, conventional audiometry was conducted by the university's students under the supervision of a qualified audiologist, or by a second qualified audiologist. In the adolescent sample, conventional audiometry was conducted by a third qualified audiologist. In both samples, the smartphone threshold test was facilitated by the first author. Test duration was recorded by the application during the test procedure. Once the test procedure was complete, the test administrator uploaded the test results to the hearData server. The administrator was then able to access the cloud-based server to review the test results.

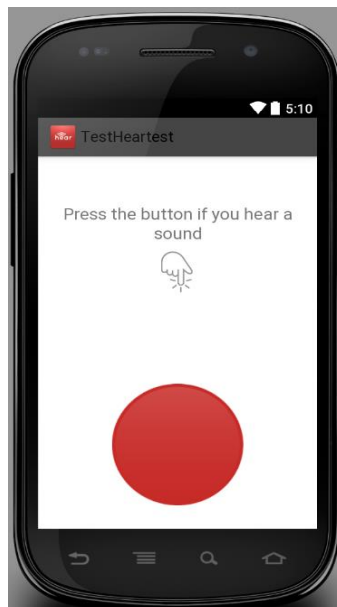


Figure 1. hearTest response button

3.3.4 Analysis

Results were analysed to account for the possible influence of a floor effect because testing was only conducted down to 10 dB HL. A comparative analysis between thresholds (conventional vs smartphone audiometry) was done where thresholds of 10 dB HL in either test condition were excluded. Within the adult sample, there were 17 instances, out of a possible 300 instances, where responses could not be obtained at the maximum intensities on the hearTest but were obtained at higher intensities through conventional audiometry. In those instances, comparisons could not be made. Threshold data for conventional audiometry and smartphone audiometry (>10 dB HL) were analysed descriptively for average differences, average absolute differences and respective distributions. Corresponding thresholds between conventional and smartphone audiometry were determined and expressed as a percentage of cases within 5 dB, within 10 dB and differing by 15 dB or more. Correspondence between conventional and smartphone test duration was determined.

Statistical analyses were performed using SPSS (SPSS v22., Chicago, Illinois) and Microsoft Excel (Microsoft Inc., Redmond, Washington). The data were not normally distributed (Shapiro-Wilk Test of Normality) necessitating non-parametric analyses (Wilcoxon Signed Ranks Test) to determine if there were significant differences between conventional audiometry and smartphone testing ($p < .01$).

3.4 RESULTS

3.4.1 Smartphone threshold accuracy and test duration – adults

There was no statistically significant difference between smartphone and conventional thresholds in the adult sample across all frequencies except at 4 kHz ($p > .01$). The majority (70.6%) of thresholds obtained through smartphone and conventional audiometry differed by 5 dB or less (table 2). Further analysis was conducted on the floor scores, which showed that 90.5% of the thresholds obtained within the adult sample were not affected by the floor effect in either condition (table 3).

Mean test durations for hearTest (6.75 min Average, 1.5 SD) and conventional audiometry (6.65 min Average, 2.5 SD) were not significantly different ($p > .01$; Wilcoxon).

Table 2. Average difference* and correspondence between smartphone and conventional audiometry per frequency for the adult population (n=30)

		Frequency (kHz)				
		0.5	1	2	4	8
Threshold comparisons (n)		58	59	57	52	42
Average Difference (dB)	Mean	1.9	0	1.0	-3.1**	-0.1
	SD	6.4	6.8	6.7	6.4	6.8
Correspondence (%)	0 - 5 dB	69	67.8	78.9	63.5	73.9
	± 10 dB	25.9	28.8	10.6	34.6	19
	≥ 15 dB	5.1	3.4	10.5	1.9	7.1
Threshold comparisons excluding floor effect (n):		49	49	51	49	41
Average difference (dB)	Mean	2.9	1.2	1.6	-3.3**	0
	SD	6.7	6.6	6.6	6.2	6.8
Correspondence (%)	0 - 5 dB	67.3	71.4	80.5	65.3	73.2
	± 10 dB	26.5	24.5	7.8	32.7	19.5
	≥ 15 dB	6.2	4.1	11.7	2	7.3

* hearTest subtracted from conventional audiometry thresholds

** Significant difference ($p < .01$)

Table 3. Distribution of thresholds for manual and smartphone audiometry in adolescent sample (n=130 ears)

Threshold Category		Frequency (kHz)				
		0.5	1	2	4	8
1) hearTest and conventional = 10 dB (%)		6.2	6.2	6.2	72.3	82.3
2) hearTest > 10 dB and conventional = 10 dB (%)		85.4	83.8	83.1	19.2	3.1

3) hearTest = 10 dB and conventional > 10 dB (%)	0	0	0	0	6.2
4) hearTest > 10 dB and conventional > 10 dB (%)	8.5	10	10.8	8.5	8.5

Mean test durations for hearTest (6.75 min Average, 1.5 SD) and conventional audiometry (6.65 min Average, 2.5 SD) was not significantly different ($p > .01$; Wilcoxon).

3.4.2 Smartphone threshold accuracy and test duration – adolescents

The majority (84.7%) of thresholds obtained at 0.5, 2 and 4 kHz with hearTest and conventional audiometry differed by 5 dB or less and at 1 kHz the majority (79.3%) of the thresholds differed by 10 dB or less (table 4). Whilst a statistically significant difference between smartphone and conventional thresholds in the adolescent sample across all frequencies except at 8 kHz ($p < .01$) was noted, it may not be clinically significant. 90.8% of the threshold comparisons were affected by the floor effect (table 4).

Table 4. Average difference* and correspondence between hearTest and conventional audiometry per frequency for the adolescent population (n=65)

		Frequency (kHz)				
		0.5**	1**	2**	4**	8
Number of threshold comparisons (n):		130	130	130	130	130
Average difference (dB):	Mean	-4.4	-8.4	-6.6	-1.2	0
	SD	2.9	4.3	3.5	2.9	3.1
Correspondence (%):	0 - 5 dB	92.3	17.6	57.7	95.4	93.1
	±10 dB	7.7	79.3	40.8	4.6	6.1
	≥15 dB	0	3.1	1.5	0	0.8
Threshold comparisons excluding floor effect (n):		11	13	14	11	11
Average difference (dB):	Mean	2.3	1.2	-3.2	-1.4	-2.7
	SD	3.5	8	4.2	5.5	5.6

Correspondence (%):	0 - 5 dB	90.9	69.2	85.7	81.8	81.8
	±10 dB	9.1	15.5	14.3	18.2	9.1
	≥15 dB	0	15.3	0	0	9.1

** hearTest subtracted from conventional audiometry thresholds

** Significant difference ($p < .01$)

Mean test durations for hearTest (7.09 min, 1.2 SD) and conventional audiometry (3.23 min, 0.6 SD) differed significantly ($p > .01$; Wilcoxon) with a difference of 3.86 minutes between the mean times of the two methods.

Absolute average differences for the adult and adolescent samples combined (table 5), excluding the floor effect varied between 4.6 dB (4.5 SD) and 5.9 dB (4.3 SD).

Table 5. Average absolute difference for thresholds unaffected by a floor effect in the adult and adolescent samples.

	Frequency (kHz)				
	0.5	1	2	4	8
n	60	62	65	60	52
Absolute average difference	5.9	5.2	4.6	5.4	4.6
Standard deviation	4.3	4.5	4.5	3.9	4.7

3.5 DISCUSSION

Validating a new method of pure tone threshold audiometry requires comparisons against conventional manual pure tone audiometry (Mahomed, Swanepoel, Eikelboom & Soer, 2013). The current study demonstrated that hearing thresholds obtained with the hearTest smartphone application are within clinically acceptable ranges compared to conventional audiometry thresholds. Recent studies comparing mean threshold differences between conventional audiometry and automated audiometry are in agreement with the findings of the current study, yielding results that are comparable to conventional audiometry within individuals with hearing losses (Swanepoel and Biagio,

2011; Eikelboom et al., 2013; Mahomed et al., 2013; Mahomed-Asmail, Swanepoel & Eikelboom, 2016a). A comparison of the thresholds obtained through conventional and automated audiometry in this study produced threshold differences ranging between -3.3 dB (6.2 SD) and 2.9 dB (6.7 SD) for the adult sample and between -3.2 dB (4.2 SD) and 2.3 (3.5 SD) for the adolescent sample. These results are lower than threshold differences reported by Swanepoel and Biagio (2011), but are in line with a meta-analysis, on the validity of automated compared to manual threshold audiometry, conducted by Mahomed et al. (2013) as well as results obtained in studies conducted by Eikelboom, Swanepoel, Motakef & Upton (2013) and Mahomed-Asmail et al. (2016a). Absolute average threshold differences (excluding any floor effect) for the adult and adolescent samples (table 4) show variability (standard deviations) of between 4.3 and 4.6 dB across frequencies. This is comparable to typical test-retest variability (standard deviations) of between 3.4 to 4.1 dB as reported in a meta-analysis of manual audiometry (Mahomed et al., 2013).

To date, several studies comparing smartphone and conventional audiometry have been conducted, with varied results. In some instances, automated smartphone audiometry has been found to overestimate hearing thresholds (Khoza-Shangase and Kassner, 2013; Abu-Ghanem et al., 2015). In these instances, smartphone applications seem better suited as simple end-user screening tools not intended for clinical application (Abu-Ghanem et al., 2015). In contrast, some studies have found smartphone applications to produce hearing thresholds that are comparable to conventional audiometry (Foulad et al., 2013; Thompson et al., 2015). Thompson et al. (2015) utilised the iOS Shoebox tablet audiometer to obtain hearing thresholds and concluded that automated audiometry could be used to accurately determine hearing thresholds in a study sample of 44 adults and 5 children. Foulad et al. (2013) utilised the iOS EarTrumpet smartphone application and determined that smartphone audiometry is able to obtain hearing thresholds comparable to conventional audiometry without the use of additional equipment. The current study results, within the adolescent sample, agrees with Thompson et al. (2015) and Foulad et al. (2013) with findings demonstrating thresholds equivalent to conventional pure tone audiometry. The current study, however, is the first to use inexpensive Android smartphones and calibrated headphones.

Hearing threshold variation, of 10 dB or less, between two methods of hearing assessment is accepted as sub-clinical within the context of clinical diagnostic audiometry (OSHA, 1983; McDaniel, Chinn, McCall & Stewart, 2013). It should be noted that, in some instances, for example with children, a difference of 10 dB HL could potentially be significant. In the current study, with the same standard adopted during data analysis, 94.4% of the adult sample thresholds obtained, using the smartphone, were within 10 dB of the thresholds obtained using conventional audiometry. Similarly, 98% of the adolescent sample thresholds were within 10 dB. These findings are consistent with those of several similar studies utilising iOS and Android OS devices (Mahomed et al., 2013; Yeung et al., 2013; Thompson et al., 2015).

There was no significant difference in test duration within the adult sample. These findings are in agreement with those of Abu-Ghanem et al. (2015) utilising uHear. However, there was a significant difference in test duration within the adolescent sample. Conventional audiometry testing took 3.23 min (0.6 SD), these findings are in line with the study conducted by Mahomed-Asmail, et al. (2016a) which reported conventional audiometry test duration at 3.63 min (2.17 SD). The brief test duration could be attributed to the majority of these participants having normal hearing with most thresholds below 15 dB. Due to the hearTest's minimum test level of 10dB, the majority of thresholds were, in fact, minimum response levels at 10dB HL. Furthermore, findings indicated that smartphone testing took 3.86 minutes longer than conventional audiometry. The discrepancy in test duration within the adolescent sample is likely related to the standardised automated threshold method taking longer than conventional audiometry to test down to normal levels (15 dB HL and lower). The application was set with standard "waiting periods" between responses and presentation of the next intensity and/or frequency. This is however, not a concern when utilising conventional audiometry, seeing as the speed of the test is largely based on the participant's response time. Furthermore, the smartphone application requires a loading period of one to two seconds to store the threshold information at the end of each frequency's test and move on to the next frequency. This loading period is not necessary when utilising conventional audiometry. However, the exact cause remains unknown and requires further investigation.

The hearTest application shares several key features with hearScreen™ such as integrated real-time noise monitoring, instant data capturing and cloud-based data storage. Automated test paradigms, along with these quality control features, allow lay persons with limited training to facilitate hearing assessments (Swanepoel et al., 2014; Yousuf Hussein et al., 2015; Mahomed-Asmail et al., 2016a). This type of technology can ensure hearing healthcare professionals spend more time on patient management and intervention (Swanepoel et al., 2013; Clark and Swanepoel, 2014).

In developing countries, where the lack of appropriate hearing healthcare professionals and infrastructure is common (Fagan and Jacobs, 2009), the mobility of audiological equipment, with quality control features, allows for wider penetration of hearing health services (Clark and Swanepoel, 2014; Peer and Fagan, 2015). This would specifically benefit communities with residents who are treated with ototoxic medication for conditions such as Tuberculosis, HIV and Cancer as well as accompanying opportunistic infections (Harris, Peer, & Fagan, 2012). It is recommended that these individuals undergo evaluations to monitor audiological status as often as twice a week (Duggal and Sarkar, 2007), and it is therefore essential that these individuals have access to hearing healthcare services that are readily available and easily accessible. Furthermore, these services could be initiated in community health and satellite clinics or could be taken directly to at-risk patients in their homes, to make hearing healthcare services even more accessible (Fagan and Jacobs, 2009; Clark and Swanepoel, 2014; Peer and Fagan, 2015).

A limitation of this study was the influence of the floor effect, created by testing only down to 10 dB HL. However, when considering the impact of the floor effect it should be noted that threshold levels of ≤ 15 dB HL is typically taken as normal for children. While the impact of the floor effect could be a limitation in sound treated environments, smartphone testing is primarily intended for community or primary health care access where testing below 10 dB would be difficult if not impossible due to ambient noise. Therefore, it is recommended that future research be conducted to determine the ability of the hearTest

to accurately test down to 0 dB HL. Additionally, the lack of bone conduction testing results in the inability of the hearTest to determine the type of loss in individuals with a hearing loss. Furthermore, all testing was conducted in a soundproof booth. It is recommended that smartphone testing be evaluated outside of the booth employing the noise monitoring quality control features to evaluate to validity of testing outside sound treated environments. Reliable results outside of a soundproof booth could allow for a substantial reduction in the costs involved with purchasing hearing healthcare equipment. As a result, hearing healthcare services will be more readily available and easily accessible to individuals living in both developed and developing countries.

Currently, the hearTest application lays important groundwork for the development of a cost effective, commercially available and portable hearing assessment device. Future studies evaluating the effectiveness of the hearTest's air conduction threshold determination, in conjunction with bone conduction and masking, as well as the applications added features of real-time noise monitoring and data management capabilities, could give hearing healthcare professionals in underserved areas the ability to successfully assess and manage individuals suffering from a hearing loss. Potentially resulting in the disabling effects of hearing loss across the continent being significantly reduced.

3.6 CONCLUSION

The hearTest smartphone application for threshold audiometry provides hearing thresholds comparable to conventional manual air-conduction audiometry. Whilst the hearTest smartphone application does not allow for differential diagnoses, because it does not include bone conduction audiometry, it can be used as a threshold baseline and monitoring tool. Use of smartphone-based audiometry may provide a time-efficient, cost-effective and portable solution, allowing for hearing service provision in remote and underserved areas (Swanepoel et al., 2010b; Foulad et al., 2013; Swanepoel et al., 2014).

4. DISCUSSION AND CONCLUSION

4.1 Discussion

The gold standard for hearing loss diagnosis is diagnostic thresholds audiometry (Abu-Ghanem et al., 2015). However, this may not be readily available due to the high cost of soundproof booths and appropriately trained hearing healthcare professionals in underserved communities (Abu-Ghanem et al., 2015; Clark & Swanepoel, 2014). As such, telehealth, and mHealth in particular, offer increased access to hearing healthcare services in these underserved communities (Swanepoel et al., 201b). mHealth offers new alternatives to hearing healthcare services with devices that are portable, easy to use and affordable (Mahomed-Asmail et al., 2016a; Clark & Swanepoel, 2014). Additionally, these devices yield screening results that are comparable to conventional screening audiometry (Mahomed-Asmail et al., 2016a; Mahomed-Asmail et al., 2016b; Yousuf Hussein et al., 2015).

mHealth has become more popular due to an increase in cellular networks and global access to mobile devices (Kelly & Minges, 2012; Swanepoel et al., 2014; Clark & Swanepoel, 2014). As a result, several applications have been validated in an attempt to improve hearing healthcare services (Foulad et al., 2013; Swanepoel et al., 2014; Abu-Ghanem et al., 2015; Thompson et al., 2015; Yeung et al., 2015). Validating a new method of pure tone threshold audiometry requires comparisons against the gold standard diagnostic audiometry (Mahomed et al., 2013). In order for a new test procedure to be valid, the new procedure must produce results that are comparable to conventional audiometry. When determining the comparability between test procedures, it is important to consider any variability in threshold determination caused by test-retest influences or inter-tester differences (Struwig & Stead, 2001; Margolis, Saly, Le & Laurence, 2007; Swanepoel & Biagio, 2011). Typically, when comparing test-retest validity, the same response should be obtained for both methods (Mouton & Babbie, 2007). For behavioural air conduction, test-retest results of 10 dB or less, are generally accepted as sub-clinical (OSHA, 1983; McDaniel et al., 2013). Similarly, there should be no significant

discrepancies between thresholds obtained by different testers (Stuwig & Stead, 2001; Mouton & Babbie, 2007)

Findings from the current study confirmed that hearing thresholds obtained with hearTest smartphone application are within clinically acceptable ranges when compared to conventional audiometry thresholds. Therefore, the current findings are in line with results of several recent studies comparing conventional and automated audiometry (Swanepoel & Biagio, 2011; Eikelboom, Swanepoel et al., 2013; Mahomed et al., 2013; Mahomed-Asmail et al., 2016a). A comparison of the thresholds obtained through conventional and automated audiometry, in this study, produced threshold differences ranging between -3.3 dB (6.2 SD) and 2.9 dB (6.7 SD) for the adult sample and between -3.2 dB (4.2 SD) and 2.3 (3.5 SD) for the adolescent sample. These results are lower than threshold differences reported by Swanepoel and Biagio (2011), but are in line with a meta-analysis, on the validity of automated compared to manual threshold audiometry, conducted by Mahomed et al. (2013) as well as in studies conducted by Eikelboom et al. (2013) and Mahomed-Asmail et al. (2016a). Absolute average threshold differences (excluding any floor effect) for the adult and adolescent samples (Table 5) show variability (standard deviations) of between 4.3 and 4.6 dB across frequencies. This is comparable to typical test-retest variability (standard deviations) of between 3.4 to 4.1 dB as reported in a meta-analysis of manual audiometry (Mahomed et al., 2013).

To date, several studies comparing smartphone and conventional audiometry have been conducted, with varied results. In some instances, automated smartphone audiometry has been found to overestimate hearing thresholds (Khoza-Shangase & Kassner, 2013; Abu-Ghanem et al., 2015). In these instances, smartphone applications seem better suited as simple end-user screening tools, not intended for clinical application (Abu-Ghanem et al., 2015). In contrast, some studies have found smartphone applications to produce hearing thresholds that are comparable to conventional audiometry (Foulad et al., 2013; Thompson et al., 2015). For example, Thompson et al. (2015) utilised the iOS Shoebox tablet audiometer to obtain hearing thresholds. This study concluded that automated audiometry could be used to accurately determine hearing thresholds in a

study sample of 44 adults and 5 children. Foulad et al. (2013) utilised the iOS EarTrumpet smartphone application and determined that smartphone audiometry is able to obtain hearing thresholds comparable to conventional audiometry without the use of additional equipment. Results of the current study are in agreement with Thompson et al. (2015) and Foulad et al. (2013) yielding thresholds equivalent to conventional pure tone audiometry. The current study, however, is the first of its kind to use inexpensive Android smartphones and calibrated headphones instead of Apple iOS devices.

Hearing threshold variation, of 10 dB or less, between two methods of hearing assessment is accepted as sub-clinical within the context of clinical diagnostic audiometry (OSHA, 1983; McDaniel et al., 2013). It should be noted that, in some instances, for example with children, a difference of 10 dB HL could potentially be significant. In the current study, with the same standards adopted, results indicated that 94.4% of the adult sample thresholds obtained using the smartphone were within 10 dB of the thresholds obtained using conventional audiometry. Similarly, 98% of the adolescent sample thresholds were within 10 dB. These findings are consistent with those of several similar studies utilising iOS and Android OS devices (Mahomed et al., 2013; Yeung et al., 2013; There was no significant difference in test duration within the adult sample. These findings are in agreement with those of Abu-Ghanem et al. (2015) utilising uHear™. However, there was a significant difference in test duration within the adolescent sample. Conventional audiometry testing took 3.23 min (0.6 SD), these findings are in line with the study conducted by Mahomed-Asmail et al. (2016a) which reported conventional audiometry test duration at 3.63 min (2.17 SD). The brief test duration could be attributed to the majority of these participants having normal hearing with most thresholds below 15 dB. Due to the hearTest's minimum test level of 10dB, the majority of thresholds were, in fact, minimum response levels at 10dB HL. Furthermore, findings indicated that smartphone testing took 3.86 minutes longer than conventional audiometry. The discrepancy in test duration within the adolescent sample is likely related to the standardised automated threshold method taking longer than conventional audiometry to test down to normal levels (15 dB HL and lower). The application was set with standard "waiting periods" between responses and presentation of the next intensity and/or

frequency. This is however, not a concern when utilising conventional audiometry, seeing as the speed of the test is largely based on the participant's response time. Furthermore, the smartphone application requires a loading period of one to two seconds, to store the threshold information, at the end of each frequency's test before it moves on to the next frequency. This loading period is not necessary when utilising conventional audiometry. However, the exact cause remains unknown and requires further investigation.

The hearTest application shares several key features with hearScreen™ such as integrated real-time noise monitoring, instant data capturing and cloud-based data storage. Automated test paradigms along with these quality control features allow lay persons, with limited training, to facilitate hearing assessments (Swanepoel et al., 2014; Yousuf Hussein et al., 2015; Mahomed-Asmail et al., 2016a). This type of technology can ensure that hearing healthcare professionals spend more time on patient management and intervention (Swanepoel et al., 2013; Clark and Swanepoel., 2014).

In developing countries, where the lack of appropriate hearing healthcare professionals and infrastructure is common (Fagan & Jacobs, 2009), the mobility of audiological equipment, with quality control features, allows for wider penetration of hearing health services (Clark & Swanepoel, 2014; Peer & Fagan, 2015). This would specifically benefit communities with residents who are treated with ototoxic medication for conditions such as Tuberculosis, HIV and cancer as well as the accompanying opportunistic infections associated with these conditions (Duggal & Sakar, 2007). It is recommended that these individuals undergo evaluations to monitor their audiological status as often as twice a week (Duggal & Sarkar, 2007). It is therefore essential that these individuals have access to hearing healthcare services that are readily available and easily accessible (Duggal & Sarkar, 2007). As such, these services could be initiated in community health and satellite clinics or could be taken directly to at-risk patients in their homes, to make hearing healthcare services even more accessible (Fagan & Jacobs, 2009; Clark & Swanepoel, 2014; Abu-Ghanem et al., 2015; Peer & Fagan, 2015).

4.2 Clinical Implications

Conventional audiometry requires calibrated audiological equipment and large immobile sound proof booths. This can be rather costly and therefore limits the provision of hearing healthcare services to tertiary healthcare institutions. As such, hearing healthcare is not accessible to individuals residing in rural areas (Fagan & Jacobs, 2009). Fortunately, mhealth, and smartphone audiometry in particular, provides a method of addressing this service delivery deficit (Swanepoel et al., 2010b) and could potentially bridge geographical gaps (Swanepoel et al., 2010a).

The hearTest application provides a novel method of assessing hearing thresholds on inexpensive entry-level Android devices, coupled with commercially available calibrated headphones. The current study demonstrates that the hearTest application is able to accurately determine air conduction thresholds, by means of an automated test sequence, that can be self-administered by the patient. The hearTest provides an ideal platform for a trained paraprofessional to facilitate threshold testing at any location. This is achieved by integrated quality control measures such as real-time noise monitoring and suggested patient instructions to ensure accurate test results. Additionally, data storage onto a cloud server allows hearing healthcare professionals to access the results from any location and suggest appropriate interventions remotely. Therefore, the hearTest ultimately allows for the provision of hearing healthcare services in even remote and rural settings. It also provides the clinician with more time for management and counselling.

Hearing thresholds provided by the hearTest, alongside acoustic immittance procedures, could provide hearing healthcare professionals in the public healthcare sector with diagnostic information about the type and degree of hearing losses. This combination could be a worthwhile solution in settings where diagnostic equipment, such as a soundproof booth, is inaccessible.

The hearTest has the ability to assist with screening and monitoring difficult to test populations, such as those suffering from ototoxicity. For example, individuals undergoing treatment for HIV/AIDS, tuberculosis and cancer run the risk of developing ototoxic

hearing losses as a result of their treatment. These individuals require regular hearing assessments to monitor hearing sensitivity to minimize the risk of developing hearing losses. By implementing a technology like hearTest in local clinics, at risk individuals may not need to travel great distances to facilities with audiological equipment. As such, these individuals could receive more regular hearing evaluations, reducing the potential for debilitating hearing loss. Moreover, these individuals are often too ill to undergo hearing testing in a soundproof booth environment. In these instances, the hearTest can be taken directly to the home or hospital bed where the assessment can take place whilst still ensuring the comfort of the individual.

The hearTest could also be used in the occupational health setting to regularly screen and monitor the hearing of employees. The cost effectiveness of the hearTest, in comparison to a soundproof booth and audiometer, could allow work sites to implement more rigorous and regular hearing screening protocols, ultimately reducing the risk of noise induced hearing losses.

4.3 Critical Evaluation

A critical evaluation of the research project is crucial in order to interpret the findings of the research within the framework of its strengths and limitations. These are highlighted below:

4.3.1 Study Strengths

A number of strengths were identified in this study. Which include:

- The current study is the first of its kind to utilize an inexpensive entry-level Android smartphone coupled with commercially available Sennheiser HD 202 II supra-aural headphones, to deliver air conduction threshold testing on an automated platform. A recent study conducted by van der Aerchot et al. (submitted) has resulted in equivalent threshold sound pressure levels being determined for the Sennheiser HD 202 II supra-aural headphones.

- A reasonably large sample of participants was used to validate the hearTest. This allowed for an accurate evaluation of the reliability of the hearTest when testing both individuals with normal hearing as well as individuals with a hearing loss.
- A rigorous blinding procedure was utilized throughout data collection. Different audiologists were used to conduct conventional audiometry and hearTest. As such, the audiologists were always unaware of the previous test's thresholds when determining the second test's thresholds. Therefore, thresholds were obtained without the influence of tester bias.
- In an attempt to reduce likelihood of test order affecting the outcome of the threshold comparisons, counterbalancing was employed in both participant samples.

4.3.2 Study Limitations

A number of limitations were identified in this study. Which include:

- The influence of the floor effect is a limitation to this study. The hearTest was only able to test down to 10 dB HL. This resulted in a number of thresholds in the adolescent sample being unspecified as the hearTest did not test for thresholds between 0 dB HL to 10 dB HL.
- All testing was conducted in a soundproof booth. As such, all results were obtained in a controlled environment. Therefore, the validity of the hearTest in a clinical environment, without the use of a soundproof booth, could not be addressed in this study.
- The hearTest protocol was not administered more than once to each participant. Therefore, test-retest reliability was not evaluated and it remains undetermined if the hearTest is able to yield consistent thresholds within subjects.

4.4 Recommendations for Future Research

Future research utilizing the hearTest would be beneficial to the field of mHealth. A number of recommendations for future research are listed below:

- Threshold testing on an entry-level android with commercially available headphones is a novel concept. As such, further research is necessary to evaluate the

effectiveness of the hearTest in the healthcare sector, by utilising the device to assess and monitor individuals with hearing loss in a clinical environment.

- Research participants for this study were between the ages of 16 and 92. It is therefore recommended that future research be conducted on participants below the age of 16 to evaluate to which extent the self-administration interface can be used to obtain reliable thresholds on the automated platform.
- Reliable results outside of a soundproof booth could allow for a substantial reduction in the costs involved with purchasing hearing healthcare equipment. As a result, hearing healthcare services could be more readily available and easily accessible to individuals living in both developed and developing countries. Therefore, it is recommended that smartphone testing be evaluated outside of the booth, employing the noise monitoring quality control features, to evaluate to validity of testing outside sound treated environments
- The incorporation of automation and quality control features such as real-time noise monitoring enables testing conducted by trained paraprofessionals and the patients themselves. This gives the hearing healthcare professional more time for intervention and management of hearing losses. Therefore, it is recommended that future research be conducted with the hearTest threshold determination facilitated by minimally trained personnel and the monitoring and intervention facilitated by a qualified audiologist.
- While the impact of the floor effect can be a limitation in some instances, it is important to note that the hearTest application was intended to be conducted outside of the soundproof booth. As such, it is highly unlikely that testing below 10 dB HL will be reliable with an ambient noise presence. Therefore, it is recommended that future research be conducted to determine the ability of the hearTest to accurately test down to 0 dB HL in individuals with normal hearing.

4.5 Conclusion

Commercially available, smartphone-based, hearing assessment applications have the potential to combat global hearing loss concerns, by reducing the cost of audiological equipment and making access to hearing healthcare services more accessible (Yeung et

al., 2013; Clark & Swanepoel, 2014). Automated audiometry allows for hearing healthcare services to be provided without the direct involvement of a professional (Mahomed-Asmail et al., 2016a). Additionally, features such as real-time noise monitoring, and cloud-based data storage may allow the hearing healthcare professional to implement quality control into hearing assessments as well as simplify data management (Swanepoel et al., 2014; Mahomed-Asmail et al., 2016a).

Findings from the current study indicate that the hearTest smartphone application for threshold audiometry provides hearing thresholds comparable to conventional manual air-conduction audiometry. The results of this study indicate that, although the hearTest cannot be used as a differential diagnostic tool, it can provide accurate thresholds as a screening and monitoring tool. Numerous studies indicate that the use of smartphone-based audiometry could provide a time-efficient, cost-effective and portable solution, allowing for hearing service provision in remote and underserved areas (Swanepoel et al., 2010b; Foulad et al., 2013; Swanepoel et al., 2014). The hearTest application is one such solution that can offer some threshold information to audiologists in areas where diagnostic audiometry is scarce.

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6. APPENDICES

APPENDIX A

Ethical Clearance Form: Faculty of Humanities



Our Ref: 11074478

19 July 2016

Ms J van Tonder
9 Kanarie Street
Helikon Park
1771

Dear Ms van Tonder

TITLE REGISTRATION: FIELD OF STUDY – MCOMMUNICATION PATHOLOGY

I have pleasure in informing you that the following has been approved:

TITLE: Automated smartphone threshold audiometry: Validity and time-efficiency

SUPERVISOR: Prof DCD Swanepoel

CO-SUPERVISOR: Mrs F Mahomed Asmall

I would like to draw your attention to the following:

1. **ENROLMENT PERIOD**
 - (a) You must be enrolled as a student for at least one academic year before submission of your dissertation/essay.
 - (b) Your enrolment as a student must be renewed annually before 31 March, until you have complied with all the requirements for the degree. You will only be able to have supervision if you provide a proof of registration to your supervisor.
2. **APPROVAL FOR SUBMISSION**

On completion of your dissertation/essay enough copies for each examiner must be submitted to Student Administration, together with the prescribed examination enrolment form signed by you, which includes a statement by your director of studies that he/she approves of the submission of your dissertation/essay.
3. **NOTIFICATION BEFORE SUBMISSION**

You are required to notify me at least three months in advance of your intention to submit your dissertation/essay for examination.

Yours sincerely


for DEAN: FACULTY OF HUMANITIES

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Fax: +27 (0)12 4202698

Email: jana.bezuidenhout@up.ac.za
Website: www.up.ac.za

Please note: Ethical clearance was initially granted 5th May 2015. During the course of data collection the study title changed. The data collection process remained unchanged. Therefore, a new clearance form was issued on the 9th July 2016 reflecting the new title. A copy of the original clearance form is available on request.

APPENDIX B

Clinic Coordinator and Private Practice Consent Forms

Dear Department of Speech Therapy and Audiology Clinic Coordinator

RE: MASTER'S DEGREE DATA COLLECTION - AIR CONDUCTION THRESHOLD DETERMINATION THROUGH THE USE OF A SMARTPHONE-BASED HEARING TEST

Participation In Research Project

I, Jessica van Tonder, am a Master's Degree student in Communication Pathology, at the University of Pretoria. I am required to conduct a research project to obtain my degree. My project focuses on determining air conduction thresholds through the use of a smartphone-based hearing test called the HearTest™.

What Is This Project About?

Hearing loss is one of the most prevalent sensory deficits affecting individuals today. The World Health Organization (2013) estimates that 5.3% (360 million people) currently live with a disabling hearing loss. In South Africa, a major challenge to successfully treating disabling hearing losses is the shortage of hearing healthcare professionals as well as the cost of the equipment needed to conduct hearing evaluations.

Therefore, in an effort to address these challenges, the current study is aimed at determining accuracy and programme performance of smartphone-based air conduction threshold determination.

What Will Be Required Of Me If I Choose to Participate?

An air conduction audiogram will be conducted in your practice's audiological booth on any patients who are willing to participate in the study. Thereafter, the same air conduction test will be conducted on a Samsung Trend Neo smartphone. The test will take approximately 15 minutes or less and will be done free of charge.

Ethical considerations that will be taken into account during this study:


- Your patients will not be exposed to any risks.
- The confidentiality and anonymity of both your practice and your patients will be ensured by means of coding of personal information.
- In accordance with the requirements of research in the field results will stored for a minimum of 15years at the Department of Speech Language Pathology and Audiology.
- Participation in this study is voluntary, should you as the practice owner or your patients wish to withdraw from the study at any time, you may do so without any negative consequences.

If you are willing to allow me to use your practice as a location to collect data, please would you be so kind as to sign the consent form below. Should you require any additional information, please do not hesitate to contact me at 079 626 1173

Kind regards


Prof. D Swanepoel
Principal Researcher


Ms J van Tonder
Research Assistant


Ms. F. Mahomed
Lecturer: Audiologist


Prof. B Vinck
HOD: Department of Speech Language
Pathology and Audiology

I, _____ (name and surname), owner of
_____ (name of practice) in _____ (Location
of practice), am willing to allow Jessica van Tonder to collect data for her Master's Degree
research study entitled "Smartphone-based School Hearing Screening and Threshold Testing –
Accuracy and Programme Performance" from my audiological practice according to the
conditions stipulated in the enclosed letter.

Practice Owner's Signature

Date



Dear HearCare Staff

RE: MASTER'S DEGREE DATA COLLECTION - AIR CONDUCTION THRESHOLD DETERMINATION THROUGH THE USE OF A SMARTPHONE-BASED HEARING TEST

Participation In Research Project

I, Jessica van Tonder, am a Master's Degree student in Communication Pathology, at the University of Pretoria. I am required to conduct a research project to obtain my degree. My project focuses on determining air conduction thresholds through the use of a smartphone-based hearing test called the HearTest™.

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Ethical considerations that will be taken into account during this study:

- Your patients will not be exposed to any risks.
- The confidentiality and anonymity of both your practice and your patients will be ensured by means of coding of personal information.
- In accordance with the requirements of research in the field results will stored for a minimum of 15years at the Department of Speech Language Pathology and Audiology.
- Participation in this study is voluntary, should you as the practice owner or your patients wish to withdraw from the study at any time, you may do so without any negative consequences.

If you are willing to allow me to use your practice as a location to collect data, please would you be so kind as to sign the consent form below. Should you require any additional information, please do not hesitate to contact me at 079 626 1173


Kind regards



Prof. D Swanepoel
Principal Researcher



Ms J van Tonder
Research Assistant



Ms. F. Mahomed
Lecturer: Audiologist



Prof. B Vinck
HOD: Department of Speech Language
Pathology and Audiology

I, _____ (name and surname), owner of
_____ (name of practice) in _____ (Location
of practice), am willing to allow Jessica van Tonder to collect data for her Master's Degree
research study entitled "Smartphone-based School Hearing Screening and Threshold Testing –
Accuracy and Programme Performance" from my audiological practice according to the
conditions stipulated in the enclosed letter.

Practice Owner's Signature

Date

APPENDIX C

Adult Informed Consent Form



Date:

Dear Participant,

PARTICIPATION IN RESEARCH PROJECT

I, Jessica van Tonder, am a masters student in Communication Pathology, at the University of Pretoria. I am required to conduct a research project. My project focuses on limited hearing threshold estimation through the use of a newly developed smartphone application called the hearScreen™.

What Is This Project About?

Hearing loss is one of the most prevalent sensory deficits affecting individuals today. The World Health Organization (2013) estimates that 5.3% (360 million people) currently live with a disabling hearing loss. In South Africa, a major challenge to successfully treating disabling hearing losses is the shortage of hearing healthcare professionals as well as the cost of the equipment needed to conduct hearing evaluations.

Therefore, in an effort to address these challenges, the current study is aimed at determining accuracy and programme performance of smartphone-based hearing screening and threshold testing.

What Will Be Required Of Me If I Choose to Participate?

In addition to the diagnostic hearing evaluation, that you have made an appointment for, at the Department of Speech Language Pathology and Audiology, the student conducting your hearing evaluation will also conduct a semi-automated hearing screening and limited threshold estimation test. The test will take approximately 5 minutes or less and will be done free of charge.

Ethical considerations that will be taken into account during this study:

- You as the participant will not be exposed to any risks.
- Confidentiality and anonymity will be ensured by means of coding of personal information.
- In accordance with the requirements of research in the field results will stored for a minimum of 15years at the Department of Speech Language Pathology and Audiology.
- Participation in this study is voluntary, should you wish to withdraw from the study at any time, you may do so without any negative consequences.

If you agree to participate in this study, please sign the informed consent form attached.

Should you require any additional information, please do not hesitate to contact us.


Kind regards



Prof. D Swanepoel
Principal Researcher



Ms J van Tonder
Research Assistant



Ms. F. Mahomed
Lecturer: Audiologist



Prof. B Vinck
HOD: Department of Speech Language
Pathology and Audiology

INFORMED CONSENT:

I, _____, hereby agree to participate in the study named:

“Smartphone-based School Hearing Screening and Threshold Testing – Accuracy and Programme Performance” according to the conditions stipulated in the enclosed letter.

APPENDIX D

Parental Informed Consent Form



Dear Parent

The Department of Speech Language Pathology and Audiology at the University of Pretoria is providing free of charge hearing screening services for all Junior Tukkies between 27 June and 3 July 2015. The hearing screening usually takes 20 to 25 minutes to complete and if results suggest that further testing is required a referral letter will be provided with the hearing test results.

The hearing screening information obtained will be used for research purposes. As such, all personal information will be kept confidential and data-analysis will be conducted anonymously. Should you, or your child, wish to withdraw from the research project at any time you may do so without any negative consequences to yourself.

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

If you wish to make use of these services kindly complete the informed consent form below.

Sincerely,

Prof De Wet Swanepoel
Professor

Consent:

Herewith, I _____ (parent name) grant permission to have the hearing of my child _____ (JuniorTukkie name) screened. I acknowledge that the information will be used for research purposes as specified above.

Signature of Parent

Date

University of Pretoria
PRETORIA 0002
Republic of South Africa

Tel: 012 420 4280
Fax: 012 420 3517

dewet.swanepoel@up.ac.za
www.up.ac.za

APPENDIX E

Informed Assent Form



Dear Junior Tukkies

The Department of Speech Language Pathology and Audiology at the University of Pretoria is providing hearing screening services for all Junior Tukkies between 27 June and 3 July 2015. The hearing screening usually takes 20 to 25 minutes to complete and if your results suggest that further testing is required a referral letter will be provided with the hearing test results.

The hearing screening information obtained will be used for research purposes. As such, all your personal information will be kept confidential and data-analysis will be conducted anonymously. If you want to withdraw from the research project at any time you may do so without any negative consequences to yourself.

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

If you wish to make use of these services kindly complete the informed consent form below.

Sincerely,

Prof De Wet Swanepoel
Professor

Consent:

Herewith I _____ (Junior Tukkies name) grant permission to have my hearing screened and I acknowledge that the information will be used for research purposes as specified above.

Signature of Junior Tukkies

Date