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Neonatal hearing screening using a smartphone-based otoacoustic emission device:

A comparative study

by

Andani Madzivhandila (u15186467)

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University of Pretoria

Supervisor

Prof Leigh Biagio de Jager

Co-supervisor

Prof Talita le Roux

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Andani Gluggy Madzivhandila

Department of Speech-Language Pathology and Audiology

University of Pretoria

Email: andanigluggy@gmail.com

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"When the time is right, I the Lord, will make it happen" – Isaiah 60:22

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ABSTRACT

Early identification and intervention for childhood hearing loss assists in the reduction of delays in speech and language development. Otoacoustic emissions (OAEs) are commonly used for identifying hearing loss through newborn hearing screening (NHS). Recent technological advances in NHS have created more feasible and accessible services, however no objective smartphone-based screening applications (apps) have been validated. This study aimed to compare the screening outcomes of a smartphone-based OAE screening device to a commercially available OAE screening device. More specifically, the within-participant outcomes of the OAEs, in terms of screening concordance, signal, noise, and SNRs were compared to measure equivalence between the two devices.

NHS at two tertiary public healthcare hospitals was conducted over a period of 8 months. The primary investigator followed a one-step screening protocol by means of which only OAEs were performed on each infant rather than a two-step screening protocol of OAEs and automated auditory brainstem responses (AABR). All infants less than three months of age were eligible for the study. DPOAE and TEOAE screenings were performed using the Otodynamics ILO v6 device (comparator) and the hearX OAE device. The screening technology namely the hearOAE and Otodynamics ILO, was used in an alternating manner on each day of the data collection period. Every participant was required to undergo OAE screening, which included either Distortion Product Otoacoustic Emission (DPOAE) screening or Transient Evoked Otoacoustic Emission (TEOAE) screening.

A total of 176 infants (352 ears) (48.9% female) underwent TEOAE and DPOAE newborn hearing screening by a dedicated screener. The mean age at the time of screening was 4.5 days (SD 11.3). Statistically significant within-participant differences for DPOAE were measured for infants in the Neonatal Intensive Care Unit (NICU) on the pass/refer outcomes where infants who spent time in the NICU were 3.09 times more likely to refer DPOAE screening using the hearOAE device (p=0.029). Inter-device DPOAE comparison indicated no statistically significant difference in the refer rate between the devices (p=0.238). Similarly, inter-device differences for TEOAEs were measured for pass/refer outcomes. A statistically higher NHS pass rate was measured for TEOAEs with the hearOAE compared to the Otodynamics ILOs (p=0.009). The inter-device, within-participant diagnostic concordance was 89.7% and 85.0% for DPOAE and TEOAE respectively.

The current study concluded that the hearOAE yielded outcomes comparable to the Otodynamics ILO v6 in terms of the overall pass and/or refer outcome. This verifies the performance of the novel

smartphone-based OAE device and may facilitate increased accessibility of NHS services as mHealth is becoming a recognised alternative method in NHS programs globally.

Keywords

Infant hearing screening, mHealth, Distortion Product Otoacoustic Emissions, Transient Evoked Otoacoustic Emissions, Dedicated screener, Accessibility to NHS

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LIST OF ABBREVIATIONS

ANSD	auditory-neuropathy spectrum disorder
DPOAE	distortion product otoacoustic emissions
EHDI	early hearing detection and intervention
HL	hearing loss
HPCSA	Health Professions Council of South Africa
JCIH	Joint Committee of Infant Hearing
LMIC	low-middle-income countries
NHS	infant hearing screening
NICU	neonatal intensive care unit
OAE	otoacoustic emissions
PHC	primary healthcare
SA	South Africa
SNHL	sensorineural hearing loss
SNR	signal-to-noise ratio
SOAE	spontaneous otoacoustic emissions
TEOAE	transient evoked otoacoustic emissions
UMIC	upper-middle-income countries
UNHS	universal infant hearing screening
WHO	World Health Organisation

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1. INTRODUCTION

1.1 Background

According to Mulwafu et al. (2016), hearing is the most common sensory disability in the world and is a growing cause for worry. When an infant has a hearing loss, it can have long-term effects such as emotional instability, cognitive impairments, delayed communication, and eventually vocational difficulties and career limitations (Bezuidenhout et al., 2021; JCIH, 2019a; Kim et al., 2017; Olusanya, 2011; Wroblewska-Seniuk et al., 2018). Hearing loss has been described as an unheeded epidemic due to its unnoticeable, yet highly prevalent nature (Swanepoel et al., 2007). Compared to industrialized countries, where the incidence of hearing loss is believed to be between two and four per 1,000 live births, low-middle-income countries (LMICs) are predicted to have a higher incidence of 6 per 1,000 live births (Olusanya, 2011). A meta-analysis literature review study indicated that 1% of children in LMICs have hearing loss, which is a significant figure considering the density in the world population (Ganek et al., 2023).

It is estimated that by 2050 over 700 million people will have incapacitating hearing loss and nearly 80% of these people live in LMICs (Swanepoel et al., 2009; WHO, 2023). Sadly, estimates place the number of South African newborns who will receive a hearing test at less than 10% of one million, meaning that children who are deaf or hard of hearing will likely not receive the critical early auditory stimulation they need. (Meyer et al., 2012; Ehlert & Coetzer, 2020) Because of this, unless greater efforts are made to achieve early diagnosis of hearing loss through NHS, including in those newborns without established risk factors, over 90% of babies born in South Africa will be left without the possibility of early detection of hearing loss. (Meyer et al., 2012; Ehlert & Coetzer, 2020).

Infants diagnosed with hearing loss before the age of six months exhibit considerably greater language ability than infants diagnosed with hearing loss later in life, demonstrating the dramatic benefits of NHS (Bezuidenhout, Khoza-Shangase, De Maayer, et al., 2018; JCIH, 2019b; Olusanya et al., 2004; Wroblewska-Seniuk et al., 2017). Objectively determined physiological measures such as Otoacoustic emission (OAE) screening and AABR are recommended for NHS, which is appropriate for the target population (JCIH, 2019b).

OAE and AABR are hearing screening methods that are both objective , cost-effective, safe, and noninvasive (Chavan et al., 2021). Althoghy AABRs are more sensitive than OAEs, OAE screenings can be done in out-patients in awake infants whereas AABR requires the infant to be asleep, which is not

always attainable in varying contexts (Chavan et al., 2021). ABR tests also necessitate a more lengthy test-time and are expensive and therefore an OAE is often the first option used to detect hearing loss in infants due to its relatively safe, non-invasive, secure, low-cost and objective (Wroblewska-Seniuk et al., 2018). Evoked OAE i.e. transient evoked OAE (TEOAE) and distortion-product OAE (DPOAE), are commonly used techniques for testing the integrity of the outer hair cells of the cochlea (Dawood & Sultana, 2018). OAEs are commonly used in South Africa for NHS purposes, however the issue regarding access to healthcare is still a matter to look into (Khoza-Shangase et al., 2017; Swanepoel et al., 2004). The HPCSA has recommended primary healthcare clinics as a setting for NHS, citing the benefit of a wider accessibility that leads to higher follow-up appointment attendance and increased coverage of screened newborns (HPCSA, 2007, 2018; Kanji, 2022; Swanepoel et al., 2006).

In South Africa, there is a shortage of audiologists, resulting in limited availability and accessibility of NHS services (Khan et al., 2018). Despite a population of over 53 million, South Africa is served by only 1800 speech and hearing therapists, audiologists, and/or speech therapists, primarily concentrated in urban areas within the private sector. Access to these services is particularly challenging for individuals in rural areas (HPCSA, 2007; Khan et al., 2018).

1.2 An overview of OAEs and its use in newborn hearing screening

Over the past few years, new information has been available indicating early hearing screening benefits such as improved language, communication, and social-emotional outcomes (Shearer et al., 2019). The information has led to dramatic progress in the large-scale implementation of NHS in many parts of the world, including South Africa, where currently OAE-based NHS has been implemented (JCIH, 2019b; Bezuidenhout et al., 2021)).

A hearing screening procedure most often employed and successfully used in NHS is OAE screening. OAEs assess the integrity and function of outer hair cells within the cochlea, providing important insights into the sensitivity of one's hearing (Ramos, 2023). Although OAEs cannot estimate the type or degree of hearing loss, they are an essential tool in NHS and diagnostic audiology for the differential diagnosis of hearing conditions (Ramos, 2023). OAEs provide non-invasive recordings of physiological activity underlying normal auditory function and are easily performed in infants (Wroblewska-Seniuk et al., 2018). OAEs are either spontaneous or evoked. Spontaneous otoacoustic emissions (SOAEs) occur in the ear without external stimulation while evoked OAEs are measured after the presentation of a stimulus namely, transient stimulus such as a click or tone burst (TEOAE), or a pair of pure-tone

stimuli (DPOAE). The most recorded OAEs in screening and diagnostic audiology are DPOAEs and TEOAEs.

OAE screenings are validated as reliable and objective screening procedures (JCIH, 2019a). OAE screening has been seen to be highly sensitive (between 85 and 100%) and reasonably specific (between 91 and 95%) in the generalised population (Eiserman et al., 2008). The JCIH guidelines require that a reliable NHS program should have referral rates of no more than 4% for DPOAE screening, however, most NHS programs reveal higher refer rates due to false-positives (JCIH, 2019a). The central reason for false-positive results with OAE testing is temporary conditions in the outer ear canal such the collapse of the ear canal and the presence of debris) and middle ear (e.g., the presence of amniotic fluid and mucus), as well as high ambient noise levels (van Dyk et al., 2015). These problems usually resolve within the first few hours or days after birth, and if the screening protocol involves more than one test, then the referral rate is lower.

South Africa has made advances toward attaining NHS by issuing a hearing screening position statement, which is based on the 2007 position statement of the Joint Committee on Infant Hearing (JCIH) (Bezuidenhout, et al., 2018; HPCSA, 2007). In this position statement, the Early Hearing Detection and Intervention (EHDI) guidelines suggest that all infants should undergo NHS prior to discharge from the birth hospital at no later than one month of age (JCIH, 2019b). According to most recent international guidelines, the diagnosis of hearing loss must occur before the age of three months while intervention with a traditional hearing amplification and restorative treatment with cochlear implantation should start within the first 6 months of life (Abdullahi et al., 2021; Ghirri et al., 2011).

OAE screening is widely being used for NHS in settings hospital settings, both public and private sectors. The most commonly used model to date for NHS has been a hospital-based screening; through making use of a team of dedicated screeners measuring OAEs in infants in the maternity unit prior to discharge (Bezuidenhout et al., 2021). A UNHS study conducted over a four-year period at a private hospital in SA revealed a 75 percent coverage-rate within the first 22 months when hearing screening was included in the hospital birthing package. Nonetheless, the efficiency of the programme decreased to a 20 percent coverage-rate during the following 26 months, when parents were responsible for payment of the NHS service (Swanepoel et al., 2007). In another study conducted at a secondary level hospital in SA, screening of 121 newborns out of a possible 2 704 births during indicated that challenges and barriers to the implementation of UNHS were several and included noise interference; vernix in the external auditory canal of neonates; human resource challenges due to a high patient-to-Audiologist ratio, subsequently resulting in limited coverage; technical and equipment

challenges; as well as early discharge of well babies (Bezuidenhout et al., 2021; Beswick et al., 2021; Gina et al., 2021).

A model of hospital-based hearing screening prior to discharge works well in hospital settings where they are served by single large maternity units and have enough dedicated screeners (Dimitriou et al., 2016). Potential problems may arise for home-centred care and in areas covered by smaller maternity units. Furthermore, difficulties may occur with attending a hospital recall in more rural areas (Bezuidenhout, Khoza-Shangase, De Maayer, et al., 2018). In addition to the latter, challenges with screening infants within certain communities include but are not limited to demographics, accessibility, and costs (Swanepoel et al., 2006) and this has shown to be a major issue, especially in LMICs.

1.3 Current state of NHS in the South African context

As things stand, there are still not enough reliable indicators of the state of NHS programs in South Africa, either in the public or private healthcare systems (Ganek et al., 2023; Kanji, 2016). The available evidence indicates inadequate achievement with implementation of NHS programmes within the South African context, and of the implemented programs, majority of them focus only on risk-based hearing screening. Currently, in South Africa, no legislation exists to implement UNHS and because of resource limitations (HPCSA, 2018). Moreover, evidence suggests that in South Africa, where different types and levels of healthcare exist (primary, secondary and tertiary), NHS programmes have neither been standardised, nor have they been uniformly or universally implemented nationally (Beswick et al., 2021) .

It is however noteworthy that SA has made advances towards achieving universal newborn hearing screening (UNHS) by issuing a hearing screening position statement, which stipulates guideline for NHS. These guidelines propose that: all infants should be screened by 1 month of age, a full diagnostic assessment should be offered by 3 months of age for those infants who fail the initial screening test and infants who are identified with a hearing loss should receive appropriate intervention by no later than 6 months of age.

Although the principles of EHDI programs are supported by the Integrated National Disability Strategy White Paper and the Position Statement produced by the Health Professions Council of South Africa, they are not mandated by hospital management or included as part of mandatory maternal birthing services (HPCSA, 2018; Swanepoel et al., 2009; Mbeki, 1997). Consequently, efforts to implement

EHDI programs remain unsystematic and only existing in certain hospitals with the precise status needing further research (Swanepoel et al., 2009).

In 2008, one year after the recommendations from the HPCSA regarding EHDI were published, Theunissen and Swanepoel reported that only 27 percent of public-sector hospitals in SA were implementing NHS in any form (Theunissen & Swanepoel, 2008). A national survey of audiological services in the private healthcare sector in SA indicated a notable delay in identification and intervention of hearing loss where NHS was available in 53 percent of private healthcare obstetric units in SA of which only 14 percent provided universal screening. (Meyer et al., 2014). Furthermore, with UNHS not being mandated by the SA Department of Health, there is a scarcity of contextually relevant evidence regarding challenges encountered while implementing NHS in public healthcare sector.

1.4 Challenges and barriers to NHS services and accessibility

The authors of this study proposed that some of the causes for the limitations in NHS programs included lack of equipment to screen, budgetary constraints, limited human resource capacity, as well as lack of political mandate by the South African government (Bezuidenhout et al., 2021). These findings have highlighted the need for ensuring that context-specific studies in NHS are conducted to warrant improvements such as smartphone-based OAEs and accessibility to NHS.

Findings of a South African study conducted at public health-sectors in two provinces indicated that there was a shortage of formal, standardized, and systematic EHDI employment at three levels of healthcare (primary, secondary, and tertiary) with reasons such as insufficient knowledge, lack of equipment, budgetary constraints, and human resource capacity challenges being cited for this (Khoza-Shangase et al., 2017). Regardless of the level of healthcare, EHDI implementation as advocated by the HPCSA, currently does not seem feasible, unless barriers are addressed, and NHS becomes nationally mandated (Khoza-Shangase et al., 2017). Regrettably, even in a country like South Africa, where established healthcare infrastructure is developed compared to other LMICs, the vast majority of infants unfortunately have no prospect of having their hearing screened (Kanji, 2016; Swanepoel et al., 2009; World Bank, 2020). The process of screening all newborns for hearing loss at birth is known as universal newborn hearing screening (UNHS). South Africa currently lacks legislation mandating UNHS, and due to resource constraints, targeted screening has been opted for (HPCSA, 2018).

Screening babies with risk factors for hearing loss is known as targeted hearing screening. However, this approach has the danger of excluding a significant number of children with hearing loss since it assumes that the risk factors listed are universal (Bezuidenhout, 2021). Khoza-Shangase endorses adoption of targeted NHS programs as a starting point, particularly in a hospital-settings with inclusion of NHS at the first follow-up visit for all babies, including those without risk factors (Beswick et al., 2021). . This way, NHS coverage can be expanded through integration of maternal-child health services.

An additional way to help overcome the barriers NHS implementation due to lack of equipment, human resources as well as high costs, is through the use of technological advances. The use of mHealth screening tools has been given attention in recent literature in response to the inaccessibility of hearing healthcare services (Swanepoel, 2015). mHealth can therefore help with the bridging of limitations to access of hearing healthcare, especially in LMICs (van Wyk et al., 2019).

1.5 Summary of gaps in the literature regarding smartphone-based NHS

In the increasing scope of digitally enabled audiology, the emerging mHealth sphere is extremely promising and opens novel opportunities for clinicians. In the past years rapid growth of the number and variety of mHealth solutions in hearing healthcare, more especially smartphone-based applications have been expanding with growing interest (Paglialonga et al., 2018). Increasing public knowledge and accessibility to hearing care through the use of digital platforms, such as mHealth technologies, is a scalable solution. At the end of 2019, there were 3.8 billion smartphone users worldwide; ninety percent of these users were new users from LMICs, a growth of 250 million users in just one year (De Sousa et al., 2022). Because of this, mHealth solutions for hearing loss have rapidly increased over the past ten years, especially for hearing screening (De Sousa et al., 2022).

Novel mHealth innovations can now tackle needs and challenges more effectively than conventional hearing healthcare delivery models (Pinciroli & Moen, 2015). Apps in particular are now making the leap from early adopters to mainstream and are giving the way to an enormously outstanding mHealth domain in hearing healthcare. A study revealed that App-store search queries returned 30 apps that could be used for ear and hearing assessments, the majority of which were for performing audiometry (Bright & Pallawela, 2016). The literature search identified 11 eligible validity studies that examined 6 different apps; the uHear was validated in the highest number of peer reviewed studies against gold standard pure tone audiometry (n=5). In a recent clinical trial involving 201 pediatric ears across three healthcare facilities, a low-cost OAE probe demonstrated 100% sensitivity and 88.9% specificity in detecting hearing loss, comparable to results achieved with commercial equipment (Chan et al., 2022). However, this study did not address the OAE device itself; rather, it solely addressed the probe design

(Chan et al., 2022). Another study, carried out at Seattle Children's Hospital, compared the outcomes of an open-source DPOAE probe with a commercially available OAE device that costs around $5,000, utilizing inexpensive, off-the-shelf headphones and microphones costing $10 and the results were comparable (Ali, 2023). There is a gap in the literature regarding objective smartphone-based OAE screening measures in Sub-Saharan Africa, making this study the first of its kind.

1.6 Future direction and innovations

The emergence of equipment that capitalizes on technology and connectivity advances enables affordable and accessible models of service delivery for community-based hearing care (Swanepoel, 2017). Connectivity is rapidly growing with increasingly widespread delivery into underserved communities where audiological services may be enabled through mHealth models (Swanepoel et al., 2010). Benefits of smartphone-based hearing test solutions for both consumers and clinicians, include accessibility, affordability, advanced sensors, and software-based quality control, alongside integrated cloud-based data management (Swanepoel et al., 2019).

Rapid global development in connectivity and technology is shifting the model of accessible hearing healthcare accessibility. When it comes to using smartphone apps to identify, diagnose, and even treat hearing loss, consumers and healthcare professionals have more alternatives than ever before (Swanepoel et al., 2019). Undesirably, only a few of the available apps have been validated in peer-reviewed studies (Bright & Pallawela, 2016), and of the apps that have been validated, further independent research is required to fully understand their accuracy and validity at detecting ear and hearing conditions (Bright & Pallawela, 2016). Further research and validation efforts are therefore necessary to determine whether smartphone-based hearing screening is a feasible and accurate screening tool for NHS programs (Irace et al., 2021).

1.7 Rationale

Late identification of hearing loss in an infant may result in long-term consequences including emotional conflicts, communication delays, cognitive deficits, and subsequently, future vocational challenges and restrictions (JCIH, 2019a; Wroblewska-Seniuk et al., 2018). It was found in a study that children with hearing loss confirmed by ≤ 9 months of age had significantly better scores than those confirmed later on tests of receptive language and expressive language, this therefore emphasizes the importance of NHS as means identify hearing loss before 6 months of age (Pimperton et al., 2017).

The JCIH recommends objective physiological measures as methods to screen for hearing loss in infants due to the poor sensitivity demonstrated by the results yielded by subjective measures (HPCSA, 2007). In some instances, infants go unscreened due to the accessibility barrier. Underserved

regions, especially in LMICs may incorporate mHealth as a way to provide NHS as well as other screening services (Swanepoel et al., 2010).

The WHO guidelines acknowledge the use of digital health and mHealth as a growing method of healthcare (World Health Organization, 1980). Increasing smartphone-based hearing screening is penetrating the world globally, making smartphone-based health devices more accessible. Furthermore, the use of mHealth-based applications for NHS in the South African context may provide resources that will improve accessibility to NHS thus reducing disparities in early intervention. The lack of comprehensive comparative studies between traditional OAE devices and smartphone-based OAE devices in NHS makes this further research relevant in current literature. This study, therefore, aimed to compare the screening outcomes of a smartphone-based DPOAE and TEOAE screening device with that of a conventional, commercially-available OAE device.

2. METHODOLOGY

2.1 Research aim

This study aimed to compare the screening results of a smartphone OAE screening device to an OAE device that is commercially available.

2.2 Research design

A cross-sectional study is a type of research design where you gather data from different individuals at a single point in time (Kesmodel, 2018). A cross-sectional, within-participant comparative design was employed to address the study's aim Each participant had to go through OAE screening, which consisted of either Transient Evoked Otoacoustic Emission (TEOAE) or Distortion Product Otoacoustic Emission (DPOAE) screening. This study collected quantitative data of NHS screening outcomes and was comparative as two devices were used to collect this the same data for outcome comparison purposes. A cross-sectional, within-participant comparative design was deemed appropriate for this study as the population was not selected based on exposure or outcome. To date, the ILO system (Otodynamics Ltd., Hatfield, UK) has been the primary tool used in clinical practice to evaluate TEOAEs (Kochanek et al., 2015). This system was chosen for the current investigation because it was developed in collaboration with the OAE pioneer, Prof. David Kemp, in the late 1970s and is often cited in literature as a reference OAE device (Kochanek et al., 2015). The NHS results from DPOAE and TEOAE were assessed.

2.3 Research context

Pelonomi District hospital and Universitas Academic Hospital are located in the greater Mangaung municipal area and have been serving the communities in and around Free State as well as patients from the Eastern Cape, Northern Cape and Lesotho since 2002. Universitas Academic Hospital is the first ever public-private healthcare partnership of its kind in South Africa and is managed by Netcare.

The NICU at Universitas Academic Hospital delivers care to infants with complex conditions requiring specialized care, therefore only mothers with risk-factors give birth at Universitas Academic Hospital. The NICU can accommodate 12 patients and is divided into three areas to separate infants with medical conditions from patients with surgical conditions and those who need isolation due to infections. The high-care Unit has the capacity to admit 12 infants, and the neonatal ward 16. The lodger facility provides accommodation for 24 mothers (UFS, 2022) . Universitas Academic Hospital

accounts for 70 births on average per month, as opposed to Pelonomi Hospital that accounts for 200 births on average per month. The neonatal unit at Pelonomi Tertiary Hospital is a 34-bedded unit but can admit 40-50 patients. The Kangaroo-Mother-Care Unit (KMC) has a capacity for 20 mother-infant-pairs, with a further 30 beds for lodger mothers (UFS, 2022).

These two tertiary public hospitals are the only ones providing risk-based hearing screening in the Free State. Both hospitals have OAE and AABR screening equipment, although issues with calibration often times arise, consequently leading to lengthy periods of no NHS.

2.4 Ethical clearance considerations

When conducting research ethically, one of the fundamental principles is protecting the human dignity and rights of the participants involved in the study (Chabon et al., 2011). The fundamental ethical principles of justice, autonomy, beneficence, and non-maleficence were ensured by following guiding principles and values. Furthermore, institutional review board the University of Pretoria's Faculty of Humanities' Research Ethics Committee Pretoria (HUM034/0820) (Appendix A); Free State Department of Health (FSDoH) (Appendix B); and the National Health Research Database (NHRD) (FS_202102_006) (Appendix C) were obtained before the collection of data commenced. The individual ethical principles and applications employed during the study are listed and explained below.

Permission

In order to obtain permission to perform the study at Universitas Academic Hospital and Pelonomi Academic Hospital, an information letter outlining the study's protocols was given to each institution's head of department for approval (Appendix B).

Informed consent

All research participation should be voluntary, and participants need to provide informed consent. Participants should also be informed of the aims, methodology, potential risks, and benefits of the study (Brent & Leedy, 1990). A letter explaining the purpose of the research was provided to each hospital (Appendix A), the CEO of the hospital provided written informed consent for the researcher to use the hospital as a research site. Mothers of each participant also received a letter explaining the research and requesting permission for their infant to participate in the research study. The mothers provided written informed consent for the infant to participate.

Anonymity

In this study, every participant's anonymity was maintained by making use of an alpha-numeric system instead of names.

Confidentiality

Caution was taken to maintain the confidentiality of all participants (Brent & Leedy, 1990). Participants' results were kept private unless the participant's mother had granted permission for disclosure. Information was stored securely on an encrypted device and a cloud database.

Skills of the researcher

The researcher was competent due to her qualification and experience as an Audiologist. The research data collection process was supervised in the beginning stages to ensure protocols were being followed. The research study was also be supervised to ensure a seamless research process. All the professionals involved in this study were registered with the Health Professions Council of South Africa (HPCSA)(de Kock et al., 2016). The researcher is ethically obliged to be experienced, truthful, and capable to conduct the various audiological testing.

Protection from harm

According to ethical principles, the researcher may not expose the participants to any form of anxiety, discomfort, or pain that may arise from the research study, within all probable limits. In this study, the welfare of the participants was taken into consideration by making use of non-invasive test procedures including otoscopy, DPOAE, TEOAE as well as ABR is some subsets. No harm was inflicted thereof as outlined in the information letter (Appendix E).

Benefits

All participants were informed that there were no direct benefits for them by consenting to participate in this study, other than infants who failed the NHS were referred to the Audiology and ENT departments of the hospital for further audiologic testing and/ or otological management and follow up (Appendix F).

Release of findings

Caregivers of participants were given information letters informing them that the results obtained in the current study may be published in scientific journals in the (Appendix G). To ensure this research is available to the broader scientific community, a research article was hence compiled and submitted

for publication. Additionally, a research dissertation was compiled and made available both online and in hard copy at the University of Pretoria library.

Data storage

All data pertaining to this study will be stored electronically at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for at least 15 years (Appendix G). Additionally, the research datasets were uploaded the University of Pretoria's Research Data Repository.

Referencing

When cited in the research, all references to previous works should be recognized (Creswell & Clark, 2007). By acknowledging everyone who provided input, plagiarism was prevented in this study. The work of the researcher is reflected in this research report. The University of Pretoria's rules for appropriate citation and referencing of all secondary material used in this dissertation were followed. The researcher has signed a declaration of originality.

2.5 Research participants

The target population for this study was infants born at Pelonomi District Hospital, and Universitas Academic Hospital. The inclusion criteria were infants three months of age or younger, as well as the ability and willingness of a participant or parent / legal representative to sign a consent form. The exclusion criteria were infants with active otorrhea or those diagnosed with neurological disorders at birth.

A total of 352 ears were screened for the purpose of this study. The mean age at the time of screening was 4.5 days which is more than the typical median age of identification of hearing loss at the Otorhinolaryngology Clinic at Universitas Hospital (44.5 months) (Butler et al., 2013). The mean age of hearing loss identification is far older than the benchmark suggested by the HPCSA, of 4 months of age (HPCSA, 2018). Statistical power was calculated before data collection using ANOVA to ascertain that a suitable sample size was available (Leedy & Ormrod, 2014). The statistical power analysis was indicative of 80% power, given 9% discordance between the screening devices. The sample size, even with excluded data, was sufficient enough to answer the research question at hand (Schmidt et al., 2018).

2.6.1 Data collection apparatus and materials

Following all necessary ethical approvals, and permission from the FS DoH (Appendix B) to use Universitas Academic Hospital and Pelonomi district hospital as sites for the study, the data collection commenced. NHS was conducted in the post-natal maternity ward and the neonatal intensive care

unit (NICU) of the hospitals over a period of 8 months. Within participant DPOAE and TEOAE screening outcomes of a smartphone-based OAE device (hearOAE) were compared to that of the Otodynamics ILO V6. Infants were identified according to the inclusion criteria outline in section 2.5. Data collected for these infants included either TEOAE or DPOAE results for each infant. A detailed description of the materials and procedure used is described below. Otoscope: Welch-Allyn otoscope used to examine the outer ear canal.

Speculum: cone-shaped attachment.

Alcohol swabs: used to disinfect the speculum after use.

hearOAE device: A device consisting of two parts; first, the Codec device that contains the hardware (version 0503) and software (version 2020-11) for signal generation and measurement and second, a probe connected to the Codec made up of two drivers/receivers and a microphone (version 1.0). The hearOAE was connected to and operated using hearOAE application (V1.3-dev) loaded on a smart tablet, Samsung Galaxy Tab A, via Bluetooth. The hearOAE was calibrated according to EN 60645-6 'Electroacoustics – Audiometric equipment – Part 6: Instruments for measurement of OAEs'.

Otodynamics ILO v6: A portable device operated through a laptop and software (version 6) that stored test results on the laptop database. A probe-cavity check for the Otodynamics was performed on a weekly basis using an optically transparent 1cc probe cavity.

Probe tips: available in various sizes and inserted into the participant's ear in order to measure middle ear functioning.

Table 1 represents the collection parameters and pass criteria for the equipment used for DPOAE testing.

Table 1. Distortion-product otoacoustic emissions (DPOAE) collection parameters and pass criteria for hearXand Otodynamics ILO v6

Parameter	User-adjustable limits for setting protocol	Adjusted protocol
Frequencies (kHz)	1, 1.5, 2, 3, 4	1, 1.5, 2, 3, 4, 6
Pass Criteria – Number of Bands Passed	3,4/4 OR 3, 4, 5,6/6	4/6
Pass Criteria – SNR Level (dB SPL)	6, 9, 12	6
Level (L1/L2)	65/55 OR 75/70	65/55
Noise rejection level (dB SPL)	40-60 50	50

dB: decibel; DPOAE: distortion-product otoacoustic emissions; kHz: kilohertz; L1: level 1; L2: level 2; F1: frequency 1; F2: frequency 2 SPL: sound pressure level

Table 2 represents the collection parameters and pass criteria for the equipment used for TEOAE testing.

Table 2. TEOAE collection parameters and pass criteria for hearOAE and Otodynamics ILO v6

Parameter	User-adjustable limits for setting protocol	Adjusted protocol
Frequencies (kHz)	1, 1.5, 2, 3, 4	1, 1.5, 2, 3, 4
Pass Criteria – Number of Bands Passed	3,4/4 OR 3, 4,5/5	3/5
Pass Criteria – SNR Level (dB SPL)	3, 4, 6, 9	3
Sweeps	80-300	240
Target stimulus (dB SPL)	70-90	80
Noise rejection level (dB SPL)	40-60	50

dB: decibel; kHz: kilohertz; TEOAE: transient-evoked otoacoustic emissions SPL: sound pressure level

Rationale for adjusted protocols for DPOAE and TEOAE

The choice of a protocol very much depends on the purpose of the screening and what information a clinician aims to gain from obtaining the measurement (Ramos, 2023). The adjusted protocols for the current study were therefore selected on the basis of being able to compare the two devices with the same criteria. The adjusted protocol ensured that the screening results were not only valid, but also had the exact same parameters for both the Otodynamics ILO as well as the hearOAE device.

2.6.2 Data collection procedures

An NHS programme was implemented at two tertiary hospitals. The screener completed a test form prior to each screening including an information and informed consent form signed by the parent or caregiver. The NHS was performed in a non-sound treated rooms by the primary investigator. This setting is one that we generally faced with in SA, where NHS is performed in acoustically sub-optimal contexts (Kanji, 2016). The researcher used two types of equipment (hearOAE screener and Otodynamics ILO v6) with the same testing protocol and pass criteria for comparison purposes. Although a sound level meter was not used when conducting screenings, both screening devices measured noise levels through the probe microphone and would indicate if noise levels were too high. The start ear between each test was alternated in a randomised manner. The screening equipment was also alternated daily. Alternating them assisted in avoiding equipment and test-ear bias. The probe-tip was cleaned with an alcohol swab or dipped in isopropyl alcohol after each measurement for infection control. The body of the OAE machines was also cleaned using a soft, dry cloth as per device-care recommendations. No abrasive cleaning agents, thinners or benzene were used. Prospective data was captured over eight months.

Prior to screening, an otoscopic examination was performed using a Welch Allyn otoscope to check for any active discharge prior to the OAE screening. If obvious discharge was detected unilaterally, the other ear was still tested. Infants presenting with any otologic discharge were referred to an ear-nose-throat (ENT) specialist in the hospital for further evaluation (Appendix F).

Next, a bilateral screening with either DPOAE or TEOAE was performed with both the Otodynamics ILO and hearOAE devices. Either screening device was used to perform the screening in a randomized, alternating method between the infants using a pre-compiled list. Completed OAEs were automatically recorded, and the results were displayed on the screen of tablet or the laptop as either a pass or a refer specific to their frequencies. The results of the NHS were communicated to the infant's mother. A test form was completed for every participant screened at the hospitals and the results were transferred to the infant's file (Appendix H). Screening results were recorded in the participant's Road-to-Health booklet. In the case where the infant was crying or unsettled, the test was terminated, and the mother was allowed to soothe the infant before the continuation of the test. In event of a refer result, a second screening was performed using the Otodynamics ILO and if the second screening also referred, the mother was counselled and issued with a referral letter (Appendix F) for tympanograms and/or a diagnostic assessment. Only the initial screening result was used for the objectives of this study.

Lastly, the raw data collected was exported from the Otodynamics software and the hearOAE cloud, afterwards, prepared for analysis. Data that could not be used i.e., where only one measurement could be obtained because of the infant being unsettled, or where screening was incomplete was removed from the dataset. The data was then consolidated on an Excel spreadsheet for further analysis.

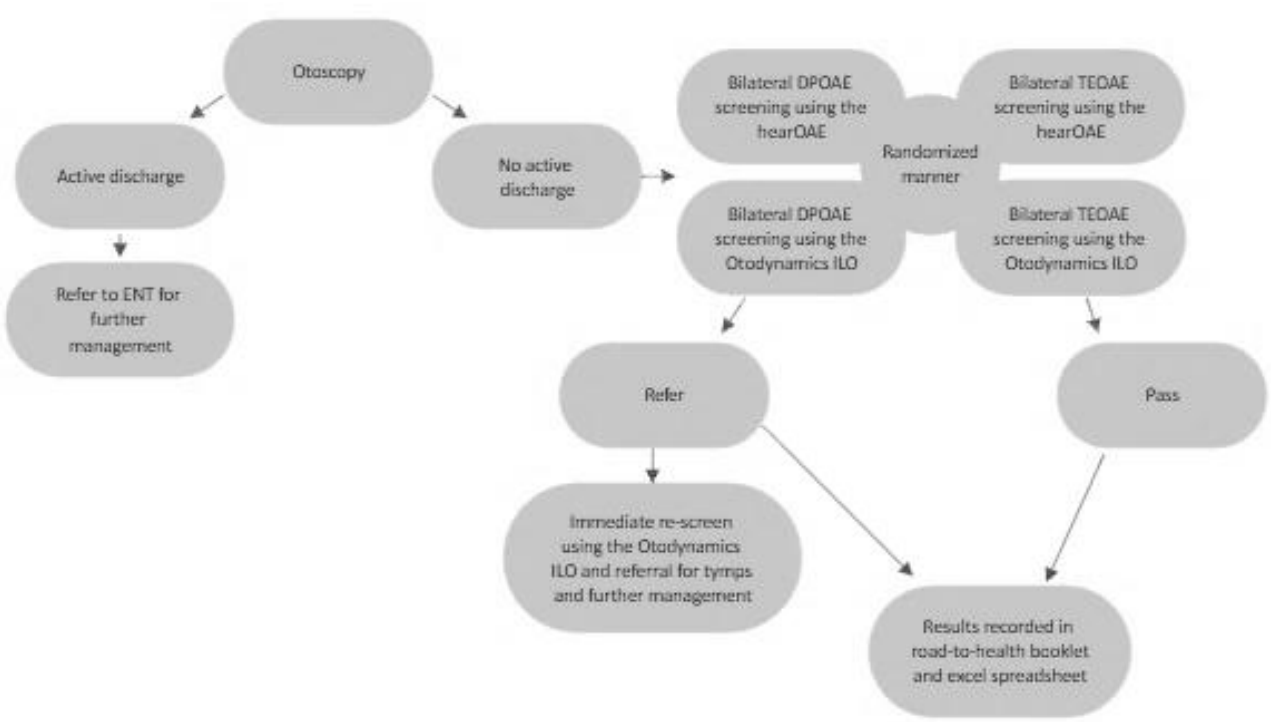

Figure 1. Flow diagram illustrating the screening protocol used in the study

2.7 Data processing and analysis

A total of 176 infants were included in the sample with a total of three ears excluded from the infant group: two ears were within-participant comparison using TEOAEs with both hearOAE and Otodynamics ILO could not be recorded, and one ear where within-participant comparison using the DPOAEs with both devices could not be completed.

All data from the Otodynamics ILO device was exported to Microsoft Excel. The data from the hearOAE device was stored remotely on a cloud-based database. The data from the two devices was then transferred to SPSS v28 software and analyzed using a 5% level of significance. Only the data from the initial NHS was used, therefore, if a re-screening was performed, results for the test were not included for the purpose of this study. The absolute amplitude of the OAE was referred to as the 'signal,' and the difference between the absolute amplitude of the OAE and the noise floor was referred to as the SNR. These, together with the noise floor, were measured in decibel sound pressure level (dB SPL). Both mean and total (summed) OAE signal, SNR, and noise levels were calculated across frequencies to account for any frequencies with missing data with one or both devices. In order to achieve this, frequency-specific OAE measurements in dB were converted to Pascal, summed and averaged across frequencies, and then converted back to dB in order to determine the total and mean OAE signal, SNR, and noise. Frequency-specific, total, and mean OAE measurements were consequently described using mean and standard deviation (SD).

The normality of continuous variables was evaluated using the Shapiro-Wilk test. The parametric paired t-test (t) was used for variables that were normally distributed, whereas, for variables that were non-normal, the nonparametric Wilcoxon signed-rank (WSR) test was used to test for differences in cases where the same participants were involved. The WSR test (Z_{WSR}) was utilized for all frequencies except 1 kHz, where paired t-test was used to determine the significance of differences between SNR, overall noise, and overall signal of the two screening technologies. The Mann-Whitney U-test (Z_U) was applied to evaluate if the device outcomes differed with respect to infant age at testing. The Pearson Chi-square test (X^2) was applied also applied to the categorical data to evaluate the differences between the two devices. Binary logistic regression analysis was performed to identify the associations of the categorical and continuous independent variables (age, status, and device) with the dependent variables (pass/refer). The percentage concordance in outcome (for both pass and refer outcomes) between the two devices for both DPOAEs and TEOAEs was calculated per ear specifically.

2.8 Validity and reliability

Reliability refers to the extent to which the same answers can be obtained using the same instruments more than one time (Mann, 2003). Validity in research is the ability to conduct an accurate study with the right tools and conditions to yield acceptable and reliable data that can be reproduced (Chabon et al., 2011). Researchers rely on carefully calibrated tools for precise measurements. The researcher enhanced both the reliability and validity in the current study.

Firstly, the choice of data collection materials included an established OAE device (Otodynamics ILO v6) which was one of the first OAE devices founded in the late 1970s and has therefore been validated and deemed a reliable OAE screener over the years (Hurley & Musiek, 1994). A statistical power analysis was performed prior to commencement of data collection to determine the significance of the sample size of the population and appropriate time scale for the study was selected to allow for sufficient time to collect enough data. The power calculations indicated 80% power, given 9% discordance between the screening devices.

During the period of data collection, probe calibration was performed in both equipments prior to the commencement of screening at each NHS site. This ensured reliability of the screening outcomes. The researcher coded the data into an Excel spreadsheet as well as on a cloud-based system. Quality monitoring of data entries was applied on weekly basis in the electronic data sheet. Additionally, another Audiologist and an engineer verified the data entries so that the data's accuracy, quality, and objectivity were not compromised (Leedy & Ormrod, 2014). The primary investigator along with two additional qualified audiologists assisted with NHS and administration tasks at the data collection sites. All three audiologists were registered with the HPCSA and had a minimum of one year experience with NHS. The results were analysed using appropriate and robust statistical techniques and software as discussed in the data processing and analysis section.

3. NEWBORN HEARING SCREENING USING A SMARTPHONE-BASED OTOACOUSTIC EMISSION DEVICE: A COMPARATIVE STUDY

Authors: Andani Gluggy Madzivhandila, Prof Talita le Roux,

Prof Marien Graham, Prof Leigh de Jager Biagio

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3.1 ABSTRACT

Objective: Increasing options are becoming available for clinicians and healthcare professionals who use smartphone-based applications (apps) to identify hearing loss. The use of smartphone-based apps for newborn hearing screening (NHS) has been proposed as an alternative screening method in NHS programs. This study aims to compare the screening outcomes of a smartphone-based otoacoustic emission (OAE) screening device to a commercially available OAE screening device.

Methods: NHS was conducted in the post-natal maternity ward and neonatal intensive care unit (NICU) of two tertiary public healthcare hospitals over a period of 8 months. Within participant DPOAE and TEOAE screening outcomes of a smartphone-based OAE device (hearOAE) were compared to that of the Otodynamics ILO V6.

Results: A total of 176 infants (n=352 ears; 48.9% female) underwent NHS (DPOAE n=176; TEOAE n=176). The mean age at was 4.5 days (SD 11.3). Signal-to-noise ratio (SNR) were higher with the hearOAE with TEOAE NHS, and equivalent or higher SNR at four out of six frequencies with DPOAEs. Mean and total noise levels were significantly lower for the hearOAE compared to the Otodynamics with DPOAEs noise levels of five out of six frequencies being equivalent to, or lower than the Otodynamics ($p<0.001$). Lower noise levels are likely to be advantageous in less-than-ideal test conditions. Inter-device DPOAE comparison indicated no statistically significant difference in the refer rate between the devices ($p=0.238$). *DPOAE pass rates between devices differed in 6 ears ($p>0.05$), and in 20 ears for TEOAEs, with the hearOAE demonstrating a higher TEOAE pass rate ($p=0.009$). The HearOAE did, however, demonstrate lower noise levels at three out five frequencies, which may have impacted the pass rate.* No statistically significant correlation was found between the independent variables and the screening outcome (pass / refer) for TEOAEs using either device ($p=0.105$ to 0.810).

A high concordance of NHS outcomes within-participants of 89.7% and 85.0% for DPOAE and TEOAE respectively, was measured.

Conclusions: The mHealth based OAE device demonstrated good agreement in NHS outcomes compared to a commercially available device. This verifies the performance of the novel smartphone based OAE device, and may facilitate increased accessibility of decentralised NHS service in resource constrained populations

Keywords: Newborn hearing screening, mHealth, Distortion Product Otoacoustic Emissions, Transient Evoked Otoacoustic Emissions, telehealth, mHealth.

3.2 INTRODUCTION

Hearing loss is the most prevalent sensory disability globally and a condition that is of growing concern (Mulwafu et al., 2016). Recent estimates by the World Health Organisation (WHO) have shown an increase in the prevalence of children with disabling hearing loss (Neumann et al., 2019). It is estimated that at least thirty-four million children globally under the age of fifteen have disabling hearing loss (World Health Organisation, 2021). Congenital/early-onset childhood hearing loss is associated with delayed speech and language development (Parab et al., 2018). Cognitive, social, emotional, as well as academic development are subsequently also negatively affected (Lieu et al., 2020)(JCIH, 2019a). Newborn hearing screening (NHS) protocols reportedly reduce adverse effects in the future (Brodie et al., 2022). The Early Hearing Detection and Intervention (EHDI) benchmark of the "1-3-6 principle" as proposed by the Joint Committee on Infant Hearing (JCIH), states that all infants' hearing should be screened by 1 month, hearing loss should be diagnosed by 3 months, and intervention should commence by six months of age (JCIH, 2019a). Evidence suggests that children with hearing loss who were identified earlier and received early intervention, have better speech and language outcomes when compared to those whose hearing loss diagnosis and intervention were delayed (Yoshinaga-Itano et al., 2018)(World Health Organisation, 2021). Advocacy for universal NHS is based on two concepts. First, a critical period exists for optimal language skills to develop; and second, timely intervention of hearing loss has been shown to improve communication skills (Yoshinaga-Itano et al., 2018). The positive long-term effects of early detection and intervention through NHS on children's language, cognition, and academic development are well documented (Lieu et al., 2020)(JCIH, 2019a). NHS, subsequent diagnosis and intervention, offers children with congenital/early onset hearing loss the best chance for age-appropriate speech and language development.

The JCIH recommends objective measures as methods for NHS due to the poor sensitivity demonstrated by the results yielded by subjective measures in terms of outcomes (Yoshinaga-Itano et al., 2018). NHS protocols vary globally, and this may be due to what is considered feasible for specific contexts (Akinpelu et al., 2014). Currently, otoacoustic emissions (OAE) and/or automated auditory brainstem response (AABR) screening for infants are recommended as screening tools in NHS programs (Akinpelu et al., 2014). The most commonly used model for NHS has been a hospital-based screening program employing a team of dedicated screeners measuring OAEs in infants prior to discharge (Owen et al., 2001). Evoked OAEs, namely, transient evoked OAEs (TEOAEs) and distortion-product OAEs (DPOAEs), are commonly used techniques for testing the integrity of the outer hair cells of the cochlea due to their efficacy and test outcomes. Both TE- and DPOAEs are highly sensitive (85-100%) and specific (91-95%) (T. Dawood & Sultana, 2018)(Eiserman et al., 2008b).

A model of hospital-based NHS prior to discharge works well in hospital settings where the hospitals are served by single large maternity units (Dimitriou et al., 2016). Challenges that may occur with NHS within certain hospitals include, but are not limited to, poor infrastructure, demographics, accessibility, costs, and limited hearing screening programs, which thus affect the implementation of NHS across low-middle-income countries (LMICs) as well as upper-middle-income countries (UMICs) (Swanepoel et al., 2006)(World Bank, 2020). Challenges to NHS include insufficient resources, human resources, and high patient load (Kanji, 2016; Khoza-Shangase et al., 2017). Furthermore, the challenges in LMICs are exacerbated due to additional burdens such as poverty or life-threatening conditions, such as tuberculosis (TB) and human immunodeficiency virus and/or acquired immunodeficiency syndrome (HIV and/or AIDS) (Khoza-Shangase et al., 2017). These are viewed as a priority, whilst hearing loss may be viewed as less urgent (Khoza-Shangase et al., 2017). Moreover, the COVID-19 pandemic has put further strain on available resources (Pattisapu et al., 2020).

Countries in sub-Saharan Africa still appear to be in the initial stages of implementing NHS programs for the early identification of hearing loss, especially due to limited access to healthcare services. Evidence suggests that in sub-Saharan Africa, where several types and levels of healthcare exist, NHS programs have not been standardized or uniformly implemented (Bezuidenhout et al., 2021; Lasisi et al., 2014). Regrettably, it is estimated that less than 10% of the one million infants born annually in South Africa, for instance, will have the prospect to have their hearing screened (Meyer et al., 2012). Thus, many children in sub-Saharan Africa with congenital/early-onset hearing loss will most likely not receive NHS and consequently not receive critically required early auditory stimulation (Meyer et al., 2012). Increased efforts towards ensuring NHS are therefore required in resource-constrained contexts.

Increasing options are becoming available for consumers and clinicians who use mHealth-based smartphone applications to detect, diagnose, and treat hearing loss (Swanepoel et al., 2019). Advantages of smartphone-based digital hearing screening solutions, for both the consumer and clinician, include accessibility, affordability, and software-based quality control, alongside integrated cloud-based data management (de Kock et al., 2016)(Swanepoel et al., 2010). A study was conducted using a smartphone-based pure-tone audiometry application to subjectively screen for hearing loss in children and adults at primary healthcare clinics (Swanepoel, 2015). The application provided time-efficient identification of hearing loss, with adequate sensitivity and specificity for accurate testing in primary healthcare settings for a cooperative population (Swanepoel, 2017)(Swanepoel, 2015)(Yousuf Hussein et al., 2018). In a systematic review, it was indicated that only a few applications that are currently available for screening and diagnostic hearing assessment have been validated in peer-reviewed studies (Bright & Pallawela, 2016b). Of these applications that have been validated,

none of them have been appropriate for NHS, and further research is required to fully understand their accuracy in detecting ear and hearing pathology (Bright & Pallawela, 2016b), (Swanepoel, 2017).

A smartphone-based OAE device, the hearOAE, was recently developed by the hearX group and the screening version of the OAE software offers automation of DPOAE and TEOAE test procedures and the interpretation of the results (Swanepoel, 2015). An mHealth device such as the hearOAE has the potential to offer NHS at a significantly reduced cost, thereby increasing accessibility to the equipment and NHS services in resource-constrained communities. The integration of low-cost mHealth technologies in hearing health care facilitates the decentralization of services to communities and health centres in LMICs and UMICs as the first point of access (Yousuf Hussein et al., 2018). Several OAE systems are currently available commercially, but empirical evidence on their performance is limited for most devices. Also, to the authors' knowledge, there are no smartphone-based OAE devices available. Therefore, the current study aimed to compare the NHS outcomes of a smartphone-based OAE screener to an empirically validated, commercially available OAE device. More specifically, the within-participant outcomes of the OAEs, in terms of screening concordance, signal, noise, and SNRs, were compared.

MATERIAL AND METHODS

3.3.1 Study design

A cross-sectional, within-participant comparative design was employed to compare the screening outcomes of a smartphone-based OAE screener (hearOAE) to a commercially available, established OAE screening device (Otodynamics ILO v6). To date, TEOAEs have been assessed in clinical practice mainly using the ILO system (Otodynamics Ltd., Hatfield, UK) (Kochanek et al., 2015). This system is often considered as a reference OAE device and is frequently referred to in literature as it was created jointly with the pioneer of OAEs (Prof. David Kemp), in the late 1970s, which is why it was chosen for the purpose of the current study (Kochanek et al., 2015). Both DPOAE and TEOAE NHS outcomes were evaluated. The study was approved by the Faculty of Humanities and the Faculty of Health Sciences at the University of Pretoria (HUM034/0820), as well as by the Free State Department of Health (FSDoH), on the National Health Research Database (FS_202102_006).

3.3.2 Research setting

An NHS program was initiated at two tertiary public healthcare hospitals in the Free State province in South Africa. The NHS program at both hospitals implemented a one-step TEOAE and DPOAE screening protocol at a tertiary healthcare level where only OAEs were performed as a screening measure on each infant (Benito-Orejas et al., 2008; Sheng et al., 2021). The study was conducted in the post-natal

maternity unit, and the baby-room of the two hospitals or in a quiet adjacent room. The post-natal maternity ward of a Tertiary Hospital encompassed twenty wards with four beds in each ward. The beds were not always fully occupied. The baby-room at an Academic Hospital consists of a single ward with sixteen beds, and the infant population that underwent NHS was made up of graduates of the neonatal intensive care units (NICU) who were ready to be discharged. The infants were classified into three categories based on their risk for presenting with congenital/early onset hearing loss, namely: 'no-risk' infants; 'at-risk' infants; and infants admitted to NICU. All infants born with risk factors for hearing loss according to the JCIH EHDI position statement (2019) but were not admitted to the NICU were classified under the 'at-risk' category (JCIH, 2019a).

3.3.3 Study population

The inclusion criteria for infants were specified as infants <three months of age, as well as the willingness of the caregiver to give consent for NHS and for participation in the study. Infants with active otorrhea and those with diagnosed neurological disorders that were verified according to the information indicated in their "Road-to-Health" booklets (a record of the infant's growth, development and immunization), were excluded as study participants. Informed consent was obtained from each parent/caregiver before enrolment in the study. No parent/caregiver refused to consent to the NHS service and to participate in the study.

A total of 176 infants (352 ears; 48.9% female) underwent hearing screening by a dedicated screener. Of the total sample, 50% (n=176 ears) of infants were screened with DPOAE and 50% (n=176 ears) were screened with TEOAE. The mean age at the time of screening was 4.5 days (SD 11.30), with the minimum age being a few hours after birth and the maximum age being approximately (13 weeks). For the total sample, the mean birth weight was 303.66 grams (SD 0.46) (n=176). The majority (72.2%) of the infants were categorized as no-risk infants, whereas 13.0% were considered 'at-risk.' Infants who were admitted to the NICU amounted to 14.8% of the study sample.

3.3.4 Material and apparatus

DPOAE and TEOAE screenings were performed using both the commercially available OAE screening device, namely the Otodynamics ILO288 Echoport Plus OAE system, as well as the smartphone-based OAE screener device, the hearOAE. The Otodynamics ILO OAE device operated through a laptop and software (version 6) that stored test results on the laptop database (Abdollahi et al., 2016; J. H. Kim et al., 2011). The manufacturers of the hearOAE device (hearX) complied with recommended manufacturing practices as dictated by ISO 13485 and 21 CFR part 820. The hearOAE consists of 1) the Codec device that contains the hardware (version 0503) and software (version 2020-11) for signal

generation and measurement; and 2) a probe connected to the Codec made up of two drivers/receivers and a microphone (version 1.0). The Codec device is powered by a rechargeable battery. The hearOAE was connected to and operated using hearOAE application (V1.3-dev) loaded on a smart device, Samsung Galaxy Tab A, via Bluetooth.

Prior to commencement of data collection, the hearOAE was calibrated according to EN 60645-6 'Electroacoustics – Audiometric equipment – Part 6: Instruments for measurement of OAEs'. Device validation was done in accordance with the requirements of EN 60645-6, §6 'Demonstration of conformity with specification'.

The hearOAE used a single-option operation and was solely dedicated to screening, while the Otodynamics ILO devices required a menu of steps because it has multiple clinical applications. Probe tips in various sizes were used to measure the OAEs, and alcohol swabs were used to disinfect reusable probe tips after each use. Probe cavity check for the Otodynamics was performed on a weekly basis using an optically transparent 1cc probe cavity. Responses at 1, 2, and 4 KHz were observed where any variation in response greater than 3 dB SPL was accepted as significant. In the case where the probe was off-calibration, the sound tubes were checked, and the couplers were changed then calibration was repeated. The hearOAE probe cavity check followed a similar procedure. To check hearOAE volume calibration, "cavity check" tab on the start screen was selected, then the probe was inserted into the volume cavity of the Codec and a green tick was displayed on the screen once calibration was successfully complete. The researcher could not move onto the screening protocol screen in the case where the probe was off-calibration. Re-calibration had to therefore be repeated for researcher to continue with NHS.

The DPOAE screening protocol used included a 65/55 dB SPL stimulus intensity for the lower f1 frequency and higher f2 frequency. The frequencies tested were 1, 1.5, 2, 3, 4 and 6 kHz for DPOAE in both screening devices. The overall pass criterion for DPOAE screening was a DPOAE signal-to-noise ratio (SNR) of greater than or equal to 6 dB for four out of six test frequencies in both screening devices (Kanji & Naude, 2021). The frequencies tested for TEOAEs were 1, 1.5, 2, 3, and 4 kHz. TEOAE stimulus intensity level was presented at 80 dB SPL, and the overall pass criterion was an SNR of 3 dB or more in three out of five frequencies. Both devices required a probe fit check before the commencement of each OAEs screen. The hearOAEs integrated cloud-based data management system allowed for remote monitoring of testing, thus allowing for an audiologist or program coordinator to intervene when required. The data collected was stored on a secure AWS cloud server. AES256 encryption was used to encrypt the data at rest in the cloud. The cloud data management system was also fully POPIA

compliant. Additionally, the integrated cloud-based data management system also allowed for advanced features such as location-based referrals and reporting.

3.3.5 Screening personnel

The first author (an audiologist with experience in NHS) was the designated screener at the two hospital sites. Two additional qualified audiologists assisted with NHS and administration tasks at the data collection sites.

3.3.6 Protocols and methods

A bilateral screening with either DPOAE or TEOAE was performed with both the Otodynamics ILO and hearOAE devices. Either screening device was used to perform the screening in a randomized, alternating method between the infants using a pre-compiled list. Bilateral screening was employed with either DPOAE or TEOAE.

In instances where an infant became restless or irritable during the NHS, the parent/caregiver was asked to attempt to feed, swaddle, and/or calm the infant. If the screener was unable to test an infant due to high noise levels and restlessness, the caregiver was asked to return at a follow-up appointment. Infants with a unilateral or bilateral refer outcome were referred for a second screening, scheduled to coincide with their next post-natal follow-up visit. The follow-up screening was performed using the hospital's OAE screening device (Path Medical OAE screener). Only DPOAE was performed for the follow-up screening. The follow-up screening did not follow the protocol of the current study, and these results were not included in the data reported. If a second unilateral or bilateral refer result was obtained, the infant was referred directly to the respective tertiary hospital for tympanometry, diagnostic audiological and ear, nose, and throat (ENT) services where considered necessary. Parents/caregivers who consented to participate were counselled regarding normal speech, language, and hearing development, regardless of NHS outcome.

3.3.7 Data analysis

A total of 176 infants were included in the sample. DPOAE screening was completed in 175 infant ears while TEOAE screening was completed in 174 infant ears. A total of three ears were excluded from the infant group: two ears were within-participant comparison using TEOAEs with both hearOAE and Otodynamics ILO could not be recorded, and one ear where within-participant comparison using the DPOAEs with both devices could not be completed.

All data from the Otodynamics ILO device was exported to Microsoft Excel. The data from the hearOAE device was stored remotely on a cloud-based database. The data from the two devices was then

transferred to SPSS v28 software and analyzed using a 5% level of significance. Only the data from the initial NHS was used. The absolute amplitude of the OAE was referred to as the 'signal,' and the difference between the absolute amplitude of the OAE and the noise floor was referred to as the SNR. These, together with the noise floor, were measured in decibel sound pressure level (dB SPL). Both mean and total (summed) OAE signal, SNR, and noise levels were calculated across frequencies to account for any frequencies with missing data with one or both devices. In order to achieve this, frequency-specific OAE measurements in dB were converted to Pascal, summed and averaged across frequencies, and then converted back to dB in order to determine the total and mean OAE signal, SNR, and noise. Frequency-specific, total, and mean OAE measurements were consequently described using mean and standard deviation (SD).

The normality of continuous variables was evaluated using the Shapiro-Wilk test. The parametric paired t-test (t) was used for variables that were normally distributed, whereas, for variables that were non-normal, the nonparametric Wilcoxon signed-rank (WSR) test was used to test for differences in cases where the same participants were involved. The WSR test (Z_{WSR}) was utilized for all frequencies except 1 kHz, where paired t-test was used to determine the significance of differences between SNR, overall noise, and overall signal of the two screening technologies. The Mann-Whitney U-test (Z_U) was applied to evaluate if the device outcomes differed with respect to infant age at testing. The Pearson Chi-square test (X^2) was applied also applied to the categorical data to evaluate the differences between the two devices. Binary logistic regression analysis was performed to identify the associations of the categorical and continuous independent variables (age, status, and device) with the dependent variables (pass/refer). The percentage concordance in outcome (for both pass and refer outcomes) between the two devices for both DPOAEs and TEOAEs was calculated per ear specifically.

3.4 RESULTS

DPOAE

Within-participant comparisons between the DPOAE measures across frequencies with the Otodynamics ILO and hearOAE screening devices are presented in Table 3. Both the mean and total (summed) signal, noise, and SNR values across frequencies are shown.

Table 3. ***DPOAE mean and standard deviation for mean and total signal, noise, and SNR (n=175 ears)***

	Otodynamics ILO (dB SPL)		hearOAE (dB SPL)	
	Mean	SD	Mean	SD
TOTAL				
Signal**	14.57	10.51	10.98	9.60
Noise**	9.50	6.40	5.84	5.54
SNR*	18.36	12.19	17.40	9.40
MEAN				
Signal**	7.45	10.37	2.63	9.44
Noise**	2.37	6.34	-2.51	5.44
SNR**	11.24	11.85	9.05	9.26

*dB: Decibels, SD: Standard deviation, SPL: Sound Pressure Level; * p<.05; ** p<0.001*

Mean and total OAE, signal, and noise levels in consecutive measurements for six frequencies (1, 1.5, 2, 3, 4, and 6 kHz) were recorded. A Wilcoxon signed rank test revealed statistically significant within-participant DPOAE differences between devices with reference to both total and mean signal, noise, and SNR values across frequencies (t=-7.90 to -3.00; p=0.000 to 0.004). SNR was significantly higher for the Otodynamics ILO (total=18.86 dB; mean=11.24 dB) when compared to the hearOAE (total=17.40 dB; mean=9.05 dB). Noise levels were, however, significantly lower for the hearOAE (total= 5.84 dB; mean= -2.51 dB) than for the Otodynamics ILO (total=9.50 dB; mean=2.37 dB). There was no statistically significant difference in the refer rate between devices (X^2(1, n=176)=2.000; p=0.238). Within-participant diagnostic concordance between devices was 89.7% for DPOAE screening.

Table 4 represents the SNR, signal, and noise levels per frequency for DPOAE in both the Otodynamics ILO and the hearOAE devices.

Table 4. ***Frequency-specific DPOAE screening variable outcomes for Otodynamics and hearOAE (n=175 ears)***

	Frequency	Otodynamics		hearOAE	
		Mean	**SD**	**Mean**	**SD**
Signal (dB SPL)	1 kHz*	4.57	8.94	4.49	10.84
	1.5 kHz**	4.56	11.97	1.04	11.74
	2 kHz**	6.64	12.65	2.29	12.45
	3 kHz**	2.36	13.01	-1.27	12.77
	4 kHz**	1.52	13.18	-2.97	11.51
	6kHz**	4.77	15.00	-3.31	11.12
Noise (dB SPL)	1 kHz*	5.39	7.14	3.16	6.40
	1.5 kHz**	2.21	6.09	-2.55	6.21
	2 kHz**	-1.31	5.92	-6.31	5.63
	3 kHz**	-4.88	5.75	-9.75	5.30
	4 kHz**	-6.89	5.63	-11.66	4.35
	6 kHz**	-9.15	4.68	-12.68	4.90
SNR (dB SPL)	1 kHz*	-0.83	7.83	1.34	9.14
	1.5 kHz	2.35	10.93	3.59	9.29
	2 kHz	7.95	11.72	8.59	10.76
	3 kHz	7.24	12.02	8.48	11.29
	4 kHz	8.42	12.45	8.69	10.19
	6 kHz**	15.24	15.23	9.37	11.08

*dB: Decibels, SD: Standard deviation, SPL: Sound Pressure Level * p<0.05; ** p<0.001*

Statistically significant differences between signal (*t*=-6.535 to -3.942; all p<0.001) and noise (*t*=-8.037 to -4.386; all p<0.001) levels were measured at each frequency. No statistically significant differences in SNR levels were measured between devices at 1.5 to 4 kHz (*t*=-0.930 to -0.229; p=0.117 to 0.482). Statically larger SNRs were measured with the Otodynamics ILO at 1 kHz (*t*=-2.632; p=0.008). Noise levels were statistically lower for all frequencies with the hearOAE compared to the Otodynamics ILO (t=-4.374 to 0.369; p=<0.001 to 0.014).

TEOAE

Within-participant comparisons between the TEOAE measures across frequencies with the Otodynamics ILO and hearOAE screening devices are presented in Table 5.

Table 5. ***TEOAE mean and standard deviations for signal, noise, and SNR and mean signal, noise, and SNR (n=174 ears)***

	Otodynamics (dB SPL)		hearOAE (dB SPL)	
	Mean	SD	Mean	SD
TOTAL				
Signal**	10.94	6.33	13.40	6.39
Noise*	9.72	3.85	10.43	4.53
SNR**	9.25	5.25	11.18	5.01
MEAN				
Signal**	3.95	6.33	6.41	6.39
Noise*	2.73	3.85	3.44	4.53
SNR**	2.26	5.25	4.19	5.01

*dB: Decibels, SD: Standard deviation, SPL: Sound Pressure Level; * p<.05; ** p<0.001*

Statistically higher SNR (Z_{WSR}=-6.664; p=0.002), signal (Z_{WSR}=-6.199; p<0.001), and noise levels (Z_{WSR}=-2.021; p=0.043) were recorded for the hearOAE compared to the Otodynamics ILO. The total SNR for the Otodynamics ILO was overall 1.93 dB lower than the hearOAE (p<0.001). The DPOAE pass rates of the devices varied in 6 ears (p>0.05), and for TEOAEs, there were differences in 20 ears (p=0.009), with the hearOAE showing a greater TEOAE pass rate. A within-participant percentage of concordance between devices of 85.0% was calculated.

Table 6 displays the frequency-specific SNR, signal, and noise levels for TEOAE in both the Otodynamics ILO and the hearOAE devices.

Table 6. ***Frequency-specific TEOAE signals, SNR, and noise levels for Otodynamics and hearOAE (n=174 ears)***

	Frequency	Otodynamics		hearOAE	
		Mean	**SD**	**Mean**	**SD**
Signal (dB SPL)	1 kHz	2.25	7.98	3.40	6.91
	1.5 kHz**	1.57	7.54	6.67	7.74
	2 kHz**	4.39	8.07	7.99	7.55
	3 kHz**	0.83	6.46	4.94	5.79
	4 kHz	2.82	7.02	2.97	5.77
Noise (dB SPL)	1 kHz	3.33	5.15	2.56	6.02
	1.5 kHz	1.54	4.96	2.26	5.29
	2 kHz**	1.87	4.63	2.45	5.18
	3 kHz**	1.16	4.03	3.11	4.81
	4 kHz	1.68	4.96	1.52	4.96
SNR (dB SPL)	1 kHz*	-1.09	7.80	0.84	5.20
	1.5 kHz**	0.03	6.48	4.41	6.24
	2 kHz**	2.51	7.14	5.55	6.44
	3 kHz**	-0.29	4.03	1.82	4.81
	4 kHz	1.13	6.11	1.45	4.27

*dB: Decibels, SD: Standard deviation, SPL: Sound Pressure Level * p<0.05; ** p<0.001*

SNR, signal, and noise levels were not significantly different between devices at 4 kHz (Z_{WSR}=0.369 to 0.764; p=0.166 to 0.724). Noise levels were lower than, but not significantly so, for the hearOAE compared to the Otodynamics at 1, 1.5 kHz, and 4 kHz (t=-1.358 to -1.579; p=0.114 to 0.764), as was the signal at 1 kHz (t=-1.384; p=0.166). Statistically larger SNRs were measured with the hearOAE than with the Otodynamics ILO at 1, 1.5, 2, and 3 kHz (Z_{WSR}= -5.933 to -1.936; all p=<0.001).

Relationship between overall outcomes and infant variables

Binary regression models assessed whether age and status (no risk, at risk, or NICU) were significant predictors of passing or referring the DPOAE and TEOAE screening. Table 5 presents the relationship between the dependent infant variables on the DPOAE screening outcomes (viz. pass or refer) for both devices. The independent variables considered in the regression analyses were age (days), and risk category (at risk, no risk, and NICU).

Table 7. ***Binary regression analysis results for the significance of DPOAE variables on overall screening outcome for Otodynamics and hearOAE (n=175)***

Independent variables	(EXP) β	SD	p-Value	95% C.I. for β Lower	95% C.I. for β Upper
hearOAE					
Age (days)	0.984	0.021	0.425	0.945	1.024
Status			0.089		
At risk	1.287	0.556	0.650	0.432	3.829
NICU	3.091	0.516	0.029*	1.125	8.491
Otodynamics ILO					
Age (days)	1.153	0.066	0.031*	1.013	1.312
Status			0.445		
At risk	1.199	0.526	0.746	0.399	3.610
NICU	1.941	0.248	0.207	0.693	5.442

*C.I.: Confidence Interval, SD: Standard Deviation, * p<0.05*

Age was a statistically significant predictor of outcome (p=0.013; *B*: -0.004; 95% C.I. lower: 1.013, 95% C.I. upper: 1.312). For every day increase in age, the infants were 1.15 times more likely to refer DPOAE hearing screening with the Otodynamics ILO device. Status (NICU) also indicated statistically significant effect on the pass or refer outcome (p=0.029; *B*: 1.129; 95% C.I. lower: 1.125, 95% C.I. upper: 8.491). Binary regression analysis showed that when using the hearOAE, infants who spent time in the NICU were 3.09 times more likely to refer DPOAE screening using the hearOAE device.

Table 8 presents the relationship between infant age and risk status on the TEOAE screening outcomes (pass or refer) for both devices.

Table 8. ***Binary regression analysis results for the significance of TEOAE variables on overall screening outcome for Otodynamics and hearOAE (n=174)***

Independent variables	(EXP) β	SD	p-Value	95% C.I. for β Lower	95% C.I. for β Upper
hearOAE					
Age (days)	0.557	0.024	0.557	0.968	1.063
Status			0.572		
At risk	0.501	0.440	0.501	0.568	3.182
NICU	0.496	0.444	0.496	0.310	1.764
Otodynamics ILO					
Age (days)	0.015	0.024	0.528	0.969	1.064
Status			0.269		
At risk	0.879	0.450	0.810	0.371	2.168
NICU	0.443	0.502	0.105	0.166	1.186

*C.I.: Confidence Interval, SD: Standard Deviation, * p<0.05*

There was no statistically significant association between the independent variables and the screening outcome (pass and refer) for TEOAE with either device (p=0.105 to 0.810).

3.5 DISCUSSION

The current study compared the NHS outcomes of a hearX developed smartphone-based OAE device (hearOAE) with that of a commercially available device (Otodynamics ILO v6). Inter-device differences were noted within participants in the OAE SNR, signal (OAE response amplitude), and noise. Significant differences in the effect of independent variables (age and status) on the overall screening outcomes were also noted for DPOAEs between the two devices. Infants who spent time in the NICU were 3.09 times more likely to refer DPOAE screening using the hearOAE device. For every day increase in age, the infants were also 1.15 times more likely to refer DPOAE hearing screening with the Otodynamics ILO device. Fundamentally however, the percentage of concordance of NHS outcomes between the novel smartphone-based OAE and the conventional, commercially available Otodynamics device was high, namely 89.7% and 85.0% for DPOAE and TEOAE, respectively.

Mean and total DPOAE SNR was significantly higher for Otodynamics when compared to the hearOAE (p<0.001). However, when looking at frequency-specific information, a significantly lower SNR for the

hearOAE was only evident at 6 kHz (p=0.002), while higher, albeit non-significant SNRs were recorded for the hearOAE compared to the Otodynamics ILO at 1.5, 2, 3, and 4 kHz. The DPOAE SNR at 1 kHz was significantly higher for the Otodynamics ILO compared to the hearOAE device (p=0.008). Stronger SNRs were therefore evident at five out of the six DPOAE frequencies with the hearOAE than with the Otodynamics ILO. Previous research has reported that with DPOAE NHS, SNR is commonly measured at frequencies of 2, 3, and 4 kHz, with the exclusion of 6 kHz (Wagner et al., 2008; Zare et al., 2015). In a recent study, it was noted that high-frequency OAE measurements resulted in a reduction in the OAE failure rate and false-positive rate (Akinpelu et al., 2019). Lower frequencies are therefore more susceptible to ambient background noises. Consequently, SNR differences noted at 6 kHz in the current study may have minimal implications in clinical settings depending on the screening protocol selected by the user.

With regards to TEOAEs, both SNR and signal, totalled and averaged across frequencies, was statistically higher for the hearOAE device compared to the Otodynamics ILO (p<0.001). Frequency-specifically, results again demonstrated higher SNR and signals measured using the hearOAE versus the Otodynamics ILO at each frequency (p<0.001). Screening outcomes are typically based on SNR, rather than signal. It is therefore noteworthy that the hearOAE demonstrated higher TEOAE SNR across all frequencies tested, and higher DPOAE SNR at 1 to 4 kHz.

The noise levels in large maternity units and NICUs frequently exceed the maximum acceptable level of 65 dBA (adjusted decibels) recommended by the American Academy of Pediatrics (Lieu et al., 2020)(Salina et al., 2010). Noise is a critical parameter in NHS results especially if testing takes place in suboptimal contexts such as noisy hospital wards or post-natal clinics. The current study revealed that total and mean noise levels for DPOAE were significantly lower for the hearOAE device in comparison to the Otodynamics (p<0.001). Significant differences for TEOAE noise levels were only noted at 2 and 3 kHz where noise levels were lower for the Otodynamics compared to the hearOAE, but equivalent or lower for hearOAE at three out of five TEOAE frequencies (viz. at 1, 1.5, and 4 kHz; p=0.114 to 0.764). The differences in noise levels recorded between devices were unsurprising given the dynamic nature of both physical noise from changing states of infants, and ambient noise in hospital wards where the screening took place. Nevertheless, the significantly lower total and mean noise levels measured with the hearOAE DPOAE compared to the Otodynamics ILO, with equivalent or lower noise levels at the majority of the TEOAE frequencies, suggests an advantage of the hearOAE device in noisy test conditions, as may be encountered with decentralised NHS service provision.

No significant within participant inter-device differences were noted in the DPOAE refer rates (p=0.238). Conversely, there were notable differences with the hearOAE exhibiting a higher TEOAE

pass rate with 20 ears demonstrating different outcomes of the 174 ears screened (p=0.009). The higher noise levels measured with the Otodynamics at 3 out of 5 frequencies (viz. 1, 1.5, and 4 kHz) may have contributed to the higher HearOAE pass rate. It is not clear whether this increased pass rate indicates a higher risk of false-negatives, or if and how it relates to the sensitivity and specificity of the HearOAE device in terms of identification of hearing loss in infants as the outcomes of the diagnostic assessments the infants were not followed in the current study.

The mean age of infants at NHS was 4.5 days but ranged from the day of birth to 13 weeks chronological age. As infants develop over the first days and months of life, their physical activity and alertness increase (Bezuidenhout et al., 2021; Bezuidenhout, Khoza-Shangase, De Maayer, et al., 2018). The increased noise levels may therefore explain why, with the Otodynamics ILO, for every day increase in age, the infants were 1.15 times more likely to refer to DPOAE hearing screening. Critically, as NHS was performed prior to discharge from the maternity unity, older infants reflect a longer stay in the maternity unit, and likely an associated increase in the number of risk factors for congenital and/or early onset hearing loss (Khairy et al., 2018; Wroblewska-Seniuk et al., 2018). Although the majority of the infants in the current study presented with no risk factors for congenital or early onset hearing loss (72.2%), 14.8% of infants were NICU graduates.

In the current study, infants who spent time in the NICU were 3.09 times more likely to refer DPOAE screening using the HearOAE device. The reason for this is unclear. Further investigation within this population would be needed to shed light on the results of the hearOAE screening for this infant demographic.

Hearing health care is currently moving toward equipment that is more compact, and intuitive (Tucci et al., 2010). Hearing screening has seen increasing use of mHealth approaches to improve access, quality, and convenience of hearing health care services (Frisby et al., 2021). A review revealed more than 80.0% of available smartphone-based audiometric applications have been designed to perform audiometry, with less than 15.0% performing otoscopy (Bright & Pallawela, 2016a). To the author's knowledge, the hearOAE is the first smartphone-based OAE device (Bright & Pallawela, 2016a). Innovations, such as the hearOAE can offer alternative models of NHS service provision that have the potential to increase and decentralise access to ear and hearing health care to underserved and resource-constrained populations by virtue of the reduced cost, increased mobility, leading to increased accessibility (Martínez-Pérez et al., 2013).

The hearOAE's usability in terms of overall user experience and ease of use was not assessed for the purpose of the current study. This qualitative metric is essential for assessing clinical utility and simplicity of application, particularly for various user types and differences in learning curves for each,

if any. As stated by Oosthuizen et al. (2023), high usability would increase user acceptance of non-traditional screening techniques while also directly lowering training costs and time (Oosthuizen et al., 2023).

The NHS results in terms of sensitivity and specificity of identifying hearing loss were not compared in the current investigation. To address this limitation, a longitudinal study that incorporates the results of diagnostic testing for infants who passed and failed hearing screening would be necessary. It is recommended, however, that more research be done on the actual sensitivity and specificity of the hearOAE device. When a single technology methodology is employed for NHS, as was the case in the present study, there is a chance of false-positive results because OAE screening may overlook auditory neuropathy spectrum disorder (ANSD) and is more sensitivity to conductive pathology (van Dyk et al., 2015).

The current study was able to demonstrate equivalence of NHS outcomes of a novel smartphone based OAE device as compared to a well-known, commercially available device. Usability of the device in both hospital-based and decentralised settings by screening personnel with a variety of levels of health care training must still be explored. This may also lead to optimization of a NHS protocol, considering aspects such as choice of frequencies tested and pass criteria. Considering the affordability of available subjective smartphone-based hearing screeners, audiologists could similarly be motivated to train increased number of personnel to facilitate and expand on NHS.

3.6 CONCLUSION

Within-participant comparison of the NHS for the hearOAE device using both TEOAEs and DPOAEs compared to a commercially available OAE screener demonstrated equivalence in outcomes of $\geq$85%. Crucially, for screening protocols, SNR were higher with the hearOAE with TEOAE NHS, and equivalent or higher SNR at four out of six frequencies for DPOAEs. Mean and total noise levels were significantly lower for the hearOAE compared to the Otodynamics with DPOAEs, with noise levels at three out of six frequencies with the hearOAE being equivalent to or lower, for TEOAEs. Lower noise levels are likely to be advantageous in less-than-ideal test conditions. This, and the equivalence of NHS outcomes, verifies the performance of the novel smartphone based OAE device, and may facilitate decentralised NHS service in resource constrained populations.

Disclosure of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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4 DISCUSSION AND CONCLUSION

The purpose of this study was to compare a smartphone-based OAE screener to that of an already existing OAE screener, i.e., the Otodynamics ILO v6. As an alternative to traditional techniques of identifying children with hearing loss, smartphone-based hearing screeners have recently been developed (Louw et al., 2017; Manayan et al., 2022). While there is still more to be done in terms of UNHS implementation (Wroblewska-Seniuk et al., 2017), existing research clearly highlights the critical role that NHS plays in the early detection of hearing loss. NHS also highlights the possibility of optimizing a child's intrinsic ability to develop speech and language on par with peers who have normal hearing through early intervention (HPCSA, 2018; Neumann et al., 2019; Yoshinaga-Itano et al., 2018b). This present study was the first to evaluate NHS using smartphone-based OAEs in the Sub-Saharan region. Smartphone-based OAE screening is a promising low-cost solution to the challenge of building scalable hearing screening programs in resource-constrained settings (Ali, 2023).

4.1 Summary of study results

NHS was chosen to be performed at two tertiary hospitals in the underserved regions in the province of Free State (UFS, 2022). NHS was performed on 176 newborns (352 ears) who were admitted to either one of these facilities. Infants underwent NHS using both the Otodynamics ILO and hearOAE and screening results were compared within participants. The total percentage of concordance of NHS outcomes between the innovative hearOAE and the conventional, commercially available Otodynamics ILO equipment was comparable.

Signal-noise-ratio and signal levels

Frequency-specific DPOAE SNR inter-device differences were only noted at 6 kHz for the hearOAE ($p=0.002$). The mean and total DPOAE SNR was however significantly higher for Otodynamics when compared to the hearOAE ($p<0.001$). While higher SNRs were recorded for the hearOAE at 1.5, 2, 3, and 4 kHz with the hearOAE, differences were significant.

With regards to TEOAEs, both the SNR and the signal, totalled and averaged across frequencies, were statistically higher for the hearOAE device compared to the Otodynamics ILO ($p<0.001$). Results demonstrated statistically higher SNR and signals measured using the hearOAE versus the Otodynamics ILO at each frequency ($p<0.001$). Succinctly, the hearOAE demonstrated higher TEOAE

SNR across all frequencies tested, and higher DPOAE SNR at 1 to 4 kHz when compared to the Otodynamics ILO device.

Noise floor

The current study revealed lower DPOAE noise levels for the hearOAE device in comparison to the Otodynamics ($p<0.001$). On the other hand, significant differences for TEOAE noise levels were only noted at 2 and 3 kHz, where noise levels were lower for the Otodynamics compared to the hearOAE, but equivalent or lower for hearOAE at the remaining three out of five TEOAE frequencies (1, 1.5, and 4 kHz) ($p=0.114$ to 0.764). Nevertheless, the significantly lower total and mean noise levels measured with the hearOAE DPOAE compared to the Otodynamics ILO, suggests an advantage of the hearOAE device in noisy test conditions, as may be encountered with contexts such as maternity wards.

Effects of independent infant variables on newborn hearing screening outcomes

The Otodynamics ILO demonstrated increased DPOAE noise levels. Furthermore, for every day increase in age, the infants were 1.15 times more likely to refer to DPOAE hearing screening with the Otodynamics ILO device, and this is consistent with the higher noise levels reported in the hearOAE device. Although the majority of the infants in the current study presented with no risk factors for congenital or early onset hearing loss (72.2%), 14.8% of infants were NICU graduates. These NICU graduates were found to be 3.09 times more likely to refer DPOAE screening using the hearOAE device. This is also in line with earlier studies that, when using the DPOAE technique for screening, revealed a higher rate of hearing loss in NICU infants compared to healthy infants (Kim et al., 2017; Wroblewska-Seniuk et al., 2018; JCIH, 2019). Despite the latter, no significant differences were noted in the outcomes of the two devices for infants who presented with no risk ($p<0.001$). In addition to this, no significant differences were noted for TEOAEs when analysing the effect of the independent variables on the overall pass or refer outcome ($p=0.105$ to 0.810).

Refer rates

DPOAE refer rates showed no significant within participant inter-device differences ($p=0.238$). Contrariwise, TEOAE refer rates did show significant differences between the two devices ($p=0.009$), with the hearOAE demonstrating a higher pass rate. This finding likely relates to the higher SNRs measured for TEOAE in the hearOAE device. A key finding of the currently study was that the percentage of concordance of NHS outcomes between the novel hearOAE and the conventional, commercially available Otodynamics ILO device was high viz. 89.7% and 85.0% for DPOAE and TEOAE, respectively.

4.2 Clinical implications

The clinical implications of the findings of this study have a direct impact on the current NHS practices and can be summarized according to three main inferences. Firstly, given that the hearOAE outcomes align closely with the outcomes of the Otodynamics ILO system, the utilization of automated OAEs presents a dependable method for conducting NHS in community clinics and maternity units, facilitated by smartphone-based OAE technology, which is appropriate in such settings as it provides cost effective and accessible method of NHS. Secondly, smartphone-based automated OAE screening would enable lay people (who have been trained) to be able to perform NHS, thus adding to the facilitation of decentralisation of services by increased human resources from which to recruit screeners (Lasisi et al., 2014; van Wyk et al., 2019; Yousuf Hussein et al., 2018). Lastly, smartphone-based OAE screening can be expanded for screening of populations other than for infants, such as for school-going children and adults. School screenings can assist in identifying children who were missed due to the lack of UNHS programmes in SA (Brodie et al., 2022). Comprehensive clinical implications of the findings of this comparative within participant study are discussed below in terms of clinical implications for healthcare systems and clinical implications for individuals performing NHS.

Clinical implications for healthcare systems

The result of the current study builds on the existing knowledge of innovative mHealth approaches rapidly emerging and becoming important for public healthcare in LMICs and underserved regions (du Plessis et al., 2022). In addition, the availability of smartphones and increased internet access have created an opportunity to optimize the implementation of mHealth services and potentially increase the efficiency of various service-delivery cadres in healthcare systems (du Plessis et al., 2022; Frisby et al., 2021). Current literature demonstrates that hearing healthcare is currently moving toward equipment that is more compact, and intuitive (du Plessis et al., 2022; Irace et al., 2021; Manayan et al., 2022; Tucci et al., 2010). The present study's findings might persuade healthcare systems to employ smartphone-based NHS techniques in order to preserve the calibre, enhance accessibility, and provide ease for those receiving hearing healthcare services (Frisby et al., 2021). In order to support and expand NHS services, audiologists may also be encouraged to train more staff members, given the accessibility of objective smartphone-based hearing screeners.

Clinical implications for individuals performing NHS

The current study was able to demonstrate equivalence of NHS outcomes of a novel smartphone-based OAE screening device compared to a well-known, commercially available OAE screening device. The comparison of a smartphone-based OAE screener in this study indicated a high concordance of

outcomes with both NHS methods i.e., DPOAE and TEOAE. Presently, the South African public healthcare setting faces significant challenges with regard to numerous factors including limited resources, socio-economic status of the population served, and limitations to accessibility to hearing healthcare services (Kanji, 2016). The results of this study can therefore form part of key considerations when implementing policies and guidelines for NHS that currently exist in healthcare systems (Kim et al., 2017; Wroblewska-Seniuk et al., 2018). This would aid in guiding professionals on how to effectively implement mHealth-based NHS. The successful utilisation of low-cost smartphone-based technology yielding valid NHS outcomes can facilitate early identification of hearing loss (World Health Organisation, 2021), which is the standard of care Audiologist trained hearing screeners aim for to ensure optimal outcomes for infants with hearing loss.

The high percentage of concordance between the hearOAE and Otodynamics supports current literature that stipulates that mHealth is a reliable tool to use not only for NHS, but also for conventional hearing screening as well (Chan et al., 2022; Dawood et al., 2020; Yousuf Hussein et al., 2018). The current study results also highlighted that there were no significant differences noted between the two devices for infants who presented with no risk on the overall pass or refer outcome. This therefore is indicative of the comparability between the two devices for well-babies in terms of the overall screening outcomes. Furthermore, no significant differences in terms of the pass or refer outcomes were noted for TEOAEs when analysing the effect of the independent variables on the overall outcome between the two devices. This demonstrates the accuracy of the OAE device screening results based on smartphones and encourages clinicians to go beyond traditional hearing screening techniques. Audiologists often consider OAE testing as a standard of care for NHS (Benito-Orejas et al., 2008). While research encourages a two-stage (OAE and AABR) screening protocol, AABR screening is rare in the public health sector of South Africa due to the significantly increased costs compared to OAE screening (van Dyk et al., 2015). The costs associated with AABR include, but are not limited to, equipment purchase (which is often more expensive than OAE devices), consumables, and calibration expenses. Utilizing different, more cost-effective technologies such as the hearOAE in various health contexts, may therefore be instrumental in ensuring that such screening programs in LMICs countries are successful.

The lack of EHDI services can be attributed to several factors including a high burden of infectious diseases, restricted resources and the lack of tertiary education for Audiologists or other hearing healthcare specialists (Swanepoel et al., 2009). Being one of just three sub-Saharan African countries to provide a professional tertiary audiology qualification (EduRank, 2023), South Africa is uniquely positioned to advocate that Audiologists assume a leadership role in advocating for, and advancing, EHDI services across the region. In light of the growing global acceptance of telehealth and the limited

availability of OAE resources in LMICs, Improved accessibility for hearing screening in nearby clinics, hospitals, and during home visits can be achieved by using mHealth solutions, such the hearOAE, according to audiologists and community healthcare professionals. As a result of the decentralization of services, infants with hearing loss will be able to receive intervention earlier in accordance with the proposed EDHI guidelines (HPCSA, 2018). This will have a significant positive impact on the speech and language development of these children (Olusanya et al., 2004; Wroblewska-Seniuk et al., 2018).

Critical evaluation of study

Appropriate interpretation, as well as a comprehensive evaluation of research findings within the framework of its strengths and limitations, is critical to maintain academic integrity (Leedy & Ormrod, 2020). These are highlighted below:

Study strengths

Strengths of the current project include the following:

- This study was the first to investigate the outcomes of a smartphone-based OAE device, namely the hearOAE. Accordingly, the study successfully compared the screening outcomes of the hearOAE to the Otodynamics ILO.
- Within-participant comparison design was suitable in determining whether the outcomes of the hearOAE were equivalent to those of the Otodynamics device.
- This research took both a clinical and translational approach that sought to produce valid and applicable results that directly benefit NHS implantation. NHS was performed on no-risk as well as high-risk babies in sub-optimal contexts. This is a strength due to the testing setting, which involved a group of unselected newborns born within a specific time frame and may therefore demonstrate the impact of automated smartphone-based OAE screening on improved accessibility and thus help public healthcare systems and clinicians to consider smartphone-based OAE screening in routine screening of hearing as well as NHS in different infant populations.
- NHS was conducted on a large sample size of 352 ears that allowed researchers to control the risk of reporting false-negative or false-positive findings. The statistical power study revealed 80% power with 9% discrepancy among the screening devices. Schmidt et al. (2018) found that the sample size was adequate to address the study topic, even with the removed data (Schmidt et al., 2018).

- Based on the dearth of reports from the sub-Saharan African region which reflects a lack of EHDI services, the current study aids in highlighting the efficacy of the hearOAE on the accessibility to NHS and subsequently improving EHDI serves.
- The smartphone-based software made use of cloud-based data storage. system and can therefore be revisited for use in future studies (Leedy & Ormrod, 2014). Thus, the NHS program coordinator can supervise on services from any place, thereby enhancing the accessibility of healthcare for hearing healthcare and expanding the opportunities for remote treatment or future research. The collected data was also kept safe on an AWS cloud server. The data that was stored in the cloud at rest was encrypted using AES256. The cloud data management solution complied with POPIA regulations to the latter.

Study limitations

Limitations of the current study include the following:

- Usability in terms of the ease of use and overall user experience of the hearOAE was not determined. This qualitative measure is imperative in evaluating ease of implementation and clinical use, especially for different users. Expanding the user base of automated smartphone-based hearing screeners can help boost human resource. In other words, high degree of usability of the hearOAE, could lead to improved accessibility to NHS through the employment of CHWs to conduct the hearing screenings by increasing human resource capacity. High usability would also immediately affect training time and costs by cutting them down, and it would also increase user acceptance of non-traditional screening techniques which has not yet been investigated (Oosthuizen et al., 2023).
- Test-time was not considered in the comparison of the screening devices for the purpose of this study, which forms part of crucial aspects to consider in NHS. Ideally, hearing screening should be time-efficient to allow for a larger number of infants receiving NHS services. Testers aim to perform NHS after the infant has been f
- ed to reduce the influence of physiological noise on the OAE result (Olusanya, 2011), in the case where the infant is restless, a quicker test-time is imperative.
- Diagnostic testing was not performed to determine comparative sensitivity and specificity of the two devices for the objectives of this study and therefore, further objective screening (AABR) could not be conducted alongside with OAE NHS. The current study therefore did not make use of a two-stage protocol. A possibility of false-positives arises when a one-stage protocol is implemented as OAE screening can miss low-frequency or mild degrees of hearing

loss, or auditory neuropathy spectrum disorder (ANSD) (van Dyk et al., 2015). This therefore reduces the sensitivity of the NHS.

4.3 Recommendations for future research

The results obtained and the conclusions drawn from this study revealed several aspects that require further investigation.

- The use of smartphone technology using automated OAEs to reduce costs should be further investigated to allow healthcare to move in the direction of mHealth based services (Bamford et al., 2007; Chan et al., 2022; Grill et al., 2006). The empirical results of this study establish a foundation of equivalency between a smartphone-based device and one that is already on the market, which may be utilized to direct future research on cost-reduction through the reduction of equipment procurement for the implementation of NHS.
- Hearing screening using smartphone-based automated OAEs in other populations such as children of school-going age and adults should be further investigated. As UNHS has not yet been fully mandated in the South African contexts, many infants go unscreened. The screening of older populations could therefore assist in further identifying missed hearing losses (Eksteen et al., 2019).
- Future studies should also investigate the feasibility of smartphone-based UNHS within underserved areas of South Africa. This can be done through research on the feasibility of trained CHWs to perform NHS in local clinics and home-visits should be included to relieve the burden of shortage of Audiologists on a large scale (Owen et al., 2001; van Wyk et al., 2019).
- The current knowledge and attitudes of clinicians toward mHealth in hearing healthcare should be subjectively investigated. Subsequently, this may ensure that clinicians are motivated to perform UNHS and perhaps train CHWs in NHS to improve accessibility.
- Usability of the device in both hospital-based and underserved remote areas by screening personnel with a variety of levels of healthcare training must still be explored. Conducting a qualitative study through surveys that could give us information regarding Audiologists' and CHWs or lay volunteers' experiences with the ease and efficiency of operating the smartphone-based OAE device. Consequently, the usability of the device would indirectly influence the number of infants screened from grassroots levels such as primary-level clinics.
- Further evaluation of an optimized NHS protocol with the hearOAE would be advantageous. This may include variable test time depending on response levels and exclusion of low frequencies to reduce test time and minimize the effect of ambient and myogenic noise.

- The scarcity of literature concerning automated OAEs in the reliability of NHS can serve as an impetus for researchers to explore the feasibility of alternative objective smartphone-based screening tools, particularly in suboptimal setting (Chan et al., 2022; Neumann et al., 2019).

4.4 Conclusion

Even with South Africa being an UMIC, access to NHS services is still severely limited. Integrating mHealth services with established NHS screening methods is a novel approach. Results of this study demonstrated comparable within participant OAE screening outcomes between a commercially available and a smartphone-based device. It provided an opportunity for mHealth based OAE screening to be considered as an alternative method of service provision, especially in underserved areas. Leveraging innovative mHealth applications, such as the hearOAE smartphone application, holds promise in mitigating various challenges encountered when conducting NHS across diverse settings, hence facilitating decentralised NHS services in resource constrained populations. The true sensitivity and specificity of each device were not determined through diagnostic testing in the current study; however, further investigation is recommended in future studies.

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APPENDICES

APPENDIX A

ETHICAL CLEARANCE (HUMANITIES)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Humanities 100
Since 1919

16 February 2021

Dear Miss AG Madzivhandila

Project Title:	Neonatal hearing screening using a smartphone-based otoacoustic emission device: Acomparative study.
Researcher:	Miss AG Madzivhandila
Supervisor(s):	Dr TE le Roux Prof L Biagio de Jager
Department:	Speech Language Path
and Aud **Reference number:**	15186467
(HUM034/0820) (Amendment)**Degree:**	Masters

Thank you for the application to amend the existing protocol that was previously approved by the Committee.

The revised / additional documents were reviewed and **approved** on 16 February 2021 along these guidelines, further data collection may therefore commence (where necessary).

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

We wish you success

with the project.

Sincerely,

Prof Innocent Pikirayi
Deputy Dean: Postgraduate Studies and Research
EthicsFaculty of Humanities
UNIVERSITY OF PRETORIA
e-mail:PGHumanities@up.ac.za

APPENDIX B

ETHICAL CLEARANCE (FS DOH)

health
Department of
Health
FREE STATE PROVINCE

05 May 2021

Ms A Madzivhandila
Dept. of Speech-Language Pathology and Audiology
UP

Dear Ms AG Madzivhandila

Subject: Neonatal hearing screening using a smart hone-based otoacoustic emission device: A comparative study.

- Please ensure that you read the whole document, Permission is hereby granted for the above — mentioned research on the following conditions:
- Participation in the study must be voluntary
- A written consent by each participant must be obtained.
- Serious Adverse events to be reported to the Free State department of health and/ or termination of the study
- Ascertain that your data collection exercise neither interferes with the day to day running of Universitas Hospital nor the performance of duties by the respondents or healthcare workers.
- Confidentiality of information will be ensured and please do not obtain information regarding the identity of the participants.
- Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of Pretoria and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of Pretoria and to Free State Department of Health.

Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to sebeelats@ fshealth.gov.za before you commence with the study

- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with Institution Manager on commencement for logistical arrangements see 2 nd page for contact details.
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- As part of feedback, you will be required to present your study findings/results at the Free State Provincial health research day

Trust you find the above in order

Kind Regards

Dr D Motau
HEAD: HEALTH
Date: 6/5/2021

Head : Health
PO Box 227, Bloemfotein, 9300
4th Floor, Execuâve Suite, Bopheb House, cnr Maitland and, Harvey Road, Bloemfotein
Tel: (051) 408 1646 Fax: (051) 408 1556 e-mail:khusemi@fshealth.gov.za@fshealth.gov.za/chikobvup@fshealth.govza www.fs.gov.z

APPENDIX C

ETHICAL CLEARANCE (HEALTH)

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

Institution: The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 03/20/2022.
- IORG #: IORG0001762 OMB No. 0990-0279 Approved for use through February 28, 2022 and Expires: 03/04/2023.

16 April 2021

Endorsement Notice

Ethics Reference No: HUM027/1219
Title: Universal OAE hearing screenings in neonates: improving access by reducing costs

Dear Andani Madzivhandila

The **New Application** as supported by documents received between 2021-02-16 and 2021-04-14 for your research, was approved by the Faculty of Health Sciences Research Ethics Committee on 2021-04-14 as resolved by its quorate meeting.

Please note the following about your ethics approval:
- Ethics Approval is valid for 1 year and needs to be renewed annually by 2022-04-16.
- Please remember to use your protocol number (HUM027/1219) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, monitor the conduct of your research, or suspend or withdraw ethics approval.

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

We wish you the best with your research.

Yours sincerely

Professor Werdie (CW) Van Staden
MBChB MMed(Psych) MD FCPsych(SA) FTCL UPLM
***Chairperson**: Faculty of Health Sciences Research Ethics Committee*

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

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

Fakulteit Gesondheidswetenskappe
Lefapha la Disaense tša Maphelo

APPENDIX D

LETTER TO CEOs OF TSHWANE DISTRICT HOSPITAL, STEVE BIKO ACADEMIC HOSPITAL, PELONOMI DISTRICT HOSPITAL AND UNIVERSITAS ACADEMIC HOSPITAL:

English

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Attention: Dr. SS Nkusi

CEO: Tshwane District Hospital

Dear Dr. Nkusi,

PARTICIPANT PERMISSION FOR A RESEARCH STUDY

I hereby request permission to conduct a research study in fulfilment of a Master's degree, using participants from Tshwane District Hospital.

Title of the study:

Improving access to Neonatal Hearing Screening by using a mHealth based otoacoustic emission device of the study:

Participant selection:

During this study, 3 objectives will be fulfilled. For the first two objectives, 150 infants (male and female) prior to discharge, post-birth, will be selected for the screening. Participants (infants) will be selected from Tshwane District Hospital in the maternity wards. They will be selected by means of non-probability purposive sampling. All participants should be older than 24 hours with no active discharge or fluid draining from the ears bilaterally.

For the third objective, Audiologists will be selected to from Tshwane District Hospital. They will be selected by means of purposive sampling. All participants will be qualified Audiologists who are registered with the HPCSA.

Procedure:

Measurement instruments:

hearXOAE device: A device designed to measure screening and diagnostic OAEs in response to acoustic stimuli as an objective indication of cochlear functioning. A probe is inserted into the external ear canal to record this response.

Otodynamics ILO v6: A portable and PC-enabled device that will be used to record screening DPOAEs and TEOAEs measurements in all participants.

Data collection procedures:

The study will be conducted to evaluate the performance of hearX OAE device, compared with another comparative device for infant hearing screening (NHS). The researcher will conduct DPOAE and TEOAE measurements, in a non-soundproof room with the child in a state of natural sleep in a common crib or the mother's arms. The two different protocols will be used on alternating days to ensure minimum test time per infant. The OAE hearing screening will be performed at Tshwane District Hospital in the maternity ward.

The average time for the total OAE measurement (placement of ear tips not included), will be approximately 10 min. The time for testing will allow a 1min rest between the tests. Infants will be tested with TEOAEs (Transient Evoked Otoacoustic Emissions) and DPOAEs (Distortion Product Otoacoustic Emissions) on different days.

Audiologists selected to participate will perform the same tests, thereafter, they will be asked to complete a short survey about the overall usability of the hearOAE in comparison to the equipment the Audiologist uses. A scale will be provided to them so that they can rate the hearOAE screener's usability.

Ethical considerations:

Ethics will comply with the guidelines provided by the Faculty Ethics Committee.

Considerations will include having maternal written permission before the screening. Caregivers should be informed of the purpose of the study and may withdraw from the study at any time in the process.

Risks and benefits:

Participation in the study does not involve any additional cost to participants but offers no financial benefit. There are no risks involved for the participants to participate in the project. Participants will be allowed to take frequent breaks to alleviate the risk of fatigue. The obtained results may lead to new insights into better objective measures of hearing and consequently lead to objective screening and diagnosis of hearing loss that is cost-effective and accessible to all. This will not only reduce the time it takes to conduct hearing screening, but it will also offer objective measures of outer hair cell functioning of the cochlea (organ of the ear). This study will also provide you with information on the infant's hearing and if a further investigation will be needed.

Any infants with refer results on NHS (Infant hearing screening) will be referred to the Audiology and ENT departments of the hospital for further audiologic and/ or otologic management and follow up.

Please contact us should you require further information.

Contact Information:

Andani Madzivhandila – Andanigluggy@gmail.com

0837004100

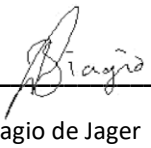
Prof Leigh Biagio – leighbiagio@up.ac.za

(012) 420 6774

Sincerely,

Andani Madzivhandila

Researcher



Prof Leigh Biagio de Jager

Supervisor

Dr. Talita le Roux

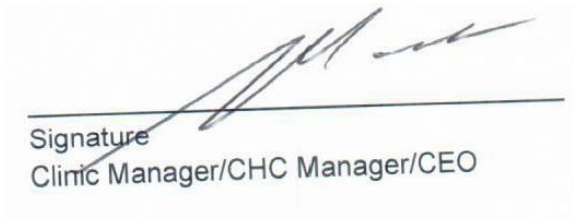
Co-supervisor

INFORMED CONSENT FOR CEO of Tshwane District Hospital

I, Dr. Sasha Nkusi hereby consent that the researcher may use Tshwane District as a site for their data collection. They may screen infants from the hospital as their participants for the study. Audiologists from Tshwane District Hospital may also be selected to participate in this study.

I understand that I will not receive any monetary benefit reimbursement. I am aware that participants can withdraw at any point in the study if they so wish to do.

I understand that every effort will be made that participants are not harmed in this research study.



Date: 6/11/2020

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Humanities 100
Since 1919

Attention: CEO of Universitas Academic Hospital

Request for conducting research at Universitas Academic Hospital:

Dear CEO,

PARTICIPANT PERMISSION FOR A RESEARCH STUDY

I am a community service Audiologist at Universitas Academic Hospital and I hereby request permission to continue with my research study in fulfilment of a Master's degree, using participants from Universitas Academic Hospital.

The study commenced in 2020, however, due to the COVID-19 pandemic, was unable to get completed in a year. I therefore require approximately 3 months of data collection at the hospital (these will fall outside of working hours). The period will most likely be from the end of February to the end of May. Ethical considerations will also be taken into account during the data collection period (please see Ethical Considerations paragraph).

Title of the study:

Infant hearing screening using a smartphone-based otoacoustic emission device: A comparative study

Participant selection:

During this study, two objectives will be met. A subset of infants prior to discharge, will be selected for screening. Participants will be selected from Universitas Academic Hospital in the maternity wards. Participants will be selected by means of non-probability purposive sampling. All participants should be older than 24 hours but younger than 1 month with no active discharge or fluid draining from the ears bilaterally.

Procedure:

Measurement instruments:

hearX OAE device: A device designed to measure screening and diagnostic OAEs in response to acoustic stimuli as an objective indication of cochlear functioning. A probe is inserted into the external ear canal to record this response.

Otodynamics ILO v6: A portable and PC-enabled device that will be used to record screening DPOAEs and TEOAEs measurements in all participants.

Data collection procedures:

The study will be conducted to evaluate the performance of hearX OAE device, compared with another comparative device (already in clinical use) for infant hearing screening (NHS). The primary investigator and the Audiologist at the hospital will conduct DPOAE and TEOAE measurements, in a non-soundproof room with the child in a state of natural sleep in a common crib or the mother's arms. The OAE hearing screening will be performed at Universitas Academic Hospital in the maternity ward.

The average time for the total OAE measurement (placement of ear tips not included), will be approximately 10 min. The time for testing will optimally allow a 1min rest between the tests. Infants will be tested with TEOAEs (Transient Evoked Otoacoustic Emissions) as well as DPOAEs (Distortion Product Otoacoustic Emissions).

The Audiologists that perform the assessments will be required to fill out a survey thereafter.

Ethical considerations:

Ethics will comply with the guidelines provided by the Faculty Ethics Committee and Health Sciences Ethics Committee.

Considerations will include having maternal written permission before the screening. Caregivers will be informed of the purpose of the study and may withdraw from the study at any time in the process.

Risks and benefits:

Participation in the study does not involve any additional cost to participants but offers no financial benefit. There are no risks involved for the participants to participate in the project. Participants will be allowed to take frequent breaks to alleviate the risk of fatigue.

The obtained results may lead to new insights into better objective measures of hearing and consequently lead to objective screening and diagnosis of hearing loss that is cost-effective and accessible to all. This will not only reduce the time it takes to conduct hearing screening, but it will also offer objective measures of outer hair cell functioning of the cochlea (organ of the ear). This study will also provide you with information on the infant's hearing and if a further investigation will be needed.

Any infants with refer results on NHS (infant hearing screening) will be referred to the Audiology and ENT departments of the hospital for further audiologic and/ or otologic management and follow up.

Please contact us should you require further information.

Contact Information:

Andani Madzivhandila – Andanigluggy@gmail.com

0837004100

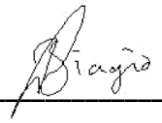
Prof Leigh Biagio – leighbiagio@up.ac.za

(012) 420 6774

Sincerely,

Andani Madzivhandila

Researcher



Prof. Biagio de-Jager

Supervisor

Dr Talita le Roux

Co-supervisor

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Humanities 100
Since 1919

Request for conducting research at Pelonomi Hospital

Allied Health Manager:

To whom it may concern,

PARTICIPANT PERMISSION FOR A RESEARCH STUDY

I hereby request permission to conduct a research study in fulfilment of a Master's degree, using participants from Pelonomi Hospital.

Title of the study:

Neonatal hearing screening using a smartphone-based otoacoustic emission device: A comparative study

Participant selection:

During this study, two objectives will be met. A subset of infants (male and female) prior to discharge, post-birth, will be selected for screening. Participants (infants) will be selected from Pelonomi Hospital in the maternity wards. Participants will be selected by means of non-probability purposive sampling. All participants should be older than 24 hours with no active discharge or fluid draining from the ears bilaterally.

In fulfilment of objective 3, Audiologists will be selected to conduct hearing screening using the Hear OAE device and comparing it to that which they use at Pelonomi Hospital for infant hearing screening. They will then be expected to fill out a survey for the equipment.

Procedure:

Measurement instruments: hearX OAE device: A device designed to measure screening and diagnostic OAEs in response to acoustic stimuli as an objective indication of cochlear functioning. A probe is inserted into the external ear canal to record this response.

Otodynamics ILO v6: A portable and PC-enabled device that will be used to record screening DPOAEs and TEOAEs measurements in all participants.

Data collection procedures:

The study will be conducted to evaluate the performance of hearXOAE device, compared with another comparative device for infant hearing screening (NHS). The primary investigator and the Audiologist at the hospital will conduct DPOAE and TEOAE measurements, in a non-soundproof room with the child in a state of natural sleep in a common crib or the mother's arms. The OAE hearing screening will be performed at Pelonomi Hospital in the maternity ward.

The average time for the total OAE measurement (placement of ear tips not included), will be approximately 10 min. The time for testing will optionally allow a 1min rest between the tests. Infants will be tested with TEOAEs (Transient Evoked Otoacoustic Emissions) and DPOAEs (Distortion Product Otoacoustic Emissions).

The Audiologists that perform the assessments will be required to fill out a survey.

Ethical considerations:

Ethics will comply with the guidelines provided by the Faculty Ethics Committee.

Considerations will include having maternal written permission before the screening. Caregivers should be informed of the purpose of the study and may withdraw from the study at any time in the process.

Risks and benefits:

Participation in the study does not involve any additional cost to participants but offers no financial benefit. There are no risks involved for the participants to participate in the project. Participants will be allowed to take frequent breaks to alleviate the risk of fatigue. The obtained results may lead to new insights into better objective measures of hearing and consequently lead to objective screening and diagnosis of hearing loss that is cost-effective and accessible to all. This will not only reduce the time it takes to conduct hearing screening, but it will also offer objective measures of outer hair cell functioning of the cochlea (organ of the ear). This study will also provide you with information on the infant's hearing and if a further investigation will be needed.

Any infants with refer results on NHS (Infant hearing screening) will be referred to the Audiology and ENT departments of the hospital for further audiologic and/ or otologic management and follow up.

Please contact us should you require further information.

Contact Information:

Andani Madzivhandila – Andanigluggy@gmail.com

0837004100

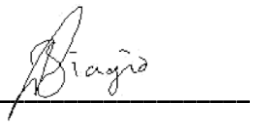
Prof Leigh Biagio – leighbiagio@up.ac.za

(012) 420 6774

Sincerely,

Andani Madzivhandila

Researcher



Prof. Biagio de-Jager

Supervisor

Dr Talita le Roux

Co-supervisor

APPENDIX E

INFORMATION AND CONSENT LETTER TO PARENT/GAURDIAN (Group 1):

English and Sesotho

PARTICIPANT'S INFORMATION & INFORMED CONSENT DOCUMENT

STUDY TITLE: Neonatal hearing screening using a smartphone-based otoacoustic emission device: A comparative study

Principal Investigators: Andani Gluggy Madzivhandila

Institution: University of Pretoria

DAYTIME AND AFTER HOURS TELEPHONE NUMBER(S):

Daytime number/s: (051) 405 3261

After hour's number: 083 700 4100

DATE AND TIME OF FIRST INFORMED CONSENT DISCUSSION:

				:
date	**month**	**year**		**Time**

Dear Prospective Participant Parent

Dear Mr. / Mrs.....

1) INTRODUCTION

You are invited to volunteer for a research study. I am doing research for a Master's degree purpose at the University of Pretoria. This information in this document is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this document, do not hesitate to ask the

researcher. You should not agree to take part unless you are completely happy about all the procedures involved.

2) THE NATURE AND PURPOSE OF THIS STUDY

The purpose of this research project is to compare a new mHealth-based hearing screening device to conventional hearing screening devices. In so doing, we will enable the more widespread provision of neonatal hearing screening services since the mobile device is more cost-effective, and if found to be equally effective.

3) EXPLANATION OF PROCEDURES AND WHAT WILL BE EXPEXTED FROM PARTICIPANTS.

A brief explanation of the tests will be conducted to you. The outer ear of your infant will then be observed to see if there are any anomalies or active discharge. The researcher will perform two hearing screening tests by placing an ear tip in the infant's ear for a few seconds. Two different types of equipment will be used, and the results will be recorded. The first type of equipment is the *OtoDynamics ILO v6* device and the other type is the *hearOAE* device (cell phone based OAE). These two devices both measure otoacoustic emissions in the ears, or in short OAEs. OAEs are measured by inserting a small probe into each of the infant's ear canals. OAEs are sounds echoed back by the inner ear when responding to a sound. There are hair cells in the inner ear that respond to sound by means of vibrations. The vibrations produce a very soft sound that echoes back into the ear. These echo sounds are then measured as OAEs. Each test will take between 30 seconds and 2 minutes (subject to how quiet infant is). Sounds will be presented into your infant's ear while being asleep. The infant will not need to respond at all.

The probe-tip will be cleaned with an alcohol swab or dipped in isopropyl alcohol after each measurement. Each infant will be tested with a clean probe-tip. The body of the OAE machines will also be cleaned using a soft, dry cloth. No abrasive cleaning agents, thinners or benzene will be used. The researcher/Audiologist will also disinfect his/ her hands by sanitising before and after testing each infant.

4) POSSIBLE RISKS AND DISCOMFORTS INVOLVED

There are no risks involved for your infant to participate in the project. The sounds played in the infant's ear are harmless and are played at a comfortable level.

5) POSSIBLE BENEFITS OF THIS STUDY

This study provides no medical or other benefits for yourself or your infant; however, the obtained results may lead to new insights into better objective measures of hearing and consequently lead to objective screening and diagnosis of hearing loss that is cost-effective and accessible to all. This will not only reduce the time it takes to conduct hearing screening, but it will also offer objective measures of outer hair cell functioning of the cochlea (organ of the ear). This study will also provide you with information on the infant's hearing and if a further investigation will be needed.

6) COMPENSATION

You will not be paid to take part in the study. There are no costs involved for you to be part of the study.

7) YOUR RIGHTS AS A RESEARCH PARTICIPANT

Your participation in this trial is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your access to other medical care.

8) ETHICS APPROVAL

This Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria, telephone numbers 012 356 3084 / 012 356 3085 and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2013), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of the Declaration may be obtained from the investigator should you wish to review it.

9) INFORMATION

If I have any questions concerning this study, I should contact:

Andani Madzivhandila – Andanigluggy@gmail.com

0837004100

Prof Leigh Biagio de Jager – leigh.biagio@up.ac.za

(012) 420 6447

Dr Talita le Roux - talita.leroux@up.ac.za

(012) 420 4884

10) CONFIDENTIALITY

All information obtained during the course of this study will be regarded as confidential. Each participant that is taking part will be provided with an alphanumeric coded number e.g. A001. This will ensure confidentiality of information so collected. Only the researcher will be able to identify you as participant. Results will be published or presented in such a fashion that patients remain unidentifiable. The hard copies of all your records will be kept in a locked facility at The University of Pretoria for a period of 15 years.

11) CONSENT TO PARTICIPATE IN THIS STUDY

- I confirm that the person requesting my consent for my child to take part in this study has told me about the nature and process, any risks or discomforts, and the benefits of the study.

- I have also received, read, and understood the above written information about the study.
- I have had adequate time to ask questions and I have no objections to participate in this study.
- I am aware that the information obtained in the study, including personal details, will be anonymously processed, and presented in the reporting of results.
- I understand that I will not be penalized in any way should I wish to discontinue with the study and that withdrawal will not affect my further treatments.
- I am participating willingly.
- I have received a signed copy of this informed consent agreement.

_____ _____

Participant's name (Please print) Date

_____ _____

Participant's signature Date

_____ _____

Researcher's name (Please print) Date

_____ _____

Researcher's signature Date

PARTICIPANT'S INFORMATION & INFORMED CONSENT DOCUMENT

SEHLOOHO SE ITHUTOANG: Ho hlahlojoa ha lesea nakong ea bokhachane ho sebelisa sesebelisoa se tsoang ho smartphone

Bafuputsi ba ka sehloohong: Andani Gluggy Madzivhandila

Setheo: Univesithi ea Pretoria

NAKO EA METSOALLE LE MOR'A MORA OA LIHORO

Linomoro tsa mots'eare: (051) 405 3261

Ka mor'a nomoro ea hora: 083 700 4100

LETSATSI LE NAKO EA PUISANO EA PELE EA TSEBISO:

letsatsi	khoedi	selemo	nako

Motsoali ea Ratehang oa Morupeluoa

Ratehang Monghali / Mofumahali..... .....

1) **SELELEKELA**

U mengoa ho ithaopa bakeng sa boithuto ba lipatlisiso. Ke etsa lipatlisiso molemong oa degree ea Master Univesithing ea Pretoria. Tlhahisoleseling ena e tokomaneng ena ke ho u thusa ho nka qeto ea hore na u ka rata ho nka karolo. Pele o lumela ho nka karolo phuputsong ena o lokela ho utloisisa ka botlalo se amehang. Haeba u na le lipotso, tse sa hlalosoang ka botlalo tokomaneng ena, u se ke oa tsilatsila ho botsa mofuputsi. Ha ua lokela ho lumela ho nka karolo ntle le haeba u thabile ka botlalo ka mekhoa eohle e amehang.

2) TLHAHO LE MORERO OA THUTO ENA

Morero oa morero ona oa ho etsa lipatlisiso ke ho bapisa sesebelisoa se secha sa tlhahlobo ea kutlo sa mHealth le lisebelisoa tse tloaelehileng tsa tlhahlobo ea kutlo. Ka ho etsa joalo, re tla nolofalletsa phumants'o e pharalletseng ea lits'ebeletso tsa tlhahlobelo ea masea a sa tsoa hlaha kaha sesebelisoa sa mohala se baballa chelete e ngata, mme haeba se ka fumanoa se sebetsa ka ho lekana.

3) TLHALOSO EA LITLHAKISO LE SEO SE TLA BONOLOA HO BATHO-SEBELETSI.

U tla fuoa tlhaloso e khuts'oane ea liteko. Tsebe e kantle ea lesea la hau e tla bonoa ho bona hore na ho na le liphoso kapa ho tsoa mali ho sebetsang. Mofuputsi o tla etsa liteko tse peli tsa ho hlahloba litsebe ka ho beha ntlha ea tsebe tsebeng ea lesea metsotsoana e seng mekae. Ho tla sebelisoa mefuta e 'meli e fapaneng ea lisebelisoa mme liphetho li tla rekota. Mofuta oa pele oa lisebelisoa ke sesebelisoa sa Maico Euroscan mme mofuta o mong ke sesebelisoa sa hearOAE (selefouno se thehiloeng ho OAE). Lisebelisoa tsena tse peli li lekanya tlhahiso ea otoacoustic litsebeng, kapa ka li-OAE tse khuts'oane. Li-OAE li lekanyetsoa ka ho kenya probe e nyane likaneng tsohle tsa tsebe tsa lesea. Li-OAE ke melumo e buuoang morao ke tsebe e ka hare ha e araba molumo. Ho na le lisele tsa moriri tsebeng e ka hare e arabelang molumo ka ho thothomela. Ho thothomela ho hlahisa molumo o bonolo haholo o khutlelang tsebeng. Melumo ena ea echo e ea lekanngoa joalo ka li-OAE. Teko ka 'ngoe e tla nka pakeng tsa metsotsoana e 30 le metsotso e 2 (ho latela hore na lesea le khutsitse hakae). Melumo e tla hlahisoa tsebeng ea ngoana oa hau ha a ntse a robetse. Lesea le ke la hloka ho arabela ho hang.

Ntlha ea lipatlisiso e tla hloekisoa ka swab ea joala kapa e kenngoe ka isopropyl alcohol kamora 'ngoe le e' ngoe ea litekanyo. Lesea le leng le leng le tla hlahlojoa ka ntlha e hloekileng ea lipatlisiso. 'Mele oa mechini ea OAE le eona e tla hloekisoa ho sebelisoa lesela le bonolo le omileng. Ha ho lisebelisoa tse hlatsoang tse

hlabang, li-thinner kapa benzene tse tla sebelisoa. Mofuputsi / Setsebi sa thuto ea kutlo le sona se tla kenya likokoana-hloko matsohong a sona ka ho hloekisa pele le kamora ho etsa liteko tsa lesea ka leng.

4) KOTSI E KA BANG LE KOTSI EA AMAHALA

Ha ho na likotsi tse amehang bakeng sa ngoana oa hau ho nka karolo morerong ona. Melumo e bapaloang ka tsebeng ea lesea ha e na kotsi ebile e letsoa boemong bo mabothobotho.

5) Melemo e ka 'nang ea e-ba teng ea thuto ena

Phuputso ena ha e fane ka melemo ea bongaka kapa ea hau kapa ea ngoana oa hau; leha ho le joalo, liphetho tse fumanoeng li ka lebisa tlhokomelong e ncha ea mehato e ntlafetseng ea kutlo mme ka hona ea lebisa ho hlahlojoeng ka sepheo le tlhahlobo ea tahlehelo ea kutlo e bolokang chelete e ngata ebile e ka fihlella ho bohle. Sena se ke ke sa fokotsa feela nako e nkiloeng ho etsa tlhahlobo ea kutlo, empa hape se tla fana ka mehato e ikemiselitseng ea ts'ebeliso ea lisele tsa moriri tsa kantle tsa cochlea (setho sa tsebe). Boithuto bona bo tla u fa leseli mabapi le kutlo ea lesea mme haeba ho hlokahala lipatlisiso tse ling.

6) MATS'ELISO

O ke ke oa lefshoa ho nka karolo phuputsong ena. Ha ho litjeo tse amehang hore u be karolo ea boithuto**.**

7) DITOKELO TSA HAO JOALOKA MOTSOALLE OA PATSO

Ho nka karolo ha hau tekong ena ke ka boithatelo 'me u ka hana ho nka karolo kapa ho emisa nako efe kapa efe ntle le ho bolela lebaka. Ho ikhula ha hao ho ke ke ha ama phihlello ea hau ea kalafo e meng.

8) KAMOO LITLHAKISO

Protocol ena e ile ea tlisoa ho Faculty of Health Sciences Research Ethics Committee, University of Pretoria, linomoro tsa mohala 012 356 3084/012 356 3085 mme tumello e ngotsoeng e fanoe ke komiti eo. Phuputso e hlophisitsoe ho latela Phatlalatso ea Helsinki (ntlafatso ea ho qetela: Mphalane 2013), e sebetsanang le likhothaletso tse tataisang lingaka lipatlisisong tsa biomedical tse amang batho / lihlooho. Khophi ea Phatlalatso e ka fumaneha ho mofuputsi haeba u ka lakatsa ho e hlahloba.

9) TLHAKISO

Haeba ke na le lipotso mabapi le thuto ena, ke lokela ho ikopanya le:

Andani Madzivhandila - Andanigluggy@gmail.com

0837004100

Moprofesara Leigh Biagio de Jager - leigh.biagio@up.ac.za

(012) 420 6774

Dr Talita le Roux - talita.leroux@up.ac.za

(012) 420 4884

10) TSHIRELETSO

Lintlha tsohle tse fumanoeng nakong ea boithuto bona li tla nkuoa e le lekunutu. Morupeluoa e mong le e mong ea nkang karolo o tla fuoa nomoro e ngolisitsoeng ka litlhaku tsa alphanumeric mohlala. A001. Sena se tla netefatsa lekunutu la tlhaiso-leseling e bokelitsoeng joalo. Ke mofuputsi feela ea tla tseba ho u khetholla. Liphetho li tla phatlalatsoa kapa li hlahisoe ka mokhoa o joalo hoo bakuli ba lulang ba sa tsejoe. Likopi tse thata tsa lirekoto tsohle tsa hau li tla bolokoa ka setsing se notletsoeng Univesithing ea Pretoria nako ea lilemo tse 15.

11) LUMELLA HO KENELA Thutong ena

• Ke tiisa hore motho ea kopang tumello ea ka hore ngoana oa ka a nke karolo phuputsong ena o mpolelletse ka sebopeho le ts'ebetso, likotsi kapa mathata afe kapa afe, le melemo ea thuto.

• Ke amohetse hape, ke balile le ho utloisisa tlhaiso-leseling e ngotsoeng kaholimo ka boithuto.

• Ke bile le nako e lekaneng ea ho botsa lipotso 'me ha ke na khanyetso ea ho nka karolo boithutong bona.

• Ke a tseba hore lesedi le fumanweng phuputsong, ho kenyeletswa le dintlha tsa motho ka mong, di tla sebetswa ka ho sa tsejoe le ho hlahiswa tlalehong ya diphetho.

• Kea utloisisa hore nke ke ka otloa ka tsela efe kapa efe ha nka lakatsa ho khaotsa ka thuto le hore ho khaotsa ho tsuba ho ke ke ha ama litlhare tsa ka tse ling.

• Ke nka karolo ka boithatelo.

• Ke fumane kopi e saennweng ea tumellano ena ea tumello e nang le tsebo.

_____ _____

Lebitso la monkakarolo (Ka kopo printa) Letsatsi

_____ _____

Tshaeno ya monkakarolo Letsatsi

_____ _____

Lebitso la mofuputsi (Ka kopo printa) Letsatsi

_____ _____

Saena ea mofuputsi Letsatsi

APPENDIX F

REFERRAL LETTER

health
Department of
Health
FREE STATE PROVINCE

Screening Referral Letter

Date_____

Infant's Name _____

Dear Parent: The infant hearing screening recently performed indicates that your child needs further evaluation. This does not mean that your child has a hearing loss, but it does mean that he or she should be evaluated by an Audiologist or a medical professional. We urge you to give this your immediate attention. Please make an appointment with your child's physician and/or Audiologist as soon as possible. If you have any questions, please contact Prof.

Biagio (leighbiagio@up.ac.za).

Dear Doctor/Audiologist: Please conduct a diagnostic assessment on the infant's hearing. I have examined_____ on __/__/__.

Screening results attached.

APPENDIX G

DATA STORAGE FORM

Faculty of Humanities
Fakulteit Geesteswetenskappe
Lefapha la Bomotho

Humanities 100
Since 1919

FACULTY OF HUMANITIES
RESEARCH ETHICS COMMITTEE

Declaration for the storage of research data and/or documents

I/ We, the principal researcher(s) Andani Gluggy Madzivhandila (u15186467)

and supervisor(s) Prof. Leigh Biagio and Prof. Talita le Roux

of the following study, titled Neonatal hearing screening using a smartphone-based otoacoustic emission device: A comparative study

will be storing all the research data and/or documents referring to the above-mentioned study in the following

Department / Centre: Speech-Language Pathology and Audiology

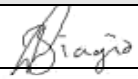
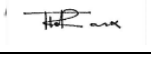
We understand that the storage of the mentioned data and/or documents must be maintained for a minimum of 10 years from the commencement of this study.

Start date of study: January 2020

Anticipated end date of study: September 2023

Year until which data will be stored: 2033

Name of Principal Researcher(s)	Signature	Date
Andani Gluggy Madzivhandila U15186467		1 September 2023

Name of Supervisor(s)	Signature	Date
Prof. Leigh Biagio De Jager		1 September 2023
Prof. Talita le Roux		4 September 2023

Name of Head of Department	Signature	Date
Prof. Jeannie van der Linde		5 September 2023

APPENDIX H

DATA COLLECTION FORM

INFANT HEARING SCREENING

Data Collection Form

Alpha-numeric code:		**Tester:**	
Age:		**DOB:**	
Date:		**Contact:**	

OTOSCOPY	
R	**L**

hearOAE

Right Ear (DPOAE/TEOAE)				**Left Ear (DPOAE/TEOAE)**	
Test	**Retest**	**SNR**	**Frequency**	**Test**	**SNR**
Pass/Refer	**Pass/Refer**		**4000Hz**	**Pass/Refer**	
Pass/Refer	**Pass/Refer**		**3000Hz**	**Pass/Refer**	
Pass/Refer	**Pass/Refer**		**2000Hz**	**Pass/Refer**	
Pass/Refer	**Pass/Refer**		**1000Hz**	**Pass/Refer**	

DP: distortion product

DPOAE: distortion product otoacoustic emissions

NF: noise floor

SNR: signal to noise ratio

TE: transient evoked

TEOAE: transient evoked otoacoustic emissions

OVERALL PASS/REFER: _____

Otodynamics ILO v6

Right Ear (DPOAE/TEOAE)			**Left Ear (DPOAE/TEOAE)**		
Test	**Retest**	**SNR**	**Frequency**	**Test**	**SNR**
Pass/Refer	**Pass/Refer**		**5000Hz**	**Pass/Refer**	
Pass/Refer	**Pass/Refer**		**4000Hz**	**Pass/Refer**	

Pass/Refer	**Pass/Refer**	**3000Hz**	**Pass/Refer**
Pass/Refer	**Pass/Refer**	**2000Hz**	**Pass/Refer**

DP: distortion product

DPOAE: distortion product otoacoustic emissions

NF: noise floor

SNR: signal to noise ratio

TE: transient evoked

TEOAE: transient evoked otoacoustic emissions

TEST TIME (in minutes)

hearOAE	
Otodynamics ILO v6	

CONCLUSION AND RECOMMENDATIONS

Summary of results and comments	**Plan of Action**	
	Monitor Hearing	
	Retest (specify date)	
	Referral to ENT	
	Other (specify)	

APPENDIX I

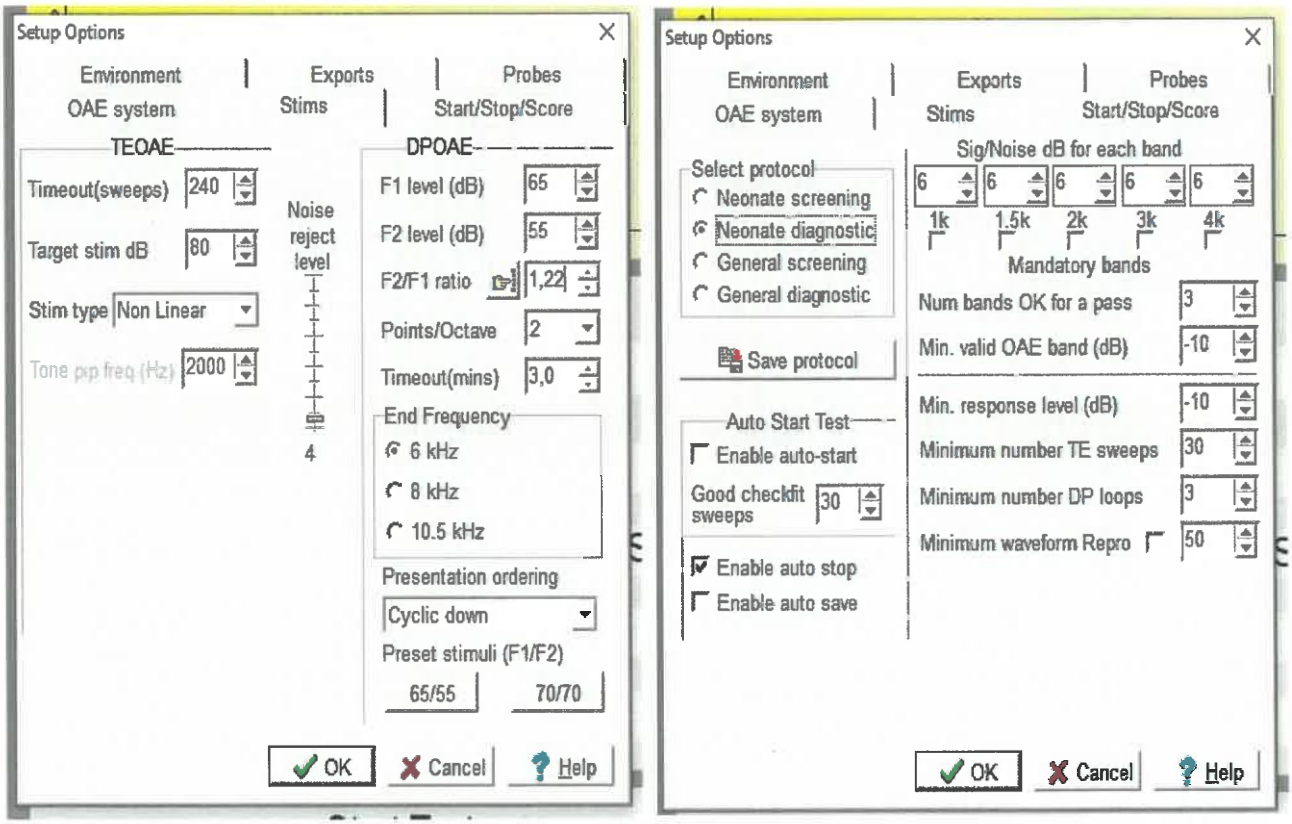
hearOAE and Otodynamics screening protocols

hearOAE Clinical Trial Protocols

Arm B: Infants

DPOAE - SCREENING

hearOAE: DP Infant Screening CT



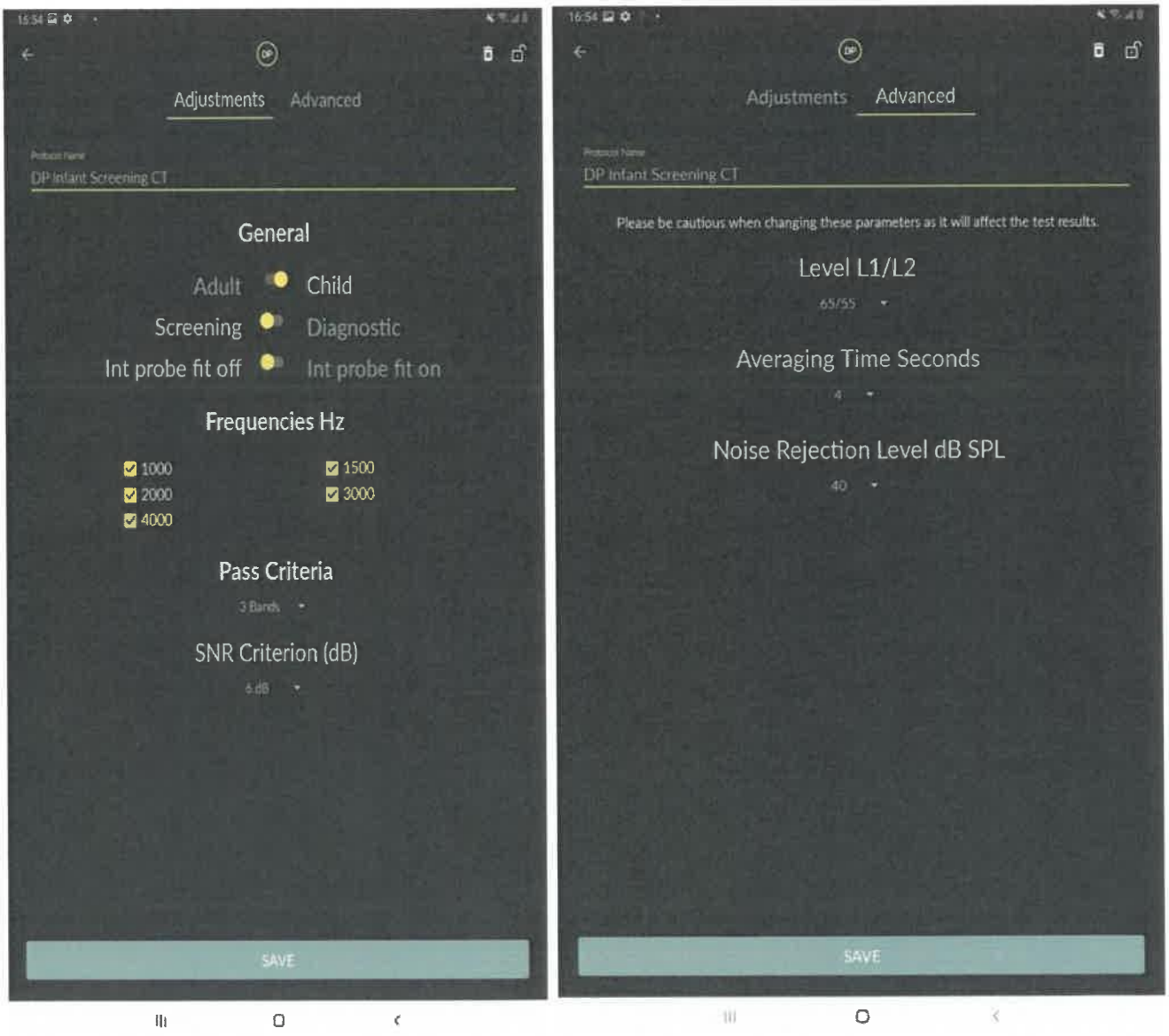
** User needs to stop test after it has repeated/ run through three times
** If the test stops after three times it indicates a pass, if the test tries to continue it indicates a fail

hearOAE Clinical Trial Protocols

Arm B: Infants

DPOAE - SCREENING

hearOAE: DP Infant Screening CT

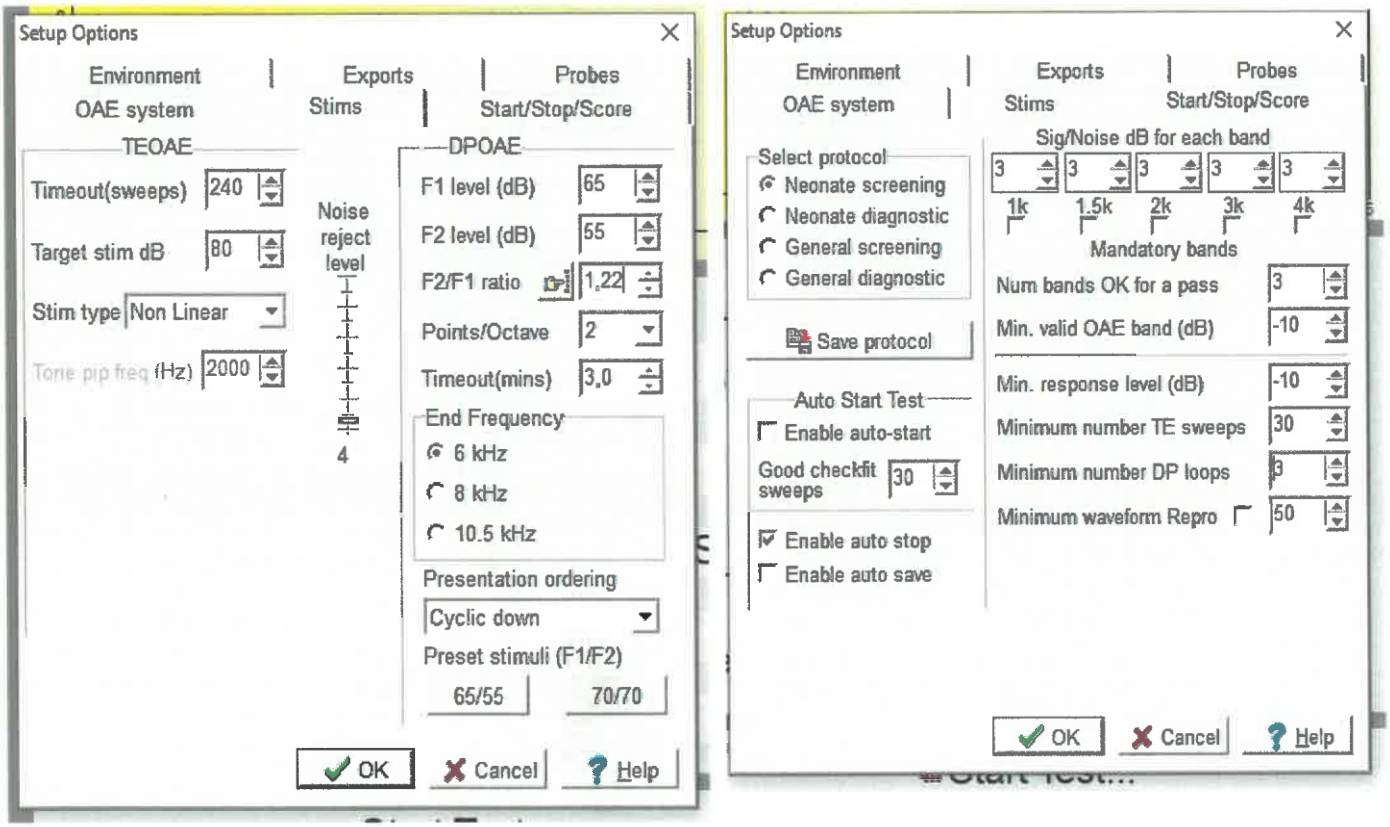


hearOAE Clinical Trial Protocols

Arm B: Infants

TEOAE - SCREENING

Otodynamics: Neonate screening



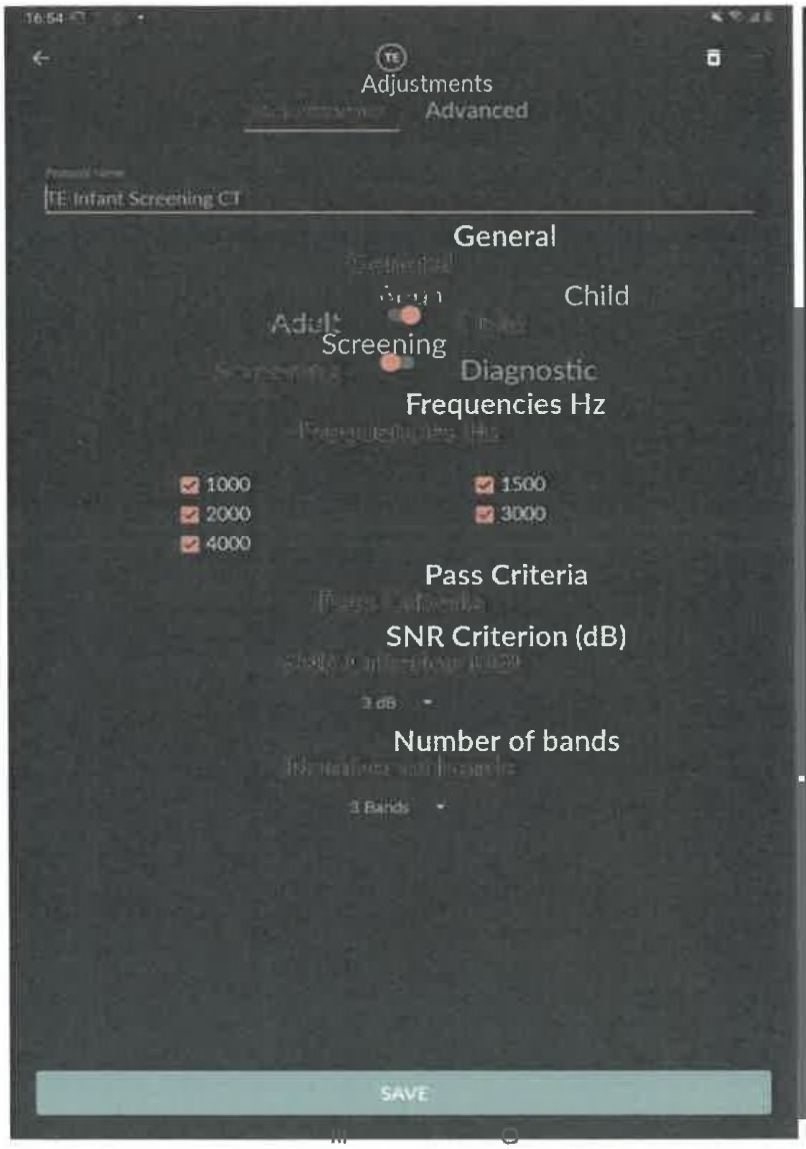
** Test stops before 240 sweeps = passed
** Test failing will show "red cross"

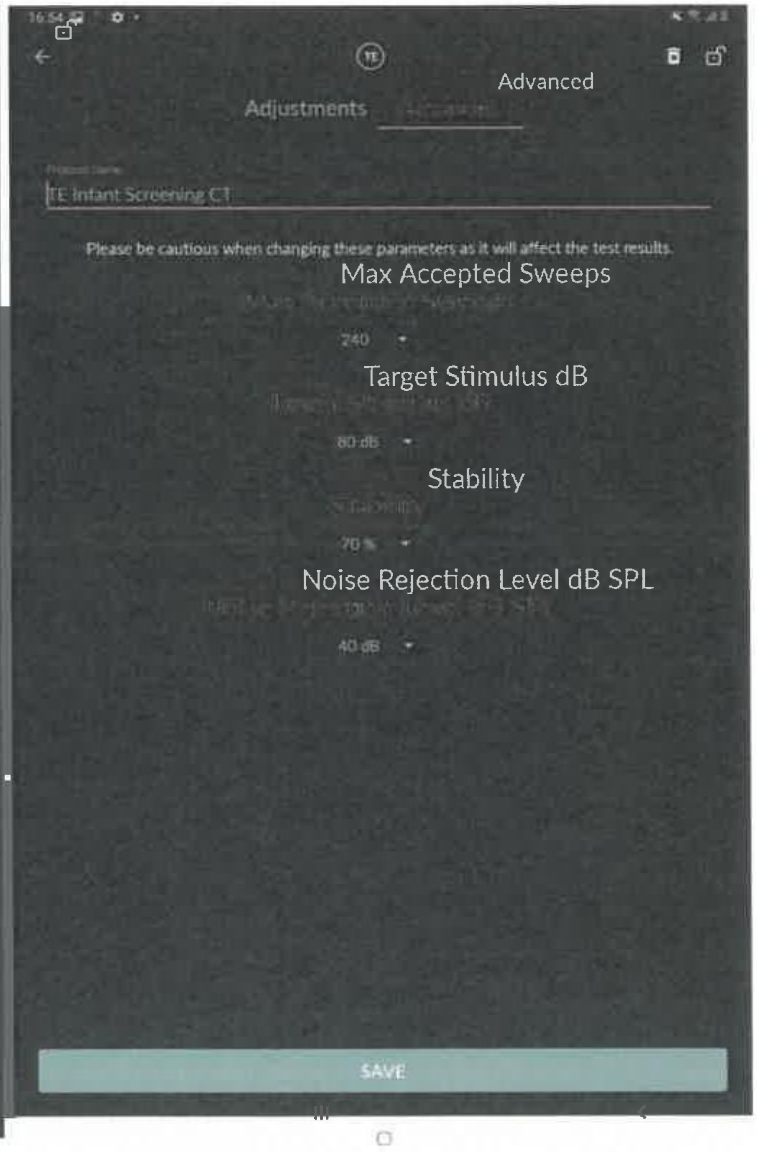
hearOAE Clinical Trial Protocols

Arm B: Infants

TEOAE - SCREENING

hearOAE: TE Infant Screening CT





APPENDIX J

PROOF OF SUBMISSION

Proof of submission (Submission IJPORL-D-23-00753)

Ms. Ref. No.: IJPORL-D-23-00753
Title: Neonatal hearing screening using a smartphone-based otoacoustic emission device: A comparative study
International Journal of Pediatric Otorhinolaryngology

Dear Prof Leigh Biagio de Jager,

Thank you for submitting your paper to International Journal of Pediatric Otorhinolaryngology. The reviewers have now commented on your paper and have recommended a Revision of your manuscript prior to consideration for publication.

For your guidance, reviewers' comments are appended below.

If you decide to revise the work, please submit a Cover Letter with your Revision in which you respond to each of the Reviewer comments and note how you have revised to manuscript to answer their critique. Also, in the Revised manuscript please denote all areas of revision by placing vertical line in the LEFT margin so that the Reviewers can identify specific areas of revision. Your Revision will not be considered for publication without said Cover Letter and clear delineation of changes made in the document. If you are prepared to undertake the work required IJPORL would be happy to consider your revised manuscript further.

To submit a revision, please go to https://www.editorialmanager.com/ijporl/ and login as an Author.

Your username is: leigh.biagio@up.ac.za