Title:

Evaluating the clinical effectiveness of a community-based hearing aid fitting service delivery model facilitated by community healthcare workers (CHWs) providing smartphone-based in-situ and pre-set hearing aid fittings in low- and middle-income communities (LMICs)

NCT Number:

NCT06982716

Document Date:

21 May 2025

May 2025

INVITATION TO RECEIVE A HEARING CHECK FOR A COMMUNITY RESEARCH PROJECT

The hearX Foundation, in partnership with the University of Pretoria, will provide hearing services in communities. Many people suffer from hearing loss, and this project aims to identify community members with hearing loss and determine how well different low-cost hearing aids and different types of hearing aid support work for adults in low—and middle-income settings.

What will I need to do if I agree to receive the hearing check?

All tests will be non-invasive, free of charge, and results will be made available to you. All testing should take about 35 minutes to complete. Should you agree to receive the hearing check, the following procedures will be followed:

- Questionnaire about your hearing (10 minutes)

Before your hearing is checked, you will be asked a few questions about your hearing as well as how you feel about hearing aids.

- Looking in your ear with a camera [Video-otoscopy] (5 minutes)

For this test, you will be required to be seated upright while your ear canal is visually inspected using an otoscope (ear-light).

- Hearing check (15 minutes)

For this check, you will wear earphones on your ears. You will be asked to respond to a soft sound (at different pitches) by raising your hand or pressing a button. This will measure how sensitive your hearing is.

Are there any risks or benefits for me if I participate in this study?

Participants will not be exposed to any risk or experience any discomfort during this test. Information obtained from this project will assist us in identifying participants for a research study on the effectiveness of hearing aids and hearing aid support programs. Participants who are not eligible for hearing aids or require additional follow-up services will be referred to public health facilities offering hearing aids or Ear, Nose, and Throat specialist services.

What are your rights as a participant?

Your participation in this project is entirely voluntary. You may decline to participate or stop at any time during the examination. This will not affect any current services you are receiving. You can consent if you wish to have your results used as part of any potential research based on this service. You can decline to have your results included in any potential research based on this service with no effect on any current services you are receiving. You can provide your contact details should you be interested in participating in potential future research. You can decline participation in potential future research or request that your contact details be removed with no effect on any current services you are receiving.

Infection control protocols

The community healthcare workers will bring in hand sanitiser, and all participants, community healthcare workers, and researchers will be required to sanitize their hands frequently. All

equipment will be sanitized before and after each participant's tests. If the participant, community healthcare workers, or researcher feels unwell on the day scheduled for testing, the testing will be postponed to a later date.

Confidentiality

All your information will be kept confidential. Once your results have been captured, a number will be allocated to your results. All data will be analysed using the alphanumerical code assigned to you. Your name will not appear on any documents.

Should you consent to have your results used for research purposes, research articles in scientific journals will not include any information that could identify you. All the data collection sheets from this project will be stored for a period of 15 years in both hard copies and scanned electronic versions.

Before agreeing to participate, you should fully understand what is involved. Please do not hesitate to ask your hearing screener if you have any questions that this letter does not fully explain. Alternatively, you can contact us at info@hearxfoundation.org or send a *please call me* to 084 393 0717 (Khayelitsha), 073 842 3344 (Drakenstein district) or 081 881 8616 (Atteridgeville).

Sincerely,

Professor De Wet Swanepoel
Professor of Audiology & Primary Investigator

CONSENT TO RECEIVING A HEARING CHECK

I, _____, hereby consent to:

	I consent to receive the hearing check and that my results be used anonymously for any possible research publications on this project.
	I consent to my contact details being stored and that I can be contacted for any potential future services or research.
	I consent to photos being taken during the hearing assessment.

I have read or been explained the content of the consent letter verbally. I understood the consent letter and have been given the opportunity to ask questions, and I am satisfied that they have been answered satisfactorily. I understand that I will not be reimbursed for participating in this project. I know that I may withdraw from the project at any time should I wish to do so. I understand that every effort will be made to ensure that I am not harmed while receiving the hearing check.

Signature: _____ **Date:** _____

Phone number: _____

AFFIRMATION OF INFORMED CONSENT BY AN ILLITERATE PARTICIPANT

(If suitable)

I, the undersigned, ……..…, have read and have explained fully to the participant, named ……, the informed consent document, which describes the nature and purpose of the study in which I have asked him/her to participate. The explanation I have given has mentioned both the possible risks and benefits of the study. The participant indicated that he/she understands that he/she will be free to withdraw from the study at any time for any reason and without jeopardizing his/her standard care.

I hereby certify that the patient has agreed to participate in this study.

Participant's name (Please print)	Date
Participant's signature	Date
CHW Name (Please print) Date	
CHW Signature Date	
Name of the person who witnessed the informed consent (Please print)	Date
Signature of the Witness	Date