Original Investigation

Effectiveness of Earplugs in Preventing Recreational Noise–Induced Hearing Loss
A Randomized Clinical Trial

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IMPORTANCE The incidence of hearing loss has risen in past years. Attendance at music festivals and concerts may contribute to this increasing problem.

OBJECTIVE To assess the effectiveness of earplugs in preventing temporary hearing loss immediately following music exposure.

DESIGN, SETTING, AND PARTICIPANTS A randomized, single-blind clinical trial was conducted on September 5, 2015, at an outdoor music festival in Amsterdam, the Netherlands. Normal-hearing adult volunteers were recruited via social media. An exclusion criterion was the participants' intention to wear earplugs. Of the 86 volunteers assessed, 51 were included in the study. All analyses were performed on an intention-to-treat basis.

INTERVENTIONS Participants were randomly assigned to a group using earplugs or an unprotected group during a 4½-hour festival visit.

MAIN OUTCOMES AND MEASURES The primary study outcome was a temporary threshold shift (TTS) on the audiogram, primarily for frequencies at 3 and 4 kHz. Secondary study outcomes included distortion product otoacoustic emission (DPOAE) measurements and claims of tinnitus using a questionnaire and tinnitus matching experiments.

RESULTS Of 51 participants included, 25 were randomized to the earplug group and 26 to the unprotected group. Nine in each group (36% and 35%, respectively) were men, and the mean (SD) ages were 27.3 (5.6) years in the earplug group and 27.0 (6.2) years in the unprotected group. Baseline demographics were similar in both groups. The time-averaged, equivalent A-weighted sound pressure level experienced was 100 dBA during the festival. A TTS over frequencies at 3 and 4 kHz after exposure was seen in 4 of 50 ears (8%) in the earplug group compared with 22 of 52 ears (42%) in the unprotected group ($P < .001$). The relative risk for a TTS after exposure was 5.3 (95% CI, 2.0-14.3) for the unprotected group vs the earplug group. The number needed to treat with earplugs for preventing 1 TTS was 2.9. The DPOAE amplitudes decreased significantly more over the frequencies 2 to 8 kHz in the unprotected group: the mean (SD) decrease in magnitude was 0.6 (2.8) dB in the earplug group vs 2.2 (1.9) dB in the unprotected group ($P = .04$). Newly induced tinnitus following sound exposure occurred in 3 of the 25 participants (12%) in the earplug group vs 10 of 25 (40%) in the unprotected group (difference, 28%; 95% CI, 3.6%-49.0%; $P = .02$).

CONCLUSIONS AND RELEVANCE Earplug use is effective in preventing temporary hearing loss after loud music exposure. The present randomized clinical trial adds proof to the scarce evidence and knowledge on this topic, which is a growing global problem.

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The prevalence of acquired hearing loss has risen in past years. The US National Health and Nutrition Examination Survey found that the prevalence of adolescents with hearing loss has increased by 31% in the 2 decades since 1988.[1]

An explanation for this trend is the increase in exposure to recreational noise, such as visiting music venues (concerts, festivals, and nightclubs). Attendees of these recreational activities can be exposed to loud music with sound pressure levels of approximately 100 to 110 dBA for several hours.[2-5] This exposure is known to cause hearing loss.[6,7]

Short-term exposure to extremely loud noise (>140 dBA) can lead directly to cochlear damage. This is referred to as *acoustic trauma* and can consequently cause permanent hearing loss.[8] However, in most cases, noise exposure causes temporary hearing loss immediately after exposure. Hearing loss can be measured objectively by temporary threshold shifts (TTSs) observed on audiograms. A TTS usually recovers several minutes to hours after the noise exposure.[9,10] After frequent exposure, however, recurrent temporary hearing loss can ultimately lead to permanent hearing loss due to damage to the outer hair cells (OHCs) in the cochlea; these hair cells play a major role in the transduction of sound by the cochlea to the auditory nerve.[11] Dysfunction of OHCs can lead to a TTS, recruitment, and loss of frequency selectivity.[12] The function of the OHCs can be mirrored in otoacoustic emissions (OAEs). A prompt decrease in OAE levels is observed in cases of noise-induced hearing loss (NIHL) due to OHC damage. Also, a subjective measure of temporary hearing damage is tinnitus, which is commonly experienced after loud acoustic stimulation attenuates; tinnitus typically subsides a few seconds to a few days after exposure.[13]

A recent prognostic study found that a TTS is the most important factor associated with the development of permanent threshold shifts.[14] In a longitudinal cohort study, hearing level thresholds increased under the influence of recreational noise during a 4-year period.[4] Several preventive strategies against recreational hearing loss from music venues exist. These include using earplugs, reducing the duration of exposure, and keeping a safe distance from the music source.[15,16] However, the general willingness to use earplugs in music venues by attendees is low.[17-19] This reluctance is partly owing to the lack of evidence and general knowledge on the effectiveness of earplugs in protecting hearing and the scarce availability of earplugs.[15] A recent systematic review[20] by our research group found only 1 randomized clinical trial (RCT) on the efficacy of earplugs in concert attendees. That RCT[21] revealed lower differences in audiometric thresholds after a concert and fewer TTSs in concert attendees who used earplugs compared with unprotected attendees. Because that study was a small RCT (n = 29) with audiometric assessment as the only outcome, a larger, well-designed RCT with multiple objective and subjective outcomes is needed.

Therefore, the purpose of the present study was to assess the efficacy of earplugs in the prevention of hearing loss in a well-designed RCT using objective and subjective outcomes. By adding more knowledge to the scarce scientific evidence of their effectiveness, we aim to highlight the importance of earplugs in an attempt to increase their use among people attending music venues, thereby decreasing the incidence of NIHL.

Key Points

Question What is the effectiveness of wearing earplugs in preventing temporary hearing loss immediately following loud music exposure?

Findings In this randomized clinical trial of 51 normal-hearing adult music festival attendees, 25 were randomized to an earplug group and 26 to an unprotected control group. The relative risk for developing a temporary threshold shift on the audiogram at 3 and 4 kHz after the festival visit was 5.3 for the unprotected group compared with the earplug group.

Meaning Earplugs are effective in preventing temporary hearing loss following music exposure.

Methods

Study Design and Participants

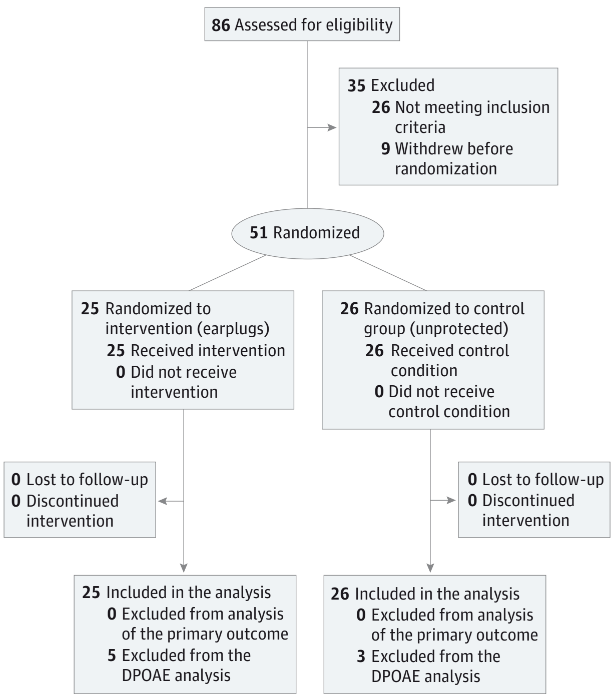
This study was a single-blinded RCT conducted by the research group of the Department of Otorhinolaryngology and Head and Neck Surgery from the University Medical Center Utrecht in association with Van Boxtel Hoorwinkels (a hearing aid distributor), Oticon Medical, and MTV Benelux. This study was designed and conducted in accordance with the Declaration of Helsinki,[22] and an exemption of full review was obtained from the Medical Ethics Committee of the University Medical Center Utrecht (WAG/OM/15/027141). Participants provided written informed consent. The trial protocol is available in the Supplement. We conducted and reported the study following the CONSORT guidelines for RCTs.

The study took place at an outdoor music festival in Amsterdam, the Netherlands, on September 5, 2015. Normal-hearing volunteers were recruited via social media advertisements. Participants were offered a free ticket to the festival and a €50 stipend after completion of the study and were eligible for inclusion if they were 18 years or older. Exclusion criteria were current ear problems (eg, otitis, otorrhea, the presence of ventilation tubes, or perforation of the eardrum), the use of a hearing aid or cochlear implant, previous ear surgery (except for the insertion of ventilation tubes), the absence of Dutch or English language skills, and the intention to use earplugs during the festival. The last criterion was specified because of the ethical consideration that participants could be randomized into the unprotected group and thus would not be allowed to use their own earplugs.

Intervention

Participants were randomly allocated to the earplug group or the unprotected group using a web-based randomization program (version 2008; Gerard E. Dallal, PhD, http://www.randomization.com) (**Figure 1**). Block randomization (n = 10) would lead to an equal distribution between the 2 groups in

Figure 1. Flowchart of Participant Pathways



The flowchart shows the exact number of participants during the study process. DPOAE indicates distortion product otoacoustic emission.

case the required number of participants could not be achieved. All participants in the intervention group used the same earplugs (MTV Soundkeepr; Standt BV) with a reported noise reduction rate of 18 dB. All participants were assigned to particular time slots for their hearing evaluations. These evaluations took place before and immediately after a 4½-hour festival visit. The participants in the intervention (earplug) group were debriefed on how to properly wear the earplugs and were advised to keep the earplugs in place for the duration of the 4½-hour festival visit. Finally, all participants were strongly advised to avoid or only moderately use alcohol and drugs.

Hearing Evaluation

The primary outcome of this study was the presence of a TTS on the audiogram after the festival visit. Secondary outcomes were differences in tinnitus perception and the magnitude of distortion product OAEs (DPOAEs) after exposure. All evaluations took place in the adjacent MTV Studio. At baseline, a questionnaire about demographics as well as the history of sound exposure and otolaryngology-related problems was completed. Air conduction audiograms for the frequencies 0.5, 1, 2, 3, 4, 6, and 8 kHz were performed by the same audiologist (including G.C.) or audiology assistant for both ears at baseline and after exposure in the same mobile audiocabin (350 Series Maxi Audiology Booth; IAC Medical) using an audiometer (AVANT A2D+; MedRx Inc) with a headphone (HDA200; Sennheiser Electronic Corp). When a participant experienced tinnitus at 1 or both evaluations, audiometric tinnitus pitch and loudness matching was performed in a separate audiocabin with the same equipment. Participants were asked to complete 3 visual analog scales for pitch, loudness, and annoyance of tinnitus using a scale from 0 (very low) to 10 (very high). The DPOAEs were measured at 18 frequencies between 2 and 10 kHz in both ears with a DPOAE probe and dedicated software (Titan DPOAE440 module and Titan Suite Software, version 3.2.1; Interacoustics) at baseline and after exposure by the same experienced researcher. We used the following protocol and settings: level 1 (L1), 55 dB; L2, 65 dB; and a frequency ratio (f1:f2) of 1.22. The frequencies measured were 2002, 2196, 2417, 2654, 2918, 3208, 3531, 3881, 4263, 4689, 5152, 5668, 6228, 6847, 7525, 8274, 9097, and 10 002 Hz because higher frequencies are more prone to TTSs due to loud noise. The database program OtoAccess (version 1.2.1; Interacoustics) was used for the extraction of the DPOAE data in DP-grams. After sound exposure, participants were asked to complete a questionnaire concerning the use of alcohol and drugs, the presence of tinnitus, and subjective hearing performance.

Sound Level at Festival and Calibration of Equipment

Two members of the research team wore calibrated noise dosimeters (DC-112 with Capture Studio Editor Software; CESVA) and visited the festival while the participants were present (7 hours 27 minutes). All instruments were calibrated according to the corresponding ISO standards. The background sound level in the audiocabins was measured before and after the study with a sound level meter (Type 2250; Brüel & Kjær) and condenser microphone (Type 4189; Brüel & Kjær) and was below the maximum tolerated levels.

Blinding

All investigators who performed the hearing evaluations were blinded for the group assignment. The 2 investigators who analyzed the data (G.G.J.R. and V.J.C.K.) were also blinded. Participants were aware of their group assignment after initial evaluations and before entering the festival.

Statistical Methods

To detect a difference of 3 dB on the audiogram between the study groups, with an SD of 2.5 dB, a power calculation with a 2-tailed α of .05 and a power of 95% showed that 20 participants were needed per group. To compensate for the expected number of withdrawals and loss to follow-up, 10 additional individuals were recruited per group, resulting in a final sample size of 60 participants. All data were normally distributed; therefore, we used mean values and performed parametric tests. Pure tone averages (PTAs) were computed for the frequencies 3 and 4 kHz and for 0.5, 1, 2, and 4 kHz for both ears. A *threshold shift* (presumed to be a TTS) was defined as an average increase of 10 dB or more after exposure at 3 and 4 kHz in 1 ear on the audiogram. We opted for 3 and 4 kHz because noise damage is known to cause threshold shifts primarily in these frequencies.[5,10]

Differences in mean values between the groups were analyzed by the independent, 2-tailed *t* test and proportions by the χ^2 test. For differences between the values before and after exposure within participants, the dependent, 2-tailed *t* test was used. The relative risk for developing a TTS was computed as the ratio between the risk for developing a TTS in the unprotected group and the risk for developing a TTS in the earplug group. The number needed to treat for preventing 1 TTS was calculated by the inverse of the absolute risk reduction. Mean DPOAE levels were computed for all frequencies between 2 and 8 kHz and for the frequencies between 3 and 4 kHz for both ears together.

In case of missing data, a complete case analysis was performed in which missing data were excluded from the analyses. An exception was the lack of approximately one-fourth of the 3-kHz thresholds in baseline audiometry owing to a failure to follow the protocol by one of the audiology assistants. We decided to interpolate the 3-kHz threshold in these cases by averaging the thresholds at 2 and 4 kHz.[23] As a sensitivity analysis for the interpolated data, we also performed a complete case analysis. All analyses were performed on an intention-to-treat basis. SPSS, version 21.0.0 for Windows was used, and $P < .05$ was considered statistically significant. The *P* values comparing audiometric results were adjusted for multiple comparisons using the Benjamini-Hochberg procedure[24] to control for the false discovery rate.

Results

Characteristics of the Study

Participants were recruited between August 26 and September 3, 2015, and data were analyzed from September 10 to 16, 2015. As shown in Figure 1, 51 of the 86 volunteers who were assessed for eligibility were included in the study. Twenty-five participants were allocated to the earplug group and 26 to the unprotected group; no participants were lost to follow-up. As presented in **Table 1**, the baseline characteristics did not differ between groups. Moreover, as evidenced by **Table 2**, the baseline audiometry characteristics did not differ between groups. For baseline DPOAEs, there was a significant difference in magnitudes between the 2 groups for 6847 Hz and 6228 Hz in the left ear ($P = .02$ for both); no other frequencies differed at baseline.

The mean (SD) time spent on the festival grounds was 270 (29) minutes for the earplug group and 277 (27) minutes for the unprotected group. The mean time-averaged, equivalent A-weighted sound pressure level was 100 dBA. In the earplug group, 12 participants (48%) spent 75% or more of their time at music stages compared with 7 (27%) in the unprotected group. None of the participants in the earplug group spent 75% or more of their time situated less than 10 m from the music speakers compared with 2 individuals (8%) in the unprotected group. None of the above-mentioned characteristics differed statistically significantly between the groups. The mean (SD) time between leaving the festival grounds and the start of the objective hearing evaluation tests was 29 (15) minutes.

Missing Data

The 3-kHz audiometric thresholds were omitted in both ears before the festival for 12 participants (6 in each study group). In 2 participants, a single audiometric value was missing for the left ear (for 0.5 kHz in 1 person in the earplug group and for 6 kHz in 1 person in the unprotected group). The DPOAE data were missing for 8 participants at baseline and after sound exposure in 1 or both ears because of the inability to conduct the test (5 participants in the earplug group and 3 in the unprotected group); the available tips on the DPOAE probe did not fit their small external acoustic meatuses.

Table 1. Participant Characteristics at Baseline and During the Music Festival

Characteristic	Unprotected Group (n = 26)	Earplug Group (n = 25)
Baseline		
Age, mean (SD), y	27.0 (6.2)	27.3 (5.6)
Male sex, No. (%)	9 (35)	9 (36)
Western ethnicity, No. (%)	24 (92)	23 (92)
Tinnitus history		
Yes, spontaneously	3 (12)	2 (8)
Yes, after listening to loud music	9 (35)	9 (36)
Never	14 (54)	14 (56)
Visits music club or festival ≥2 times/mo, No. (%)	17 (65)	17 (68)
Previous use of earplugs (%)		
Always	0	0
Often	2 (8)	2 (8)
Sometimes	12 (46)	11 (44)
Never	12 (46)	12 (48)
During Festival		
Duration of festival visit, mean (SD), min	277 (27)	270 (29)
≥75% of Time spent at music stages	7 (27)	12 (48)
≥75% of Time spent <10 m from music speakers	2 (8)	0
Alcohol use, mean (SD), units[a]	4.0 (2.2)	4.2 (2.3)
Drug use, No. (%)	6 (23)	5 (20)

[a] A unit of alcohol was defined as 10 g of pure alcohol.

Primary Outcome

There were significant differences in the proportion of TTSs between the 2 study groups. Specifically, a TTS was observed in 4 of 50 ears (8%) in the earplug group vs 22 of 52 ears (42%) in the unprotected group ($P < .001$). Table 2 provides the mean thresholds before and after music exposure as well as the differences. In the earplug group for both ears, the mean thresholds increased significantly less after exposure at 3 and 4 kHz compared with the ears in the unprotected group. For example, at 3 kHz in the right and left ears, mean (SD) increases of 3.3 (5.5) dB and 2.1 (6.2) dB, respectively, were observed in the earplug group. In contrast, more severe elevations of 8.8 (6.1) dB in the right ear and 6.5 (6.1) dB in the left ear were observed in the unprotected group. At 4 kHz, the threshold shifts for the earplug group were 1.4 (4.2) dB in the right ear and 0.0 (5.8) dB in the left ear compared with 7.9 (5.5) dB in the right ear and 7.1 (6.5) dB in the left ear for the unprotected group. The increase in PTA of 3 and 4

Table 2. Audiometry Thresholds Before and After Loud Music Exposure

Frequency, kHz	Mean (SD), dB Unprotected Group Before	After	Δ	Earplug Group Before	After	Δ	*P* Value[a]
0.5							
Right ear	1.4 (5.8)	5.2 (6.1)	3.9 (4.3)	2.4 (6.0)	4.4 (7.3)	2.0 (5.0)	.23
Left ear	0.8 (4.8)	4.4 (5.9)	3.7 (4.1)	1.3 (5.9)	4.4 (7.7)	2.9 (4.4)	.75
1.0							
Right ear	6.0 (4.0)	9.4 (6.1)	3.5 (5.1)	6.4 (5.3)	9.8 (6.0)	3.4 (4.7)	.96
Left ear	5.2 (4.1)	9.4 (5.4)	4.2 (5.4)	5.0 (6.1)	8.6 (6.9)	3.6 (5.3)	.87
2.0							
Right ear	6.5 (7.3)	11.7 (6.6)	5.2 (5.0)	5.2 (7.6)	9.2 (7.9)	4.0 (6.5)	.69
Left ear	7.7 (7.5)	11.7 (7.9)	4.0 (4.3)	5.4 (7.5)	9.8 (9.0)	4.4 (6.8)	.92
3.0							
Right ear	5.3 (7.1)	14.0 (7.6)	8.8 (6.1)	6.5 (8.0)	9.8 (10.4)	3.3 (5.5)	.007
Left ear	8.0 (6.9)	14.5 (9.6)	6.5 (6.1)	8.8 (8.2)	10.9 (10.7)	2.1 (6.2)	.04
4.0							
Right ear	2.9 (8.0)	10.8 (8.9)	7.9 (5.5)	5.6 (12.3)	7.0 (13.2)	1.4 (4.2)	<.001
Left ear	6.0 (9.9)	13.1 (10.6)	7.1 (6.5)	9.6 (9.9)	9.6 (10.9)	0.0 (5.8)	<.001
6.0							
Right ear	5.2 (8.8)	8.5 (9.0)	3.3 (8.1)	5.4 (10.3)	6.2 (8.9)	0.8 (6.9)	.45
Left ear	6.0 (6.6)	11.9 (9.9)	5.4 (7.2)	5.2 (9.4)	8.8 (10.7)	3.6 (4.9)	.50
8.0							
Right ear	10.0 (8.8)	11.7 (11.2)	1.7 (8.4)	11.8 (8.9)	13.8 (9.8)	1.9 (6.6)	>.99
Left ear	11.5 (10.3)	12.7 (9.9)	1.2 (7.3)	8.8 (8.3)	10.6 (7.1)	1.8 (5.8)	.87
PTA 0.5, 1, 2, 4 kHz							
Right ear	4.2 (4.8)	9.3 (5.7)	5.1 (3.7)	4.9 (6.4)	7.6 (6.9)	2.7 (3.8)	.07
Left ear	4.9 (4.9)	9.7 (5.9)	4.8 (4.1)	5.5 (5.8)	8.1 (7.2)	2.6 (4.2)	.15
PTA 3 and 4 kHz							
Right ear	4.1 (7.0)	12.4 (7.9)	8.3 (5.4)	6.1 (9.7)	8.4 (11.4)	2.4 (4.2)	<.001
Left ear	7.0 (7.9)	13.8 (9.6)	6.8 (5.8)	9.2 (8.2)	10.3 (10.2)	1.1 (4.9)	<.001

Abbreviations: Δ, difference between before- and after-festival thresholds; PTA, pure tone average.

[a] An independent, 2-tailed *t* test compared the differences between the unprotected and earplug groups. The *P* values were corrected with the Benjamini-Hochberg procedure.[24]

kHz was also significantly lower in the earplug group for both ears. The complete case analysis, in which all missing 3-kHz audiometric results were deleted, also showed significant differences between the earplug group and the control group for 3 kHz and the PTA of 3 and 4 kHz for the left and the right ear. The relative risk for a TTS after loud music exposure in the unprotected group vs the earplug group was 5.3 (95% CI, 2.0-14.3). The number needed to treat was 2.9: the use of earplugs in 3 individuals at this festival prevented a temporary hearing loss in 1 individual.

Secondary Outcomes

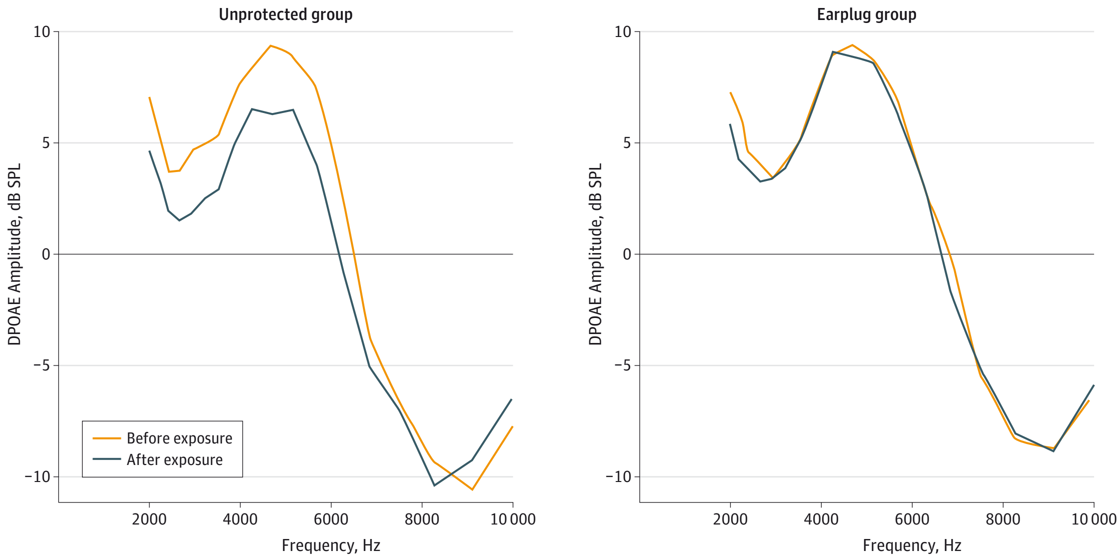
DPOAE Measurements

Figure 2 shows the DPOAE amplitude at baseline and after exposure for the earplug and the unprotected group for both ears combined. The DPOAEs in the earplug group did not change following the festival visit except for 2 frequencies: 2654 Hz (*P* = .04) and 2196 Hz (*P* = .002) for the right and left ears, respectively. In contrast, the DPOAE levels in the unprotected group decreased significantly for 22 of the 36 tested frequencies (61%). In the unprotected group, essentially all magnitudes for frequencies between 2 and 3 kHz decreased along with most of the frequencies between 3 and 6 kHz. The mean (SD) DPOAE magnitude for frequencies 2918 through 4689 Hz decreased by 0.3 (2.8) dB in the earplug group compared with 1.9 (2.2) dB in the unprotected group (*P* = .04). For all frequencies between 2 and 8 kHz, the mean (SD) decrease in magnitude was 0.6 (2.8) dB in the earplug group vs 2.2 (1.9) dB in the unprotected group (*P* = .04).

Subjective Outcome Measures

As indicated in **Table 3**, at baseline there was only 1 person in the unprotected group with tinnitus perception. After loud music exposure, there were 3 new cases of tinnitus among 25 participants (12%) in the earplug group compared with 10 of 25 participants (40%) in the unprotected group (difference, 28%; 95% CI, 3.6%-49.0%; *P* = .02). There were no differences in the objective and subjective pitch and loudness perception of tinnitus between the groups. Only 1 participant (4%) in the earplug group vs 15 (58%) in the unprotected group subjectively

Figure 2. Distortion Product Otoacoustic Emission (DPOAE) Levels Before and After Music Exposure



The mean DPOAEs for both ears are shown before and after exposure for the earplug and the unprotected group separately. A decrease in mean levels is clear for the unprotected group, whereas DPOAEs for the earplug group do not decrease significantly. SPL indicates sound pressure level.

Table 3. Tinnitus and Subjective Hearing Loss

Outcome	Unprotected Group (n = 26)	Earplug Group (n = 25)	*P* Value[a]
Tinnitus perception before festival, No. (%)	1 (4)	0	NC[b]
New tinnitus perception in 1 or both ears after festival, No. (%)	10 (40)[c]	3 (12)	.02
Objective tinnitus ADS, mean (SD)			
Pitch, kHz	3.8 (2.5)	4.7 (4.7)	.71
Loudness, dB	19.6 (8.5)	23.8 (1.8)	.54
Subjective tinnitus, mean (SD)[d]			
Loudness VAS	2.9 (1.4)	2.0 (1.4)	.41
Annoyance VAS	2.5 (1.8)	1.0 (1.4)	.29
Pitch VAS	4.6 (2.6)	5.0 (5.7)	.85
Subjective hearing loss, No. (%)	15 (58)	1 (4)	<.001

Abbreviations: ADS, right and left ear combined; NC, not calculable; VAS, visual analog scale.

[a] Determined with the χ^2 test when comparing proportions of participants with tinnitus and subjective hearing loss, and determined with the independent, 2-tailed *t* test when comparing objective and subjective tinnitus measures.

[b] Not calculable because no participants experienced tinnitus in the earplug group.

[c] Percentage is based on 25 individuals in the unprotected group who did not have tinnitus before the festival.

[d] The VAS scores ranged from 0 (very low) to 10 (very high).

thought their hearing had deteriorated (difference, 54%; 95% CI, 29.3%-70.8%; *P* < .001).

Discussion

This single-blind RCT assessed the effectiveness of earplug use at music festivals in preventing temporary hearing loss. We found that the proportion of participants with a TTS following sound exposure was only 8% in the earplug group compared with 42% in the unprotected group. The difference in threshold shifts was most evident for the frequencies 3 and 4 kHz. The DPOAE amplitude decreased significantly less for the frequencies 2 through 8 kHz in the earplug group compared with the unprotected group. In addition, a lower percentage of participants had tinnitus following sound exposure in the earplug group (12% vs 40% in the unprotected group).

As in the present study, Derebery et al[5] found a TTS in either one or both ears in 33% of participants and decreased DPOAE levels after a concert in 68%. That study, however, was not randomized, and only 3 participants wore earplugs. An RCT by Opperman et al[21] investigated the effect of earplugs during 3 concerts and found a smaller incidence of TTS in participants who wore earplugs: 4 of 15 (27%) who wore earplugs compared with 9 of 14 (64%) in the unprotected group experienced a TTS. Those authors found significantly lower differences in thresholds in the earplug group after the concert for the frequencies 0.5, 3, and 4 kHz compared with the unprotected group. Our study showed an incidence of TTS in 22 of 52 ears (42%) in the unprotected group, which is within the range of the above-mentioned studies. Our proportion of TTS in the earplug group, however, is lower than that described by Opperman et al.[21] An interesting finding was the opposite attitude toward earplug use in the study by Opperman et al, who described their participants' refusal to wear earplugs despite being offered free first-row tickets to a sold-out concert.[21] In our study, we had to exclude several participants because of their explicit wish to wear earplugs. This development may indicate that the attitude toward earplugs has begun to shift.

A strength of this study is that it was a well-designed and well-conducted RCT and the first, to our knowledge, to evaluate noise exposure and hearing loss at an outdoor music festival. Another asset is that we performed hearing evaluations within half an hour of loud music exposure after participants left the festival grounds. An additional advantage was the use of multiple objective and subjective measures of hearing loss.

A limitation of this study is that some audiometric data were missing, especially at 3 kHz. Because the effect of NIHL is seen on the audiogram primarily at the frequencies of 3 and 4 kHz, interpolation of missing data may have reduced the effects. However, our complete case analysis, in addition to the interpolated data, showed similar results. Other limitations of our study were the lack of the exact level of noise exposure per individual and the possible recovery of the TTS before the postexposure audiometry was performed. In the earplug group, the exact duration of individual earplug use and the individual noise reduction rate per frequency of the earplugs was unknown. The individual noise reduction rate relied on various user-related factors, such as insertion of the earplug in the external acoustic meatus. The last 2 limitations have probably led to an underestimation of the preventive effect of earplugs. Another disadvantage of this study is that it reports on only short-term outcomes after sound exposure. It would be interesting to analyze the effect of sound exposure on permanent hearing loss; however, a long-term controlled follow-up study of music venue attendees is difficult to realize both ethically and practically.

Conclusions

In this RCT, the proportions of participants with a TTS and tinnitus were significantly lower in the earplug group compared with the unprotected group. In addition, a significantly greater decrease in DPOAE amplitudes was seen in the unprotected group compared with the earplug group. This RCT adds evidence that earplugs are effective in preventing temporary hearing loss during high recreational music levels. Therefore, the use of earplugs should be actively promoted and encouraged to avoid NIHL.

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