



EFAS WG SHS Report 07may18

Will collaborate on this phase of the pilot project:
Belgium/Flanders, The Netherlands, Romania, Slovenia, Turkey

Inclusion criteria

Children 5 or 6 years of age
20-25 NH, 20-25 Sensorineural HL, 20-25 Conductive HL
All degrees of HL allowed with focus on HL of 20-40 dBHL
Recruitment in own pediatric clinic, or NH in schools

Test protocol

Administer SEC in noise (~5 minutes in total)

- Acclimatization/Entry: bilateral + 10 dB SNR, performance check (correct child in case of mistake). Stimulus will be presented once. If correct, the stimulus/figure will disappear. If incorrect the stimulus/figure will be repeated. (0.5 min)
- Training: bilateral training descent, 8 stimuli, start at SNR=0, 24 steps (longer than former proposal (based on first data Leuven), rule out procedure learning (1.5min)
- Interim message: YOU DID WELL! Now the real thing!
- SEC: First Left ear then Right ear, both start at 0 dB SNR, 24 steps (3min)

Tone audiogram both ears: air conduction and bone conduction (in booths, no problem with environmental noise background)

Tympanogram both ears

Questionnaire

Agreements about use of material

A number of measurement sets (with Sound Ear Check only) will be provided for partners in the pilot project. The measurement sets of calibrated headphone plus tablet with software installed, manual, training and supplementary info will be delivered, max 2 sets per partner. A price of 400 EUR per set will be requested for rent during the pilot project (400 is decided based on new tablet). The measurement sets remain property of partner Leuven and will be returned after the pilot project. Partners can make use of the test sets as long as project and collaboration runs. At the end of the study, when completed and with final procedure and test material, partners will be able to buy sets for a low price.

Agreements about data

Some data are kept in one common general database and part of the data are kept in a local database (separate from each partners own national health database), all data will be anonymized according to common key, each partner (or organization in partner country) has transcription key of own children, the key is the only information that one has access to, each partner has the freedom to use the own data.

Proposal of key for anonymized subject ID: countryname in 2 letters, tablet number in 2 digits, subject ID number in 5 digits

As an example BE0400010 for the 10th subject of the 4th tablet (the tablet number 2 of partner BE). Only the test coordinator in each partner centre has access to the coded key-name combination, and only for the own partner children. The other researchers do not have access to this key-name code.

Data to be accumulated per child in database DB:

1) automatically stored per subject in tablet DB (general DB)

tablet ID: BE04 in the example above

test moment: date and time

test results per ear: ear R or L, SRT, SD, Staircase, test duration

2) information input by site collaborator, to be typed in on tablet DB (general DB)

6 last digits of key: 400010 in the example above

Gender: M or F (on Tablet)

Age: as DD/MM/YYYY (if DD is not known, then fill in 00)

(Only age is not sufficient because change in test skills happens between 4 and 6 years of age)

3) information input by site collaborator in clinical file of subject (local DB) based on the questionnaire (for parents) of risk factors

Results of subject on local screening test: LP or LF (Left ear pass or fail), RP or RF (Right ear pass or fail)

Risk factors: Attention Deficits, Academic Achievements, native-non native, history of OME, risk upper respiratory problems, history ME problems, smoking parents, Attentional or developmental deficit, (non-)native speaker,