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)

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INVITATION TO RECEIVE HEARING AIDS

The hearX Foundation, in partnership with the hearX Group and the University of Pretoria, will be providing a hearing service in the communities. Many people suffer from hearing loss. This project aims to identify community members with hearing loss, demonstrate the potential benefit of hearing aids, fit adults with suitable hearing loss with hearing aids, and demonstrate the potential benefit of a support program for hearing aid users to help them get used to wearing hearing aids

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

All procedures should take about 70 minutes to complete. Should you agree, the following procedures will be followed:

- 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 hearing aids in your ears that will be covered by 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.

- Hearing aid fitting (50 minutes)

The hearing aids will be set to a program based on your results. After that, you will be taught how to use and look after your hearing aids and complete a questionnaire on how hearing loss has affected your life. You will need a follow-up visit six, 12, 26, and 52 weeks after the hearing aid fitting, where you will be asked to complete questionnaires. You will receive information (support program) during the first six weeks to give you more information on how to use and look after your hearing aids.

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 hearing aid fitting. Participants can keep their hearing aids once the project has been completed. Information obtained from this study will assist in increasing the effectiveness of smartphone technologies in hearing loss detection, support, and intervention. Participants will also be referred to follow-up services when and where necessary.

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 or future services you receive from the hearX Foundation that are not linked to research projects. You can only receive these hearing aids if you agree to take part in the research study. If you choose not to participate in the study, or if you withdraw from the study, you will be referred to receive hearing aid services at a government facility. 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 without affecting any current services you are receiving.

Infection Control Protocols

The community healthcare workers will bring in hand sanitizer, 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 RECEIVE HEARING AIDS

I, _____, hereby consent to:

	I consent to receive the hearing aids 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 aid fitting and follow-up visits.

I have read or been explained the content of the consent letter verbally. I understood the consent letter and have been allowed to ask questions, and I am satisfied that they have been answered satisfactorily. I understand that I can keep the hearing aids once the project is complete. I know I may withdraw from the project 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: _____

Hearing Aid Serial numbers:

Left: _____

Right: _____

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