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UNIVERSITY OF NORTHERN COLORADO

Greeley, Colorado

The Graduate School

FREQUENCY SPECIFIC HEARING ASSESSMENT NOISE:  
MINIMUM RESPONSE LEVELS AND RESPONSE  
TIME IN THE PEDIATRIC POPULATION

A Scholarly Project Submitted in Partial Fulfillment  
of the Requirements for the Degree of  
Doctor of Audiology

Justine Louise Wright

College of Natural and Health Sciences  
Department of Audiology and Speech-Language Sciences  
Audiology

May 2023

This Scholarly Project by: Justine Louise Wright

Entitled: *Frequency Specific Hearing Assessment Noise: Minimum Response Levels and Response Time in the Pediatric Population*

has been approved as meeting the requirement for the Degree of Doctor of Audiology in the College of Natural and Health Sciences in the Department of Audiology and Speech-Language Sciences.

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## ABSTRACT

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Pediatric audiological testing typically consists of using sound field testing for children six months to two years of age. It is conducted with a child seated in the center of a sound booth with speakers located on the right and left sides of the patient at varying degrees each with an object to reinforce their response. This sound field testing is completed using one of two stimuli: narrowband noise or warbled tones. A newer noise, referred to as frequency specific hearing assessment (FRESH) noise, was created to be used specifically for pediatric patients to grab their attention and respond faster to the stimulus.

Previous studies have been completed and researchers found that FRESH noise and other stimuli obtained consistent thresholds but narrowband noise highly underestimated a hearing loss (Moore & Violetto, 2016). The purpose of this study was to compare the minimum response levels (MRLs) for two different stimuli, narrowband noise and FREquency Specific Hearing Assessment (FRESH) noise, as well as the timing of each participant's head turn toward the sound source. The other purpose was to determine if FRESH noise obtained a faster head turn response as compared to narrowband noise. Data were collected from 10 children between 12 and 27 months of age within the northern Colorado area. Both the minimum response level and timing of head turn response were obtained.

It was hypothesized that FRESH noise would obtain a better minimum response level and faster head turn response than narrowband noise. It was concluded that there was no significant difference in minimum response level or timing. Further studies need to be completed with a larger sample size and various hearing losses to confirm these findings.

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## CHAPTER I

### INTRODUCTION

Audiologists performing audiological testing on pediatric patients have historically had two choices for stimuli: narrowband noise and warbled tones. These two types of stimuli were used in testing pediatrics because with young children, they often could not tolerate headphones or insert earphones so sound field testing was used in place of pure tone audiometry. In a sound field setting, pure tones could not be utilized due to standing waves, so different stimuli were needed to complete testing with this young population. A new type of stimulus is speculated to be more useful with the pediatric population in capturing their attention than previous stimuli. This new noise is called Frequency Specific Hearing Assessment (FRESH) or pediatric noise.

#### **Purpose of the Study**

Frequency specific hearing assessment noise is a relatively new type of stimulus within the field of audiology. The purpose of this study was to compare the minimum response levels (MRLs) for two different stimuli, narrowband noise and FREquency Specific Hearing Assessment (FRESH) noise, as well as the timing of each participant's head turn toward the sound source. A stimulus to be used with children needs to have the ability to quickly capture a young child's attention and keep them listening for the sound as they are being tested in the sound booth. Based on previous research, FRESH noise could add another type of stimulus to pediatric auditory testing repertoires. With this research showing that FRESH noise could accurately and quickly obtain MRLs, audiologists would have a third stimulus for routine testing

within the pediatric population. Based on this rationale, the following research questions guided this study.

### **Research Questions and Hypotheses**

- Q1 What are the measured minimum response levels of children with normal hearing using Frequency Specific Hearing Assessment (FRESH) noise in sound field testing in comparison to minimum response levels for narrowband noise?
- H1 The minimum response levels of children with normal hearing will be better with FRESH noise as compared to narrowband noise and will be within normal limits.
- Q2 What are the response times to FRESH noise and how do they compare to response times for narrowband noise presented in sound field?
- H2 There will be faster response times with FRESH noise than with the use of narrowband noise.

### **Summary**

In summary, FRESH noise is a new stimulus developed to test hearing thresholds of children more accurately. With a new stimulus, audiologists have access to another stimulus to more accurately obtain the MRL of children while keeping their attention for longer periods of time. This study was developed to see how narrowband noise and FRESH noise compared to each other while evaluating MRLs and response times with pediatric patients.

CHAPTER II  
REVIEW OF THE LITERATURE  
**Newborn Hearing Screening**

Prior to the 1990s, children who were born deaf or hard of hearing were not identified as having a hearing loss until as late as two or three years of age (Olusanya, 2011). However, children with more mild hearing losses between 25 and 40 decibels (dB) hearing level (HL) were often detected later than age two or three, usually when the child was already in school (Yoshinaga-Itano et al., 1998). This resulted in many children exhibiting speech and language delays as well as difficulties with social interactions (Alford et al., 2014). Because of delayed diagnosis, children were not receiving intervention services until later in childhood (Alford et al., 2014). To address this concern, many agencies such as the National Institute on Deafness and Other Communication Disorders and the Health Resources and Services Administration began discussing the idea of universal hearing screenings. With universal hearing screening, infants with hearing loss could be detected before leaving the hospital. In the 1990s, this became a reality with hospitals and birthing centers implementing hearing screenings for all children born in their facilities (Alford et al., 2014).

The Early Hearing Detection and Intervention program developed specific goals for screening and intervention with children (American Academy of Pediatrics, 2021). These goals were known as the 1-3-6 goals, with screening by the age of one month, diagnosis by the age of three months, and early intervention services by the age of six months. One month for screenings allowed babies who were born outside of a hospital or did not get tested right after birth to have a

chance to get their first audiological test completed. The three-month time for diagnosis allowed for follow-up testing to confirm a hearing loss. Lastly, beginning early intervention services and amplification at six months ensured the child is receiving invaluable speech and language input during the critical language period (American Academy of Pediatrics, 2021). These goals are important to ensure children are identified and can begin early intervention services as soon as possible to increase the language and vocabulary learning in this young population (Yoshinaga-Itano et al., 2017).

### **Cause of Hearing Loss in Pediatric Patients**

Permanent hearing loss in children could be caused by several things. Whether it be a congenital (present at birth), progressive, or acquired hearing loss, it is important to continue to monitor children with hearing loss throughout their lifespan (Sininger et al., 2010).

Approximately 50% to 60% of hearing losses present at birth are congenital. This could be due to a family history of hearing loss or a genetic disorder passed down to the child. About 20% of diagnosed hearing losses are attributed to a genetic syndrome including Down syndrome, Usher syndrome, Waardenburg syndrome and Treacher Collins (Morton & Nance, 2006). Multiple risk factors could lead to a hearing loss at the time of birth or later in life. Non-genetic risk factors include a stay in the neonatal intensive care unit for longer than five days, hyperbilirubinemia with blood exchange, in utero infections, craniofacial abnormalities, and more (American Academy of Pediatrics, 2021).

### **Prevalence of Hearing Loss in Pediatric Patients**

It is estimated that between one and three children per every 1,000 children are born with hearing loss (American Speech-Language-Hearing Association, 2009). There is an even higher

prevalence of children in the neonatal intensive care unit with hearing loss diagnosed in 32 per every 1,000 children (Hille et al., 2007). In 2017, 6,500 infants born in the United States were identified as having a permanent hearing loss. The most common congenital impairment was a sensorineural hearing loss; therefore, screening to identify is extremely important and universal newborn hearing screenings assist with diagnosis in the earliest stage possible (Northern & Downs, 2014). To continue monitoring hearing loss in children and diagnose progressive hearing loss, audiologists use sound field testing for difficult to test populations.

### **Sound Field Testing**

Martin et al. (1998) stated that practicing audiologists could be employed in a variety of settings with the majority of professionals located in hospitals (26%), physicians' offices (33%), or private practices (17%). Some other settings included industrial clinics, intervention centers, psychiatric centers, and more (Rochlin, 1993). Sound field testing conducted by audiologists is an evaluation of hearing thresholds in a sound booth using loudspeakers as opposed to ear specific transducers. There are a variety of situations in which sound field testing occurs. Most commonly, hard-to-test patients who will not tolerate earphones are evaluated with sound field testing. Hard-to-test patients could include young children or those who have a mental or physical disability and cannot be tested using traditional methods. Lastly, it is a way to evaluate hearing aid performance by comparing patients aided and unaided thresholds (American Speech-Language-Hearing Association, 1991).

Martin et al. (1998) conducted a survey of 418 audiologists in the United States; 70% said they used sound field testing for infants, toddlers, and uncooperative clients as well as a variety of other reasons. Some of these reasons included testing speech discrimination in noise, evaluating central auditory processing difficulties, and evaluating cochlear implant patients. The

number of times audiologists conducted sound field testing varied from less than five times a week to over 20 times a week (Rochlin, 1993). The type of practice and clientele seen affected just how much sound field testing was going to occur and what type of test was going to take place.

### **Sound Field Testing Applications**

Young children between birth and six months are unable to actively respond to a stimulus such as raising their hand or pressing a button. A positive aspect of sound field testing is the patient can sit in a car seat, bassinet, or in their parents' arms, and the audiologist can play the stimuli through a loudspeaker. The audiologist looks for a response such as an arm or leg movement, the ceasing of sucking on a bottle or pacifier, or a definitive eye blink. It is up to the audiologist to determine what constitutes a response. These types of evaluations are called behavioral response observations or behavioral observation audiometry (Northern & Downs, 2014).

Another type of sound field test audiologists can use is visual reinforcement audiometry (VRA). Patients between the ages of six months and two years, as well as other hard-to-test patients, are evaluated using VRA. This testing is administered with earphones or through loudspeakers in sound field and the listener is conditioned to turn their head in response to the stimulus presentation. The child is then rewarded visually with an animated toy behind plexiglass that moves, makes noise, or both. While this does not give ear-specific information when performed in a sound field, it gives the audiologist an idea as to how the better ear is performing (Northern & Downs, 2014).

## **Procedures of Sound Field Testing**

To test in a sound field, procedures and environmental requirements need to be in place to record the most accurate thresholds of patients' hearing sensitivities. Since most testing occurs in a sound booth, the booth needs to meet specific guidelines for sound field testing. Ideally, testing would be in an anechoic chamber; however, this could be difficult to obtain due to cost and availability (Walker et al., 1984). The size of the booth depends on the demographic being evaluated. For pediatric patients, the sound booth minimum dimension is 6 x 4 meters; however, for clinical applications, the minimum is 3 x 3 meters (Corrigan & Horsfall, 2019). In the sound booth, there should be as much surface area covered by an acoustic absorber as possible to ensure reflective surfaces are not interfering with the test. These surfaces could include tables, chairs, and other furniture within the sound booth. In addition, there should be enough room for the patient to be seated at a sufficient distance—approximately one meter from the loudspeakers and walls (Walker et al., 1984).

Sound field testing requires loudspeakers to play the stimuli to the patient. Loudspeakers act as a way of getting the patient to localize toward the sound source. Since there is no ear-specific information, this allows the audiologist to get an idea of how the better hearing ear is performing. Most sound booths use two speakers because they allow the stimuli to be presented from two different directions and the patient is less likely to know exactly where the sound is coming from in the sound booth (Northern & Downs, 2014). The placement of the loudspeakers is dependent on the clinic; however, 43% of audiologists place them at a 90-degree azimuth from the patient (Rochlin, 1993).

Before testing can begin, the patient needs to be placed in a location within the sound booth that allows for enough movement to face toward each loudspeaker while keeping the ear



located within the center of the speaker (one meter away). To allow for the various adjustments needed for patients, a moveable chair that has height adjustment capabilities should be available in the sound booth (Walker et al., 1984). Many audiologists place a string that hangs from the ceiling of the sound booth and then align the head of the patient with this location to ensure a consistent distance from the loudspeakers during each test. This reference point is most commonly 1 to 1.5 meters from both loudspeakers. All the information related to the testing environment needs to be documented and easily accessible, especially the calibration procedures (Corrigan & Horsfall, 2019).

### **Psychoacoustic Aspects of Sound Field Testing**

#### **Standing Waves**

Sound waves are constantly filling up space although they are not visible. When there is a specific frequency of vibration that is reflected from an object or person, an interference pattern appears and look as if the wave is standing still, which is considered a standing wave (Behrman & Finan, 2017). When two or more sound waves are together within a confined space, they cause interference and affect the sound present within the space. Within a standing wave, nodes occur at the lowest amplitude and antinodes occur at the highest amplitude. Standing waves occur during sound field testing when pure tones are used, unlike narrowband noise or warbled tones (Behrman & Finan, 2017). They occur because the frequency of the pure tone is sent through the loudspeaker and then reflected around the room, causing a change in the phase of the signal and fluctuation of the sound pressure level and a misjudgment of a patient's true threshold (Gelfand, 2010).

## **Critical Bandwidth**

In the 1940s, Harvey Fletcher introduced the critical band theory (Gelfand, 2010). This theory showed that when a signal was presented, filters surrounding the signal had the ability to mask that signal. Within the inner ear, the cochlea acts as a filter where there are multiple filters along the range of frequencies that we can hear that allow individuals to perceive sounds. As frequency increases, the bandwidth of frequencies is also increased so we can overcome more of the signal with a masker. Each frequency has its own critical bandwidth that is important for a signal to be heard and masked effectively (Gelfand, 2010). Critical bandwidth is discussed later in the chapter with the introduction of frequency specific hearing assessment (FRESH) noise.

## **Minimum Audibility Curves**

Within audiology, audibility curves are the basis for the set-up of audiometers. This is how professionals determine what 0 dB HL is going to be on the audiometer. A minimum audibility curve looks at what the minimum intensity of sound a person can detect is and how it correlates to the presence of a stimulus (Gelfand, 2010).

Two procedures were developed through research that measure the intensity of a given stimulus (Gelfand, 2010). The first curve is called a minimum audible pressure (MAP). Using earphones, a subject is placed inside a sound booth with a probe tube between the patient's tympanic membrane, or eardrum, and the earphone. This probe tube measures the amount of pressure being presented through the earphones in relation to a stimulus. The MAP shows a higher dB SPL at the lower and higher frequencies with a dip between 1-5 kHz. This dip is due to the resonant frequency of the ears, meaning there is an enhancement of specific frequencies and people can hear better at those frequencies and worse below 1 kHz and above 5 kHz. This

enhancement of frequencies comes from the ear canal, pinna, middle ear bones, and middle ear cavity (Gelfand, 2010).

The second curve is called the minimum audibility in the field (MAF; Gelfand, 2010). This procedure is similar to the MAP; however, instead of using earphones, the subject is placed in the sound booth and presented with stimuli through the loudspeakers in sound field while holding a sound level meter. Similar to the MAP curve, there is better hearing in the 1-5 kHz range and worse hearing below 1 kHz and above 5 kHz. These two curves show there is better hearing in sound field as opposed to earphones. In sound field, the person in the booth has both ears listening instead of just one with earphones. Also, there is the head shadow effect in sound field, meaning the sound is heard more intensely at one ear than the other because the sound has to make its way across the head. Generally, these minimum audibility curves show hearing is better in sound field than under earphones (Gelfand, 2010).

### **Fletcher and Munson Curves**

Also known as equal loudness level contours, the Fletcher and Munson curves were designed to display perceived loudness level across the frequency spectrum. Fletcher and Munson looked at how perception of loudness changed as frequency changed (Gelfand, 2010). Participants listened to pure tones and were asked to compare them to different tones in terms of how loud they were. The presentation was based on a 1000 Hz tone and the curve showed that as frequency was lowered, the tone needed to be of a higher intensity to equal the perceived loudness at 1000 Hz. The same went for raising the frequency—the tone needed to be more intense to equal the perceived loudness at 1000 Hz (Gelfand, 2010). As the intensity level in decibels increased, the curves followed the same pattern; yet as the intensity increased, the curves tended to become flatter. The lower frequencies had a faster loudness growth than the

higher frequencies (Gelfand, 2010). These measurements were based on phons, or units of loudness, so a 60 dB sound at 1000 Hz equaled 60 phons (Gelfand, 2010). These curves are important for the knowledge of how loudness perception works.

## **Calibration of Sound Field Audiometry**

### **Calibration Standards**

Audiological testing requires the use of calibrated equipment to ensure thresholds are accurate across all practices. However, within sound field, there are no standards for proper calibration (Beynon & Munro, 1993). There are several ways to calibrate equipment, yet measurements can still vary from test to test and practice to practice. Two components make up sound field calibration: physical and biological calibration. Physical calibration is done by measuring the sound pressure level (SPL) in the sound booth and then comparing that value to the value shown on the audiometer (Beynon & Munro, 1993). Biological calibration involves finding the threshold level of a patient and then corresponding that to the measured SPL value at the test location (Beynon & Munro, 1993).

Calibration is completed using the reference equivalent threshold sound pressure levels (RETSPL), which are found using earphone calibration levels and then translated into sound field measurements. A RETSPL is the difference between the hearing level (HL) and the output of a coupler used to calibrate the audiometer (Mueller et al., 2014). The RETSPL values for sound field are found using narrowband noise or frequency modulated tones (FM) as opposed to pure tone signals (Gelfand, 2010). Pure tone signals create standing waves in sound field and cause fluctuations in the sound pressure level in the room (Corrigan & Horsfall, 2019). The RETSPL measurements could be based on either the physical or biological calibration and could vary based on several factors including the type of stimulus, where the patient was located within

the sound booth, and the set-up of the test room and noise levels (Beynon & Munro, 1993).

Audiologists could calculate their own RETSPL measurements or use published measurements but this could lead to large variations in thresholds between practices and patients. The values practices use for sound field calibration are based on ISO 226 (1987), however, there are specific criteria the sound booth must meet to use the standardized values and many practices do not meet these specific criteria (Beynon & Munro, 1993).

The International Organization for Standardization (ISO) 226 (1987) standards vary depending on the category of sound field the test booth qualifies under. The first category is a free field sound booth, meaning there are no sound wave reflections (Beynon & Munro, 1993). The second is a diffuse field or reverberation chamber where sound waves propagate equally in each direction throughout the sound booth (Beynon & Munro, 1993). Lastly, there is a quasi-free field, which is a combination of a free field and diffuse field. Most audiology clinics have sound booths that qualify as quasi-free fields (Shaw & Greenwood, 2012). Once the specific criteria have been met, measurement standards are made using a microphone and sound level meter (SLM) to check that there are no deviations in measurements greater than 1dB (Shaw & Greenwood, 2012).

An alternative method is using the dB(A) scale, which calibrates sound field signals with a hand-held warble-tone generator or warble tones from the audiometer and a SLM (Beynon & Munro, 1993). A hand-held warble-tone generator is a portable device that plays a warbled tone and could be used to ensure the correct sound levels are being presented with a SLM. This scale adjusts the loudness of the sound within the sound field using the 40 phon equal loudness curves created by Fletcher and Munson in 1933 (as cited in Beynon & Munro, 1993). The perceived loudness levels of the subject are used to calibrate the field rather than measured SPL levels

(Beynon & Munro, 1993). A lower minimum audible field or lower intensity is needed to hear a stimulus using the dB(A) scale as opposed to RETSPL measurements. Therefore, because dB(A) and dB HL are measured differently, corrections are needed to reach relevant dB HL values from dB(A) calibration.

### **Head Movement and Positioning**

The patient's head position and amount of movement are both important for sound field audiometry calibration. There is a fixed calibration point within the test booth; yet the height of each patient can vary, making testing difficult. Pediatric patients add more difficulty due to more head movements and variations between children sitting by themselves or on a caregiver's lap during testing (Shaw & Greenwood, 2012). Narrowband noise and FM tones have low variability in thresholds due to no standing waves resulting in the test booth. Since sound field testing is performed with these two types of stimuli, the amount of head movement is not as influential to the variability of thresholds among patients (Shaw & Greenwood, 2012).

Shaw and Greenwood (2012) evaluated how different testing varied from one clinic to another. Audiologists in eight different clinics evaluated the differences in SPL measurements in six locations at various locations 0.15 and 0.30 meters around the calibration point in the sound booth. They also evaluated the differences in SPL based on the height of an infant mannequin in an infant chair and sitting in a caregiver's lap. To make these measurements, a Brüel and Kjaer (B&K) 2500 sound level meter, B&K 4189 half-inch free-field microphone, and B&K 4231 calibrator were used (Shaw & Greenwood, 2012). The stimuli were FM tones at 0.5, 1, 2, 3, and 4 kHz at 60 dB HL. The measurements varied between 2 and 5 dB at each frequency tested with more significant differences at 0.5 kHz and 3 kHz (Shaw & Greenwood, 2012). Additionally, there was a greater difference in measurements at 0.30 meters from the calibration point than at

the 0.15 meters. While this did not seem like a significant difference, it was clinically significant and could alter results of the patient thresholds.

The researchers revealed the calibration point within the sound booth was on average 0.18 meters higher than the loudspeaker. It was recommended that the patient ear height be averaged in the center of the loudspeaker and the distance from the loudspeaker to the ear be consistent within the sound booth (Shaw & Greenwood, 2012). However, due to many variations in patient height and the inability to alter the position of the loudspeaker in many situations, consistency was difficult to maintain. Another finding revealed there was less SPL variability when the infant was sitting on the caregiver's lap as opposed to sitting in an infant chair. This could be due to less movement of the infant during testing or higher levels of comfort when around their caregiver. The calibration point should be thoroughly evaluated before testing occurs within sound field audiometry to ensure less variation of tested thresholds (Shaw & Greenwood, 2012).

### **Acoustic Stimuli in Sound Field**

#### **Narrowband Noise**

One way to measure auditory thresholds within the pediatric population is with a stimulus called narrowband noise (NBN). Narrowband noise is a complex filtered noise that contains a small range of frequencies. This entails a cutoff point on both the high frequency side and the low frequency side such that the frequencies above or below are rejected from the stimulus (Kramer & Brown, 2019). Narrowband noise has been shown to have a wide frequency bandwidth, meaning more frequencies are involved within this sound compared to other types of stimuli (Shaw & Nikolopoulos, 2004). Also shown was the wider the bandwidth of the stimulus, the better children were able to locate where the sound was coming from in the sound booth

(Shaw & Nikolopoulos, 2004). The use of NBN was shown to reduce the amounts of standing waves that appeared within the sound booth, which positively affected the results of the test, and could help obtain more accurate threshold measurements (McDermott & Hodgson, 1982).

Children have been found to positively respond to narrowband noise during sound field testing (Sanders & Josey, 1970), which is why it is still used today.

### **Warbled Tones**

Warbled tones, also known as frequency-modulated (FM) tones, are a second type of stimulus that could be used in sound field to measure auditory thresholds in children. A frequency-modulated tone means the signal being presented has a varied frequency. This stimulus is more focused at a specific frequency compared to narrowband noise. When used, the results of the test are more frequency-specific than with the use of NBN (Shaw & Nikolopoulos, 2004). Warbled tones might be more frequency-specific than NBN but they could also create more standing waves within the sound booth. Overall, the use of warbled tones has been comparable to the use of narrowband noise with similar minimum response levels (MRLs) and is an option for sound field testing (McDermott & Hodgson, 1982).

### **Auditory Thresholds for Narrowband Noise Versus Warbled Tones**

McDermott and Hodgson (1982) evaluated the use of narrowband noise and warbled tones when testing children and, consequently, compared how thresholds varied between the two stimuli. The study was conducted with 39 children between the ages of 8 and 48 months. The children were separated into three groups to account for the different ages included in the study. Group A was children between the ages of 8 and 24 months, Group B was children between the ages of 25 and 36 months, and Group C was children between the ages of 37 and 48 months. Each group consisted of 13 children. With the child placed at 125-degree azimuth between two



loudspeakers in the sound booth, they were presented with either NBN, warbled tones, or live speech. The audiologist looked for a head turn response using VRA. The narrowband noise and warbled tones were centered at 500 Hz and 4,000 Hz (McDermott & Hodgson, 1982).

After the child was conditioned to turn their head when they heard the sound, the testing began with either NBN or warbled tones (McDermott & Hodgson, 1982). After a two second presentation, the audiologist marked either response or no response and continued on to the next frequency, and then the next stimulus. The children exhibited slightly poorer thresholds when using warbled tones as opposed to the narrowband noise. The children from Group A had the most similar thresholds with only 5 dB difference for 92% of the children between the narrowband noise and warbled tones. There was poorer agreement between the two older groups and the two stimuli (McDermott & Hodgson, 1982). For Group B, there was a 5 dB difference for 61% of children at 500 Hz and 23% of children at 4,000 Hz. Lastly, for Group C, the 500 Hz tone had 77% agreement and the 4,000 Hz tone had 61% agreement. These results showed there were some differences between the narrowband noise and warbled tones; however, the use of more frequency-specific stimuli would help audiologists obtain more accurate thresholds (McDermott & Hodgson, 1982).

Shaw and Nikolopoulos (2004) also evaluated the difference between NBN and warbled tones. Additionally, they measured the rates at which children oriented themselves toward the loudspeakers within the sound booth. The researchers conducted this study with 200 infants between the ages of 6 and 30 months with a mean age of 13 months over a period of three months. Each child was randomly assigned to be tested with either the narrowband noise or the warbled tones with 100 infants in each group. Within each group, the participants were divided again into Group A—children below the age of 14 months and Group B—children above the age

of 14 months. With the loudspeakers located at 90 degrees and 270 degrees azimuth and the height adjusted to be at the average head height of the infant at 75 cm, conditioning took place and then the VRA testing began. The stimuli were presented at 1,000 Hz for two seconds at 70 dB HL (Shaw & Nikolopoulos, 2004). The researchers monitored the child for deliberate head turns toward the loudspeaker and marked those as a response to the stimulus.

Interestingly, more infants responded to the NBN (69%) than the warbled tones (25%). With both Groups A and B, there was a significant statistical difference in favor of the NBN (Shaw & Nikolopoulos, 2004). The researchers then concluded it was more likely to be a head turn from an infant with the use of the NBN as opposed to the warbled tones. When using a warbled tone, they suggested there needed to be a second method to be able to get the infant to turn their head for the response to be recorded (Shaw & Nikolopoulos, 2004). A second method could include changing to using NBN, presenting the stimuli more often or directing the child's attention toward the loudspeaker to connect the sound to the animation. These studies revealed that while both NBN and warbled tones were useful for pediatric testing, NBN was the most efficient at eliciting a response.

One of the limitations related to these two studies was what was recorded as a response. When young children are being evaluated and a researcher is attempting to make their own judgment of what a response is, there could be bias in the results. One researcher's idea of a response could be different than another researcher's idea. Also, babies move their heads around and a head turn toward a loudspeaker could be the child finding interest in objects around them and not truly hearing and responding to the sound being presented. These different limitations affected just what the results of the research were going to be (Shaw & Nikolopoulos, 2004).

### **Frequency Specific Hearing Assessment Noise**

In an attempt to find more frequency-specific thresholds using a narrowband stimulus, FREquency Specific Hearing assessment (FRESH) noise was created (Norrix & Anderson, 2015). This stimulus consists of a steep filter slope to ensure the sound is not going beyond the desired frequency range—the frequency being tested at that time. This means the thresholds found using this noise are consistent with a patient’s true pure tone threshold under earphones (Moore & Violetto, 2016). A patient’s true threshold is defined as the lowest decibel level in which the patient responds two out of three times to a given stimulus. The steep filter slope is related back to the critical bandwidth, in which there is a small window of the frequency range presented as the stimulus. Narrowband noise has been found to be a good stimulus for sound field testing; however, because it is a complex noise, it contains multiple frequencies. This means when a child responds to the narrowband noise, they are not necessarily responding to the center frequency of the NBN the audiologist is presenting. All of this could lead to an underestimation of thresholds, especially with hearing losses that are sloping in the higher frequencies. An underestimation of thresholds means the test results show better hearing than should be present for that patient. Therefore, FRESH noise was developed to avoid an underestimation of thresholds, particularly with children diagnosed with a hearing loss.

Frequency specific hearing assessment noise can be used in sound field but also under earphones. Since FRESH noise is applied in different testing scenarios, it is also an option for an adult hearing evaluation. Hearing thresholds obtained using FRESH noise have been found to be close to thresholds obtained using pure tones (Moore & Violetto, 2016). Moore and Violetto (2016) evaluated how different stimuli affected thresholds of a patient with a high frequency hearing loss. The researchers found pure tones and FRESH noise thresholds were consistent with

each other and were within test-retest reliability. The thresholds obtained with narrowband noise were highly underestimated between 5 and 25 dB and did not accurately depict the hearing loss.

Norrix and Anderson (2015) evaluated the thresholds of patients using warbled tones, narrowband noise, and FRESH noise. The study was conducted with 24 adults who were split into two groups—one group was tested with a simulated hearing loss and the other group with a diagnosed sensorineural hearing loss. Participants were involved in three conditions during the study. Condition one was pure tone thresholds under supra-aural earphones. Condition two was the use of narrowband noise, warbled tones, and FRESH noise in sound field at 90 degrees azimuth. Lastly, condition three was the use of narrowband noise, warbled tones, and FRESH noise under supra-aural headphones. The researchers found that for those with a simulated hearing loss, 86% of the patients' FRESH noise thresholds were within 5 dB of the pure tone thresholds and 98% were within 10 dB (Norrix & Anderson, 2015). For the patients with a known sensorineural hearing loss, the narrowband noise was underestimated at all frequencies by about 4 dB in both sound field and under earphones. On the other hand, 74% of the thresholds under earphones with narrowband noise were within 5 dB of the pure tone threshold and in sound field, 80% of the narrowband noise thresholds were within 5 dB of the warbled tone thresholds. Overall, this study showed that patients with a flat hearing loss would have minimal differences in thresholds but narrowband noise still underestimated hearing loss by 5-10 dB (Norrix & Anderson, 2015). It was recommended that FRESH noise should therefore be used as a stimulus for both sound field testing as well as under earphones rather than NBN.

### **Attention**

One of the contributing factors to a hearing evaluation, whether the patient is an adult or child, is their ability to pay attention throughout testing. Adults are able to focus their attention

on the task but infants struggle more. Visual reinforcement audiometry was developed to overcome the obstacle of attention by giving the child positive reinforcement after they correctly responded to the stimulus. Children have been shown to pay more attention to a noise stimulus such as NBN in a sound field setting rather than a pure tone or warbled tone (Moore & Violetto, 2016).

Courage et al. (2006) evaluated the development of attention to a stimulus in infants between the ages of 3 and 12 months. Their goal was to measure the duration of the longest look toward the stimulus, the mean duration of each look done by the child, the number of looks, and the total time to accumulate. The stimuli in this study were eight diverse types of videos with either faces, characters, or shapes. While this study did not incorporate VRA or other type of audiologic stimuli, their set-up to measure attention was noteworthy. The researchers viewed recordings of the procedure to accurately measure the different attention methods. To get as accurate of a time duration of attention, the researchers viewed the video and measured to the millisecond the time spent looking at the stimulus, total time to accumulate to the stimulus, and that time was recorded (Courage et al., 2006).

### **Summary**

Completing audiological testing on children with accurate response levels can be a difficult task. With the development of FRESH noise, this stimulus could be a new and easier way to get accurate MRLs of young children. This study examined how this stimulus compared to the traditional stimulus of NBN.

One of the challenges expected to occur during testing was testing in sound field. When obtaining results with sound field, ear specific information was not found so the MRLs were based on the better hearing ear. When testing young children, the biggest obstacle was keeping

their attention to the task at hand. Being able to remain animated as the tester and get them excited about the test was a challenge that was likely to occur. This study allowed for breaks to attempt collaboration with the child and allowed for one return appointment if necessary to get MRLs of each child. In addition, the FRESH noise has been demonstrated to have better attention-grabbing abilities than NBN, which should help with the testing process.

In completing this literature review, very little research was conducted on assessing MRLs utilizing FRESH noise with children who were the prime audience for this stimulus. There was also no research on the timing of how quickly children responded to the stimulus. Research is necessary to determine the validity of FRESH noise and how it compares to NBN in young children.

## CHAPTER III

### METHODOLOGY

The purpose of this study was to compare the minimum response levels (MRLs) for two different stimuli, narrowband noise and FREquency Specific Hearing Assessment (FRESH) noise, as well as the timing of each participant's head turn toward the sound source. The methods for this study were based on those of the McDermott and Hodgson (1982) study, which was conducted to compare children's responses to narrowband noise and warbled tones. Some revisions from McDermott and Hodgson's study were made for this current study including a condensed age range, frequencies tested, loudspeaker placements, and stimuli. The current study compared the thresholds obtained using FRESH noise and narrowband noise. This study also compared the response times for both stimuli. Response time was measured as the amount of time it took for each child to turn toward the loudspeaker and was measured in milliseconds through video recording.

#### **Participants**

Participants for this study were recruited from the northern Colorado area via a recruitment flyer. The recruitment flyer was distributed through the University of Northern Colorado Speech-Language Pathology and Audiology Clinic as well as local daycares, preschools and Facebook pages. Data collection was conducted at the University of Northern Colorado after approval was obtained from the Institutional Review Board (IRB; see Appendix A). Ten participants were included in this study ranging in age from 12 to 27 months of age.

Written consent was obtained by the parent or guardian of each child prior to testing (see Appendix B). Both male ( $n = 6$ ) and female ( $n = 4$ ) participants were included in this study.

Participants included in this study had passed their newborn hearing screening and had a parental report of good health. Children who had middle ear infections or other ear abnormalities at the time of the study were excluded from the study. This was determined with a case history form completed by a parent or guardian, a visual inspection of the ear, and an otoscopic examination and tympanometry testing.

### **Materials and Instrumentation**

The GSI Audiostar Pro audiometer was used to obtain the MRLs. The audiometer was calibrated to American National Standards Institute (1968) standards within one year of data collection. The FRESH noise key feature was included on the GSI Audiostar Pro audiometer for easy access to pediatric testing with a noise stimulus. While FRESH noise was the name assigned to the stimulus on the GSI Audiostar Pro, it was denoted as “Peds noise.” Loudspeakers were positioned at 45 degrees to the left and right of the test subject inside a sound booth and arranged with the center of the loudspeaker at the average height of a child’s head when seated on a lap. The subjects sat on their parent or guardian’s lap at 1.5 meters from both speakers inside the booth. Two different stimuli were used during testing: narrowband noise and FRESH pediatric noise.

### **Procedure**

Participants were tested individually in a sound-treated room at the Speech-Language Pathology and Audiology Clinic at the University of Northern Colorado. The sound booth was a Tracoustics Inc. Acoustics Systems RS254. The maximum permissible ambient noise levels were



within American National Standards Institute (1968) specifications for sound-field testing. Testing was completed by a Doctor of Audiology graduate clinician.

Prior to testing, an otoscopic examination was conducted as well as tympanometry to ensure no infection or other ear abnormality was present. Each participant was seated on his/her parent or caregiver's lap to provide stability and comfort to the child. An assistant clinician was inside the sound booth to help center the child's attention after the presentation of each stimulus if needed. The child was conditioned to either the narrowband noise or FRESH noise at 50 dB HL prior to obtaining the MRLs. The stimuli were altered for conditioning between narrowband noise and FRESH noise, meaning the first participant was conditioned with narrowband noise, the second participant was conditioned with FRESH noise, the third with narrowband noise, and so on. This allowed for each stimulus to be used equally for conditioning. To reinforce the responses, the child was conditioned using animated toys contained in a Plexiglas container at 45 degrees to the right and left of the subject. After two correct consecutive localization responses, the minimum response level search began using either narrowband noise or FRESH noise. The initial stimulus was counterbalanced with narrowband noise versus FRESH noise to maintain consistency throughout testing. Responses were obtained using both stimuli at 2 kHz and then at 0.5 kHz. Presentation of the stimulus was altered between the left and right speaker and lasted approximately two seconds per presentation. The presentation side was determined based on where the child was looking. If the child was looking toward the right speaker, the stimulus was presented to the left speaker. If the child was looking toward the left speaker, the stimulus was presented to the right speaker. If the child was looking center, the stimulus was presented to either the right or left speaker.

Minimum response levels were determined at 0.5 kHz and 2 kHz. The order of frequency presentation began with 2 kHz and then moved to 0.5 kHz to provide high and low frequency information. Head turn toward the proper loudspeaker was recorded as a response and reinforced with approximately two seconds of the visual animation above the loudspeaker. The minimum response level was defined as the lowest level at which the child actively responded to two out of three presentations. The MRLs were found at 2 kHz for both stimuli before switching to 0.5 kHz.

### **Analysis**

To analyze the MRLs of the children and the timing of how long it took for each child to look toward the loudspeaker, a two-sampled paired *t*-test was conducted. The variables in this study were continuous. Minimum response levels were recorded on an audiogram for each individual for each stimulus. These thresholds were then transferred to an Excel document for comparison. During testing, the responses were video recorded for later analysis. Multiple cameras placed behind the patient, on the ceiling in the booth, and by the primary clinician were used to ensure responses would be recorded accurately. The recordings were used to measure the response time to the loudspeaker and animation. A time measure was taken of how quickly each participant turned toward the loudspeaker after the presentation of the stimulus. This time measurement began from the time the button to present the stimuli was pressed to when the child began their head turn toward the loudspeaker. A full head turn toward the loudspeaker was considered a response. Due to the difficulty of determining what was a true head turn response to the stimulus and to control for bias, a second clinician trained to identify a correct response provided a judgement about whether a response was present or not. Judgments on what was considered a response were made while watching the recordings of each session and an agreement was made between both clinicians.

The minimum response level was determined by the primary clinician but both clinicians agreed which head turns were used for analysis of the response times. If there was a disagreement between clinicians of whether the participant responded to the stimulus, then that response was not recorded. A second clinician, who was trained in what was considered a correct response, was used to help evaluate response times to ensure there was no bias in results. To measure the response times from the videos, time stamps were noted at the presentation of the stimulus as well as the beginning of the head turn. The difference between these time stamps was recorded.

Recordings were stored on a password protected laptop and flash drive for evaluation and measurement. All recordings were kept confidential and only viewed by the researcher, the clinician helping with data collection, and faculty committee members. No identifying information was stored with the videos; only a subject number was used to identify participants. When the research analysis was completed, videos were properly deleted from the laptop and flash drive.

## CHAPTER IV

### RESULTS

The purpose of this study was to compare the minimum response levels (MRLs) for two different stimuli, narrowband noise and FREquency Specific Hearing Assessment (FRESH) noise, as well as the timing of each participant's head turn toward the sound source. Ten children ranging from 12 to 27 months of age participated in this study; each participant passed their newborn hearing screening and did not have a history of ear infections. All participants had a clear or partially clear otoscopic examination during testing; all participants had normal tympanograms except for Participants 8 and 9 who were not able to cooperate for tympanometry. Participant 2 was unable to condition to the 0.5 kHz NBN stimulus; this was believed to be due to lack of sleep but this participant's data for 2 kHz was included in the data. Each participant responded to 2 kHz for both stimuli before responding to 0.5 kHz for each stimulus. Table 1 shows the means and standard deviations for the MRLs for both stimuli.

**Table 1**

*Means and Standard Deviations for Minimum Response Levels (in dB HL) for Narrowband Noise and Frequency Specific Hearing Assessment (FRESH) Noise*

	Acoustic Stimuli							
	NBN				FRESH			
	0.5 kHz		2 kHz		0.5 kHz		2 kHz	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Results	17.22	4.41	22.50	10.07	17.78	4.41	20.00	6.24

The average MRLs for the 0.5 kHz NBN noise and FRESH noise had a marginal difference. A two-sampled paired *t*-test was completed of the minimum response level for the 0.5 kHz NBN noise and FRESH noise was found to be not significant with a *p*-value of .681. There was also a small effect size with a Cohen's *d* value of -0.142. Comparison of the MRLs for the 2 kHz NBN noise and FRESH noise was also found to be not significant with a *p*-value of .322. The effect size for this sample was considered a medium effect size. Tables 2 and 3 show the values for significance and effect size for both MRLs.

**Table 2***Paired Samples Test for Minimum Response Levels*

Stimuli	Paired differences 95% Confidence Interval of the Difference Upper	<i>t</i>	df	Sig. (2-tailed)
0.5 kHz	2.449	-0.426	8	0.681
2 kHz	7.898	1.048	9	0.322

**Table 3***Paired Samples Effect Size for Minimum Response Levels*

Stimuli	Standardizer	Point Estimate	95% Confidence Interval Lower	95% Confidence Interval Upper
0.5 kHz	Cohen's d	3.909	-0.142	-0.795
2 kHz		7.546	0.317	-0.315

After analysis of the MRLs of each stimulus, the response times for each participant were analyzed to determine if there was a significant difference between the stimuli (see Table 4).

**Table 4***Means and Standard Deviations of Response Times (in ms) for Narrowband Noise and Frequency Specific Hearing Assessment (FRESH) Noise*

	Acoustic Stimuli							
	NBN				FRESH			
	0.5 kHz		2 kHz		0.5 kHz		2 kHz	
Results	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
	4.71	1.69	5.15	3.41	4.81	1.77	5.93	2.62

Similar to the MRLs, the means and standard deviations for both stimuli had a marginal difference. The timing measurements were not significantly different when comparing the 0.5 kHz NBN to the FRESH noise and the 2 kHz NBN to the FRESH noise. The  $p$ -values for the .5 kHz and 2 kHz were .897 and .598, respectively (see Table 5). These values also had a small effect size with values of -0.173 and -0.44 for 0.5 kHz and 2 kHz, respectively (see Table 6).

**Table 5**

*Paired Samples Test for Response Times*

Stimuli	Paired differences Confidence Interval of the Difference Upper	$t$	df	Sig. (2-tailed)
0.5 kHz	1.596	<sup>-</sup> 0.133	8	0.897
2 kHz	2.445	<sup>-</sup> 0.546	9	0.598

**Table 6**

*Paired Samples Effect Size for Response Times*

Stimuli	Standardizer	Point Estimate	95% Confidence Interval Lower	95% Confidence Interval Upper
0.5 kHz	2.204	-0.44	-0.697	0.611
2 kHz	4.505	-0.173	-0.793	0.457

## CHAPTER V

### DISCUSSION AND CONCLUSIONS

This study was conducted to compare the minimum response levels (MRLs) and timing of responses of 12- to 27-month-old children using narrowband noise (NBN) and frequency specific hearing assessment (FRESH) noise. Based on the findings in the current published literature, it was hypothesized that the FRESH noise would have a better minimum response level than NBN and that participants would respond faster to the FRESH noise than the NBN. The methodology of this study was based on McDermott and Hodgson's (1982) study with a few revisions. First, this study was condensed to using only children between 12 and 27 months of age. This age range was chosen to keep the results of the study contained into a similar age group to eliminate possible outliers based on age. Another difference was the frequencies tested. McDermott and Hodgson used 0.5 kHz and 4 kHz; however, recent clinical guidelines suggested presenting 2 kHz and then 0.5 kHz to obtain a high and low frequency information (American Academy of Audiology, 2020). Lastly, in the McDermott and Hodgson study, loudspeakers were placed at 125 degrees azimuth; however, due to restraints of the location of the door in the sound treated booth, loudspeakers were located at 45 degrees azimuth for this study.

#### **Summary and Interpretation of Results**

##### **Minimum Response Levels**

In comparing the mean MRLs between the narrowband noise and the FRESH noise, there was no significant difference. This was similar to the Norrix and Anderson (2015) study in which thresholds were found to be close in range; however, the current study did not find that



narrowband noise underestimated the threshold level of the participants as did the 2015 study. The comparison of results between the current study and the Norrix and Anderson study was difficult to make due to the use of adults with a simulated hearing loss versus children with normal hearing. The effect size of the MRLs was also determined and both had a small or medium effect size, showing that the difference between stimuli was limited.

Comparison of the MRLs to the McDermott and Hodgson (1982) study's same age group showed lower response levels for the present study than the 1982 study. Minimum response levels for the present study had mean values around 17 dB for 0.5 kHz and 20 dB for 2 kHz while the mean values for the McDermott and Hodgson study were a bit higher—around 20 dB and 30 dB for 0.5 kHz and 24 and 28 dB for 2 kHz. These values were comparing warbled tones and narrowband noise while the present study compared narrowband and FRESH noise.

There are several reasons as to why there was no significant difference between the MRLs of the participants. Measurement of the minimum response level was the lowest level a child would respond to a stimulus. This was not the child's true threshold as they are too young to get a threshold but the minimum response level was a level that provided an estimate about their hearing threshold. The procedure of this study provided a variable result between participants so the results were more of an estimate of threshold representing a range rather than a fixed value. Another reason was inconsistencies in responses. Young children could be easily distracted and want to play with toys, talk, or cuddle with their parent or guardian who was in the booth with them. This led to variability in their responses and keeping them on task was difficult. Lastly, this study was conducted on children who were noted as having normal hearing so either stimulus could be effective for finding the minimum response level as the results should be within normal limits using either stimulus.

## **Response Times**

The comparison of mean response times between the narrowband noise and FRESH noise showed no significant difference. The reasons for having no significant difference between the two stimuli were similar to the reasons for the MRLs. For a response to be counted, a full head turn was needed from the child. While testing, some children would make faces when the stimulus was presented, smile, point, or make a half of a head turn. While this was not counted as a response for this study, clinically those responses could be counted as some children would not fully turn their head toward a sound source but had a different reaction to the sound.

Conditioning the children and continuously decreasing the decibel level could lead to less and less responses because they are bored during testing and do not want to fully turn their head toward the sound source. Participants 2 and 4 were two examples of becoming bored during testing. These participants were able to condition quickly; however, they were more interested in the items throughout the booth or talking to their parent or guardian. Participant 6 was not interested in the testing but would still respond when the stimulus was presented to them, and their attention would then turn to something else quickly. This led to high variability in the timing of a head turn between children.

## **Challenges**

One of the challenges of this study was recruitment of participants. While flyers and announcements were posted throughout the University of Northern Colorado Speech-Language Pathology and Audiology Clinic, Facebook pages, and local daycares, it was difficult to find willing participants. Due to the COVID-19 pandemic, many families were hesitant to come to the clinic to be tested as noted by conversations with parents and guardians. Another challenge was the children trusting the clinicians. Participant 3 had a fear of doctors and was scared to be in the

clinic, which led to taking longer to condition than other participants. Lastly, not every participant took the same amount of time to complete the study. Some participants were excited and willing to participate, for example, Participant 1, while others needed more encouragement and reinforcement, leading to variability in test time. Test time varied from about 15 minutes to about 50 minutes.

### **Strengths and Limitations**

The greatest strength of this study was the consistency of testing and analysis. Each participant responded twice at each frequency before the minimum response level was recorded. The videos were watched once to note the response time of the participant, reviewed to ensure timing was recorded properly, and were evaluated with the graduate clinician who helped throughout data collection. Limitations of previous studies were determining what exactly was a response and clinician bias (Shaw & Nikolopoulos, 2004). This study controlled for this bias by using two clinicians to determine a response and a conclusion was made with both clinicians input on what was a response for each participant.

The greatest limitation of this study was the small sample size. Ten participants were not enough to make a definitive conclusion regarding the effects of using FRESH noise as opposed to other stimuli when testing in sound field with young children. Previous research has been conducted on the use of FRESH noise in the adult population but no research has been conducted on the pediatric population and they were the ones this stimulus was created to be used with. A larger sample size would be necessary to create a better conclusion. Furthermore, two participants refused to allow tympanometry testing to be completed. While an otoscopic examination was able to be completed, tympanometry could not give an idea as to the middle ear

function. Participant 2 also was unable to be conditioned for 0.5 kHz NBN, which led to less data for that situation.

### **Further Research**

Additional research is needed to investigate the MRLs of FRESH noise within the pediatric population. A study to specifically measure the MRLs in both normal hearing children as well as those with hearing loss could help get an even better idea about how accurate the stimulus was within sound field testing. Finally, additional research on the effect of timing for the stimulus would be needed to further determine if testing could be completed in a faster time frame than other stimuli. While children vary in their abilities, having more information on the ability to grab a child's attention could be beneficial for the effect of test time.

### **Conclusions**

In summary, information on the minimum response level and timing of 10 participants was found. Results indicated no significant difference in the minimum response level and timing of a response in a small sample of normal hearing children. Claims regarding FRESH noise and its ability to get a better minimum response level quicker than other stimuli was not found during this present study (American Academy of Audiology, 2020). Subjective bias of the head clinician was the FRESH noise was more interesting for the participants to hear and each participant had more of a reaction to the stimulus as opposed to the narrowband noise. These reactions were the children making funny faces, smiling, pointing around the sound booth, and more after the presentation of the stimulus. Further studies are needed to make a more generalized conclusion about the ability for FRESH noise to grab the attention of young children.

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APPENDIX A  
INSTITUTIONAL REVIEW BOARD APPROVAL



Date: 05/18/2021

Principal Investigator: Justine Wright

Committee Action: **Expedited Approval - New Protocol**

Action Date: 05/18/2021

Protocol Number: [2103023021](#)

Protocol Title: FRESH noise: minimum response levels and response time in the pediatric population

Expiration Date:

The University of Northern Colorado Institutional Review Board has granted approval for the above referenced protocol. Your protocol was approved under expedited category (7) as outlined below:

Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

All research must be conducted in accordance with the procedures outlined in your approved protocol.

If continuing review is required for your research, your project is approved until the expiration date listed above. The investigator will need to submit a request for Continuing Review at least 30 days prior to the expiration date. If the study's approval expires, investigators must stop all research activities immediately (including data analysis) and contact the Office of Research and Sponsored Programs for guidance.

If your study has not been assigned an expiration date, continuing review is not required for your research.

For the duration of the research, the investigator(s) must:



## Institutional Review Board

- Submit any change in the research design, investigators, and any new or revised study documents (including consent forms, questionnaires, advertisements, etc.) to the UNC IRB and receive approval before implementing the changes.
- Use only a copy of the UNC IRB approved consent and/or assent forms. The investigator bears the responsibility for obtaining informed consent from all subjects prior to the start of the study procedures.
- Inform the UNC IRB immediately of an Unanticipated Problems involving risks to subjects or others and serious and unexpected adverse events.
- Report all Non-Compliance issues or complaints regarding the project promptly to the UNC IRB.

As principal investigator of this research project, you are responsible to:

- Conduct the research in a manner consistent with the requirements of the IRB and federal regulations 45 CFR 46.
- Obtain informed consent and research privacy authorizations using the currently approved forms and retain all original, signed forms, if applicable.
- Request approval from the IRB prior to implementing any/all modifications.
- Promptly report to the IRB any unanticipated problems involving risks to subjects or others and serious and unexpected adverse events.
- Maintain accurate and complete study records.
- Report all Non-Compliance issues or complaints regarding the project promptly to the IRB.

Please note that all research records must be retained for a minimum of three (3) years after the conclusion of the project. Once your project is complete, please submit the Closing Report Form.

If you have any questions, please contact Nicole Morse, Research Compliance Manager, at 970-351-1910 or [nicole.morse@unco.edu](mailto:nicole.morse@unco.edu). Please include your Protocol Number in all future correspondence. Best of luck with your research!

Sincerely,

Michael Aldridge  
IRB Co-Chair, University of Northern Colorado: FWA00000784



*Silvia Correa-Torres*

Silvia Correa-Torres  
IRB Co-Chair, University of Northern Colorado: FWA00000784

2103023021

APPENDIX B  
CONSENT FORM



## CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH

Project Title: FRESH Noise: Minimum Response Levels and Response Time in the Pediatric Population

Researcher: Justine Wright, BS  
 Phone: xxx-xx-xxxx  
 E-mail: [justine.wright@unco.edu](mailto:justine.wright@unco.edu)

Advisor: Dr. Jennifer Weber E-mail: [jenny.weber@unco.edu](mailto:jenny.weber@unco.edu)  
 Dr. Kathryn Bright Email: [katie.bright@unco.edu](mailto:katie.bright@unco.edu)

**Purpose and Description:** The primary purpose of this study is to determine the minimum response levels of a new stimulus in the audiology field and to compare those levels to a widely used stimulus. Another purpose is to measure the response times to both stimuli and compare those results. This new stimulus is believed to be useful in testing young children and is able to grab a child's attention quicker than previous stimuli. If you grant permission and if your child indicates to us a willingness to participate, we will move to our sound booth to begin testing.

For this testing, you will be asked to fill out a case history form regarding your child's health history. Once this is completed, I will do an ear exam which include looking at the outer ear with an otoscope. The otoscope will be used to look at the inside of the ear canal and eardrum of your child. After this exam is completed, we will do a test called tympanometry. This test involves placing a soft probe in your child's ear canal and introducing a small amount of pressure to rule out the presence of an ear infection.

After these two tests are completed, we will begin our minimum response level search. This will involve you sitting in the center of the audiology sound booth with your child on your lap. I ask that you not moving during testing to not give your child any idea of where to look. Sounds will come out of the loudspeakers in the booth and will progressively get lower in loudness. The sounds will be different pitches and will sound different based on what stimulus is being presented at that time. Testing should take approximately 45 minutes from beginning to end. I will explain the test results to you at the end of the test session.

I do not foresee any potential risks associated with participation in this study. A benefit of being a participant is a free hearing examination for your child as well as a test to measure the middle ear function of your child's ear. There will not be any identifiable information in relation to you or your child with the results of this study. All participant information will be de-identified and your child will be given a participant number.

Page 1 of 2 \_\_\_\_\_  
 (Parent's initials here)

We will be videotaping the activities to back up the notes taken by the researchers. Be assured that we intend to keep the contents of these tapes private. To further help maintain confidentiality children's names will be replaced by numerical identifiers. The names of subjects will not appear in any professional report of this research.

Please feel free to phone me if you have any questions or concerns about this research and please retain one copy of this letter for your records.

Thank you for assisting me with my research.

Sincerely,

\_\_\_\_\_

Participation is voluntary. You may decide not to allow your child to participate in this study and if (s)he begins participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please sign below if you would like to allow your child to participate in this research. A copy of this form will be given to you to retain for future reference. If you have any concerns about your selection or treatment as a research participant, please contact Nicole Morse, Office of Research & Sponsored Programs, University of Northern Colorado, Greeley, CO; 970-351-1910 or nicole.morse@unco.edu.

\_\_\_\_\_  
Child's Full Name (please print)

\_\_\_\_\_  
Parent/Guardian's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Researcher's Signature

\_\_\_\_\_  
Date

If you give permission for Justine Wright to use the videotape of your child's audiological evaluation, please initial here:

\_\_\_\_\_  
Initials