The effectiveness of earplugs in preventing recreational noise induced hearing loss: an RCT

STUDY PROTOCOL
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Objective
The aim of this study is to investigate the hearing performance after a festival visit in normal hearing participants using earplugs compared to participants without the use of earplugs.

Parties
This study will be conducted by the research group of the Department of Otorhinolaryngology and Head and Neck Surgery from the University Medical Center Utrecht (UMCU) in association with Van Boxtel hoorwinkels (hearing aid dispenser), Oticon Medical and MTV Benelux.

Study design
Normal hearing subjects will be included in this single blind randomized controlled trial. After Informed Consent is obtained, subjects will be randomized in the intervention group (earplug use) or control group (no earplug use). Both groups will be evaluated before and after the festival.

Study population
Normal hearing adult subjects.

Inclusion criteria:
- Age ≥ 18 years

Exclusion criteria:
- Current otitis, otorrhoea, ventilation tube, perforation eardrum
- Hearing aid or cochlear implant
- Ear surgery in history (except ventilation tube surgery)
- Intention to use earplugs during the concert
- No Dutch or English language skills

Sample size calculation
To detect a difference of 3 dB on the audiogram between both groups, with a standard deviation of 2.5 dB, a two tailed alpha of .05 and a power of 95%, power calculation showed that 20 participants are needed per group. In order to compensate for an expected number of withdrawals and loss to follow up, 10 extra subjects will be recruited per group, resulting in a final sample size of 60 participants.
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**Intervention**
MTV Soundkeeper earplugs with a noise reduction rate of 18 dB.

**Main study parameters/endpoints**
The primary outcome:
- Performance on audiogram (0.5, 1, 2, 3, 4, 6, 8 kHz) pre- and postfestival

Secondary outcome measures:
- Tinnitus analysis by audiogram (when tinnitus is present) (pre- and postfestival)
- Distortion product otoacoustic emission (dpOAE) pre- and postfestival
- Questionnaires
  - Baseline: demographics, history of sound exposure, ENT history, tinnitus questionnaire (VAS)
  - Postfestival: concert evaluation (earplugs, music, behaviour), tinnitus questionnaire (VAS)

**Randomization**
Participants will be randomly allocated to the earplug and control groups, using a web based randomization program (randomization.com). By using a block randomization (n=10), the distribution between the two groups will be equal in case the required number of subjects cannot be realized.

**Loss to follow up**
Sample size calculation was corrected for a high loss to follow up rate. Subjects will receive an incentive of 50 euro after full completion of the study.

**Blinding**
All investigators will be blinded for the group assignment. The two investigators who will analyze all the data (GGJR and VJCK) will be blinded for the intervention during these analyses. Participants cannot be blinded for the intervention but will be asked to not disclose randomization to the investigators performing the hearing evaluations.

**Statistics**
When data is normally distributed mean values and parametric tests will be used. When data is not normally distributed, medians and non-parametric tests will be used.
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Pure tone averages (PTA) will be computed for the frequencies 3 and 4 kHz and for 0.5, 1,2, and 4 kHz for both ears. A threshold shift is defined as an average increase of 10 dB or more postfestival at 3 and 4 kHz in one ear.

Differences in mean values or proportions between the groups will be analyzed by the independent T-test or the Chi-square test in case of normally distributed data and Mann Whitney Test in case of not normally distributed data. For differences between the pre- and post-sound exposure values the dependent T-test in case of normally distributed data or Wilcoxon paired T test in case of not normally distributed data will be used. The relative risk (RR) for developing a TTS will be computed and the number needed to treat (NNT) will be calculated by the inverse of the absolute risk reduction.

For DPOAE data, the average amplitude will be computed for all frequencies between 2 and 8 kHz and for the frequencies between 3 and 4 kHz for both ears together.

All analyses will be performed on an intention-to-treat basis. SPSS version 21.0.0 for Windows will be used and a P-value <.05 is considered statistically significant.

Missing data

In case of missing data a complete case analysis will be performed.

Procedure

Location: the study will take place at the outdoor music festival Valtifest in Amsterdam, the Netherlands on the 5th of September 2015. All hearing assessments will take place at the MTV studios, which is located next to the entrance of the festival.

Procedure: all participants will be assigned to a particular time slot from 12.00 to 16.30. Per 15 minutes a group of four participants will arrive at the above mentioned location. When the participant completes all the pre festival evaluation, he or she will be randomized into the earplug or control group. Then, the participant will be instructed to come back after 4.5 hours. Participant in the earplug group will receive information about how to wear the earplugs and will be instructed to wear the earplugs for the whole festival visit. All participants will be informed that they only receive 50 euro when they are able to perform all tests after the festival.
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**Calibration:** Two members of the research team will wear calibrated noise dosimeters (CESVA DC-112) and will visit the festival during the time that participants are present at the festival. All instruments are calibrated according to the corresponding ISO standards. The background sound level in the audiocabins will be measured before and after the study with a B&K 2250 sound level meter and 4189 microphone.

**Hearing evaluations**

1. **Audiometry**

   The primary outcome of this study is the presence of a TTS on an audiogram. Air conduction audiograms will be performed for the frequencies 0.5, 1, 2, 3, 4, 6 and 8 kHz for both ears at baseline and post-sound exposure by the same audiologist or audiology assistant in the same mobile audiocabin (IAC Medical, 350 series maxi audiology booth) using the AVANTTM A2D+ audiometer with a Sennheiser HDA200 headphone. The same audiologist and the same audiocabin with the same audiometer will be used before and after sound exposure per participant.

2. **DPOAE**

   DPOAEs will be measured at 18 frequencies between 2 and 10 kHz in both ears with the Titan (Interacoustics, DPOAE440 module) at baseline and post-sound exposure by the same experienced researcher. The same audiologist and the same audiocabin with the same Titan will be used before and after sound exposure per participant.

3. **Tinnitus**

   At baseline participants are asked to complete a tinnitus questionnaire. After sound exposure tinnitus questionnaire is repeated. When a participant experiences tinnitus at one or both evaluations, audiometric
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tinnitus pitch and loudness matching will be performed in a separate audiocabin with the same equipment. Participants will be asked to complete three Visual Analogue Scales (VAS) for pitch, loudness and annoyance of tinnitus.

4. Subjective hearing loss

At baseline participants are asked to complete a questionnaire concerning the amount of festival/club visits and music perception. After sound exposure the participants will be asked to complete an evaluation questionnaire concerning subjective hearing performance.
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**Study design in graph**

- Recruitment
  - Qualified
  - Not qualified
- Inclusion
- Exclusion
- Informed consent
- Randomization
- Pre sound exposure evaluations
- Pre-sound exposure evaluations
- No earplugs during festival
- Earplugs during festival
- Post-sound exposure evaluations
- Post-sound exposure evaluations

**Anonymized**

The study will be anonymized. All participants will receive a wristband with a unique study code. This code will be identified during pre and post sound exposure hearing evaluations. In the recruitment phase of the study, participants will be recruited via social media and names and e-mail addresses will be seen by the primary investigators. Informed consent will be signed under supervision of a single researcher independent of this study. Randomization will be performed under the supervision of the same
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researcher. The primary investigators (VJCK and GGJR) will not be involved in the randomization process. Participants who wish to receive their hearing evaluation results after finalization of the study will be instructed to ask for their results via e-mail. They will be told that their results can no longer be anonymized once they will ask for their results.