

Study Title: Validation of a Smartphone-Based Hearing-in-Noise Test (HearMe)

Date: February 2nd, 2018

HearMe Study Protocol and Statistical Analysis Plan

Study Protocol

The research procedures will begin immediately after obtaining consent. The following procedure will be performed:

HearMe The subjects will be asked to complete the HearMe application on a portable iOS device provided by the research team members. The subjects will be handed an iTouch and provided instructions to complete the test. The subject will then complete the HearMe smartphone hearing-in-noise test, following the protocol described as follows:

HearMe Test Protocol

The subject will test both ears at the same time. The subject will be provided with 24 3-digit sequences (“153”, “901”, “224”, etc.). After the presentation of each 3-digit sequence, the subject will have to input/type the three digits that they heard into the smartphone application when prompted. Following completion of the test, the speech reception threshold (SRT) is determined by average the signal-to-ratio of the final 20 stimuli.

After completion of the HearMe smartphone test, an email containing the results of the participant's performance (with each subject linked to a random numerical code) on the test will be sent to a secure email account hearme@gmail.com. The email and data will be linked to a randomly generated 8-digit numeric code. Only the research team members listed on this IRB have access to the email account.

The time period to check-in, complete the applications (no more than 3 minute), and related instructions is 10 minutes total for the entire visit.

Statistical Analysis Plan

By comparing to their relevant normative data, we will determine the proportion of subjects that are abnormal at the 5% and 1% level of normal subjects for the test in the patients that had both done on the same day.

Average HearMe SRTs will be compared between the control and case groups using a student's t-test. Thresholds of subjects with hearing loss and subjects with no history of hearing loss will be compared to information already available in consented subject's electronic medical records – these measures include pure-tone audiometry thresholds and other survey/questionnaire-based measures (see outcome measures). A Pearson's correlation coefficient will be determined between the SRT and the secondary outcome measures of this study.