Randomized Trial of a Hearing Conservation Intervention for Rural Students: Long-term Outcomes

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KEY WORDS

agriculture, hearing conservation, noise-induced hearing loss, youths, randomized controlled trial

ABBREVIATIONS

NIHL—noise-induced hearing loss

ICC—intraclass correlation coefficient

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WHAT'S KNOWN ON THIS SUBJECT: The prevalence of noise-induced hearing loss in pediatric populations is increasing. In response to this trend, educational initiatives directed toward hearing conservation are being widely promoted for school-aged children, but few randomized trials have examined the efficacy of these initiatives.

WHAT THIS STUDY ADDS: Comprehensive follow-up assessment of participants in a randomized trial of a hearing conservation intervention revealed a limited, long-term increase in the reported use of hearing protection but failed to demonstrate efficacy with respect to objective measures of hearing loss.

abstract

OBJECTIVES: We had the rare opportunity to conduct a cluster-randomized controlled trial to observe the long-term (16-year) effects of a well-designed hearing conservation intervention for rural high school students. This trial assessed whether the intervention resulted in (1) reduced prevalence of noise-induced hearing loss (NIHL) assessed clinically and/or (2) sustained use of hearing protection devices.

METHODS: In 1992–1996, 34 rural Wisconsin schools were recruited and 17 were assigned randomly to receive a comprehensive, 3-year, hearing conservation intervention. In 2009–2010, extensive efforts were made to find and contact all students who completed the original trial. Participants in the 16-year follow-up study completed an exposure history questionnaire and a clinical audiometric examination. Rates of NIHL and use of hearing protection were compared.

RESULTS: We recruited 392 participants from the original trial, 200 (53%) from the intervention group and 192 (51%) from the control group. Among participants with exposure to agricultural noise, the intervention group reported significantly greater use of hearing protection compared with the control group (25.9% vs 19.6%; $P = .015$). The intervention group also reported significantly greater use of hearing protection for shooting guns (56.2% vs 41.6%; $P = .029$), but the groups reported similar uses of protection in other contexts. There was no significant difference between groups with respect to objective measures of NIHL.

CONCLUSION: This novel trial provides objective evidence that a comprehensive educational intervention by itself may be of limited effectiveness in preventing NIHL in a young rural population. *Pediatrics* 2011;128:e1139–e1146

Noise-induced hearing loss (NIHL) among pediatric populations is a growing public health concern. In a large national study, Niskar et al[1] estimated that 12.5% of ~5.2 million US children 6 to 19 years of age had noise-induced threshold shifts. More recently, studies showed that the prevalence of hearing loss among US adolescents 12 to 19 years of age is increasing over time.[2,3] Youths in agricultural communities have been identified as an "at-risk" population because of occupational noise exposures.[4,5] In fact, the prevalence of noise-induced threshold shifts among farm youths 6 to 19 years of age was found to be nearly twice that a nationally representative sample of youths.[5]

In response to the trend of increased pediatric NIHL, educational initiatives directed toward hearing conservation are being promoted for school-aged children,[1,2,6] although few randomized controlled trials have examined the efficacy of these initiatives. To address this obvious research gap, we had a rare opportunity to evaluate the long-term effectiveness of a 3-year hearing conservation intervention conducted with high school students in agricultural communities. Our objectives were to assess whether the educational intervention, which was well funded, built on theory, and comprehensive in nature, resulted in reduced prevalence of NIHL at the 16-year follow-up assessment and/or sustained hearing protection device use during that time period, compared with a concurrent control group of young rural people who did not receive the intervention. It was hypothesized that the hearing conservation intervention would result in a lower prevalence of NIHL and sustained use of hearing protection devices.

METHODS

Human Subjects

The institutional review boards of the Marshfield Clinic Research Foundation and Queen's University approved the study protocol.

Procedures for Original Randomized Trial

The original trial was reported elsewhere[7,8] and is summarized briefly here. The original trial used a cluster design involving 34 schools in rural Wisconsin with vocational agriculture programs. Schools were stratified according to the projected number of students (smaller versus larger schools), and then each school (cluster) was assigned randomly to either the intervention or control group, separately within the 2 strata. Students enrolled were in grades 7 through 9 and were regular participants in farm work at the time of recruitment. A noise exposure questionnaire was completed at baseline (1992–1993) and after 3 years (1995–1996). Audiometric examinations were completed on-site at each school by trained technicians, using a truck-mounted, mobile testing unit with a specially designed testing booth. The intervention spanned 3 years and incorporated elements of the ideal industrial hearing conservation program.[9] The intervention included classroom instruction, fitting and distribution of hearing protection devices, direct mailing of educational materials to students' homes to reinforce hearing protection messages, noise level assessments conducted at home, and yearly audiometric testing, with reinforcement of hearing-protection messages. The control group received audiometric testing at baseline and at years 2 and 3. Short-term outcomes suggested that the intervention led to significantly improved rates of hearing protection use at 3 years after the intervention,[7] but no differences were found between intervention and control groups with respect to objective audiometric measures of NIHL.[8]

Procedures for 16-Year Follow-up Assessment

Participants

A total of 690 students completed the original trial (349 in the intervention group and 341 in the control group) (Fig 1); this constituted our target cohort for the 16-year follow-up study. There were no specific exclusion criteria.

Between March 2009 and March 2010, extensive efforts were made to find and to contact all 690 members of the target cohort. The efforts started with matching of the original study participant roster with the Marshfield Clinic electronic medical record. If participants could not be matched with the electronic medical record, then telephone directories and Internet searches were used to find contact information. If such efforts were unsuccessful, then the original study parent roster was matched with the electronic medical record. If parents could not be matched with the electronic medical record, then telephone directories and Internet searches were used to find parent contact information. Attempts to contact participants were exhaustive; >1200 recruitment letters were mailed to participants and/or parents, and 3252 telephone calls were made.

Exposure Assessment

Participants in the 16-year follow-up study completed an exposure history questionnaire covering the 13 years since the last previous contact in 1996. The questionnaire focused on recreational and occupational exposures to high noise levels and exposures to smoking and chemicals with ototoxic potential. The use of hearing-protection devices for each activity and exposure was recorded. Time-weighted averages were calculated to summarize historical noise exposures and hearing protection behaviors. Part-time work was weighted as a proportion of full-time work for agricultural (38%, on the basis of means of 19.5 hours for part-time work and 51.5 hours for full-time work) and nonagricultural (51%, on the basis of means of 22.7 hours for part-time work and 44.6 hours for full-time work) industries, by using means for 2009 reported by the US Bureau of Labor Statistics.[10] Exposure measures are reported as mean times of exposure over 13 years. Protective behaviors are reported as mean proportions of time when hearing protection devices were used during exposure.

Audiometric Testing

Participants were scheduled for audiometric examinations at the Marshfield Clinic main campus or 1 of 7 satellite clinics. Examinations were conducted by licensed audiologists in clinical audiology departments, with standard operating procedures.[11] Before participant enrollment, an audiologic study protocol was developed and reviewed with all 12 audiologists involved in testing. Audiologists were not informed of individual participants' group membership (intervention or control group). Established measures were used to summarize audiogram results.

Primary Outcome Measures

All outcomes were assessed at the individual participant level. The hearing protection measure was self-reported use of hearing protection devices for each recreational and occupational category examined. Participants responded by using a 5-point Likert scale anchored by "never" and "always." Audiometric outcome measures were threshold changes from baseline to 16-year follow-up assessments in (1) individual frequencies, (2) the Occupational Safety and Health Administration standard threshold shift, representing an increase of ≥10 dB in the average for 2000, 3000, and 4000 Hz in either ear (yes or no), (3) the low-frequency average (500, 1000, and 2000 Hz), (4) the high-frequency average (3000, 4000, and 6000 Hz), and (5) the bulge depth statistic,[12] defined as the difference between mean audiometric values at 2000, 3000, and 4000 Hz and mean values at 1000 and 6000 Hz.

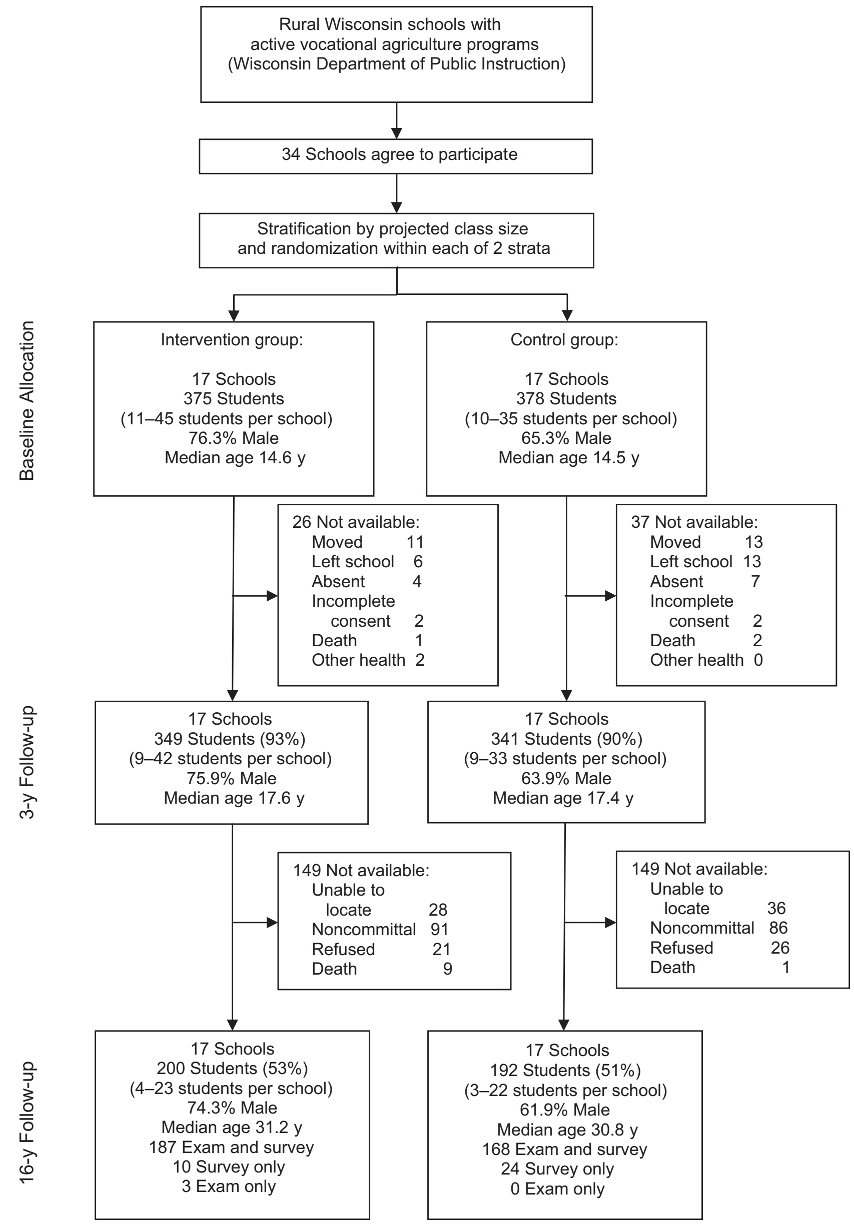

FIGURE 1
Flow diagram of original baseline allocation, 3-year assessment, and 16-year follow-up assessment.

Sample Size Calculations

The goal was to recruit as many original study participants as possible (up to 349 participants in the intervention group and 341 in the control group). *A priori* power calculations based on original study data showed an estimated power of ≥85% ($\alpha = .05$, 2-sided test) for primary outcomes assuming (1) effect sizes of 22% for the absolute difference in the use of hearing protection devices and 10 dB in the standard threshold shift, (2) an intraclass correlation coefficient (ICC) of 0.06, and (3) 60% recruitment in each group. Interim analysis of conditional power was conducted in November

2009, when it was clear that recruiting 60% of the cohort would be impossible with the existing time line. Interim estimates of ICC were lower than those used for planning, by enough to more than offset the lower recruitment rates. After all attempts at 16-year follow-up study recruitment were exhausted, recruitment ended in the original time frame (enrollment rate: 52%).

Statistical Methods

Survey responses on the use of hearing protection devices and other protective equipment were reported in 5 ordinal categories, that is, never (0% of the time exposed), sometimes (1%–33%), often (34%–66%), frequently (67%–99%), and always (100%). Before analysis, extreme categories were pooled as necessary to provide ≥10 responses per study arm in each category. A cumulative logit parameterization assuming proportional odds was used to model the use of protective equipment by exposed individuals and to test for group differences. A linear model was used to calculate adjusted mean exposures for presentation, but exposure distributions were skewed, with many 0 values and some very high values; therefore, means for exposure were much higher than medians (data not shown).

Individual frequencies were each analyzed as maximal (left or right) changes from baseline values by using logistic regression analyses to compare study arms. Cumulative logit parameterization assuming proportional odds was fit to the resulting ordinal scale (eg, 0, 5, 10, or ≥15) measures. The Occupational Safety and Health Administration standard threshold shift was analyzed by using binary logistic regression analysis to compare study arms.

Summary measures were each analyzed as maximal (left or right) changes from baseline values by using a linear model to compare study arms. The measures were first transformed,[13] to provide better approximate normality and improved statistical properties. Statistics were returned to the original scale for presentation.

All statistical models described above were adjusted for randomization according to school. A school indicator was included as a random effect in models, to estimate and to adjust for potential correlation (ICC) among subjects from the same school. As reported previously,[8] the randomized groups differed with respect to the proportions of male subjects, and substantial gender differences in hearing have been reported; therefore, all models included gender as a covariate. In secondary analyses, a simple binary covariate was used to evaluate the effects of controlling for potential variability in audiometric outcomes attributable to smoking (ever or never).

Analyses included all available data, following intention-to-treat principles. References to statistical significance are based on a 5% level of significance ($P < .05$) in 2-sided tests. No adjustment for multiple comparisons was used, but it was decided *a priori* that statistical significance at any 1 frequency would not be considered definitive without supporting trends in adjacent frequencies.

RESULTS

Recruitment and Participant Flow

A total of 392 participants from the original study were located and recruited successfully, including 200 (53%) from the intervention group and 192 (51%) from the control group (Fig 1). Equal numbers of subjects from each group ($n = 149$) did not participate in the 16-year follow-up study, primarily because of subjects not returning telephone calls after multiple attempts (noncommittal groups). Within the noncommittal groups (intervention: $n = 91$; control: $n = 86$), 27 subjects from each group agreed to participate but did not appear for the audiometric examination and/or return the survey. Sixty-four subjects could not be located, including 28 from the intervention group and 36 from the control group. Only 47 (8%) of the 616 subjects who were located declined participation. Ten subjects had died, including 9 from the intervention group ($P = .046$). This group discrepancy is likely attributable to differences in the availability of follow-up information and is reported for completeness only, because death was not a planned outcome. The cause of death was determined in 5 cases (2 drownings, 2 motor vehicle crashes, and 1 homicide). The combined numbers of subjects who either were known to have died or were unable to be located were identical ($n = 37$) in the 2 groups.

Descriptive Data

Figure 1 summarizes participant characteristics at the baseline, 3-year follow-up, and 16-year follow-up time points. The median ages of participants were comparable between the groups; however, consistent with baseline allocation, the proportion of male subjects was greater in the intervention group at the 16-year follow-up assessment (74% vs 62%). Thirty-seven participants failed to complete either the survey ($n = 3$) or the examination ($n = 34$); for consistency, all further analyses are restricted to the 355 participants who completed both the survey and the examination.

Table 1 shows the numbers and proportions of participants in the intervention and control groups with occupational and recreational high noise

TABLE 1 Analyses of Noise Exposures and Protective Behaviors in 16-Year Follow-up Assessments for Intervention and Control Groups

Noise Exposures	Exposed, *n* (%)		Exposure Time, Adjusted Mean[a]		Proportion of Time Protective Behavior Used, Adjusted Mean, %[b]		*P*[c]	ICC
	Control	Intervention	Control	Intervention	Control	Intervention		
Agriculture	122 (73.7)	145 (78.7)	176.1 wk	163.8 wk	19.6	25.9	.015	0.00
Construction	48 (25.1)	65 (27.3)	63.4 wk	79.7 wk	36.0	35.6	.587	0.03
Manufacturing	59 (35.2)	74 (39.2)	78.6 wk	90.7 wk	56.5	64.4	.480	0.10
All occupations	137 (85.1)	176 (95.4)	329.7 wk	370.0 wk	33.5	39.4	.088	0.04
All chemicals	76 (47.1)	104 (53.2)	1097.8 d	1470.0 d	21.1	21.7	.655	0.02
All recreational activities	163 (97.1)	181 (96.8)	1682.2 d	1851.8 d	16.9	20.4	.102	0.04
Personal stereos	93 (54.2)	84 (46.2)	1332.5 h	1336.5 h	60.1	62.3	.236	0.00
Gunfire	104 (68.5)	131 (71.3)	1232.4 shots	2157.5 shots	41.6	56.2	.020	0.01

The study was performed in Wisconsin. The original study period was 1992–1996, and the follow-up period was 2009–2010. Proportions exposed and all mean values were adjusted for gender and age by using statistical models. School was modeled as a random effect.

[a] Adjusted means for exposure times included subjects with 0 exposures. Times are over the 13 years since the previous contact.

[b] Protective behaviors included use of hearing protection, use of equipment for chemical protection, and stereo volume control.

[c] *P* values are from ordinal logistic mixed models for grouped outcomes.

exposures, as well as mean levels of exposure. After adjustment for gender and study design, exposures were similar in the 2 groups and showed no significant differences (results not shown). Smoking history varied somewhat according to group ($P = .044$), with 38% of the intervention group reporting current or previous smoking, compared with 26% of the control group.

Use of Hearing Protection Devices

Rates of reported use of hearing protection devices according to exposure category are summarized in Table 1 (right side). Intervention group members with agricultural noise exposure reported significantly higher rates of use of hearing protection devices ($P = .015$), compared with exposed subjects in the control group, although the proportions using devices were quite small in both groups (25.9% and 19.6%, respectively). There was a significant difference between the intervention and control groups in the use of hearing protection devices when exposed to gunfire ($P = .02$), with the intervention group reporting a larger proportion using hearing protection (56.2% and 41.6%, respectively).

Audiometric Threshold Tests

Raw audiometric data showed similar distributions between intervention and control groups for both male and female subjects (Fig 2). The highest thresholds were observed for male subjects, with 6% of male subjects showing thresholds of ≥55 dB at 6000 Hz (maximum: 90 dB; maximal increase from baseline: 75 dB) and 23% showing thresholds of ≥25 dB. The largest group difference was observed at 6000 Hz, where there was a 5 dB difference in the 75th percentile values (better hearing in the intervention group).

Group comparisons of audiometric thresholds adjusted for gender are summarized in Table 2. No significant differences between intervention and control groups were observed, and no consistent trend across thresholds was observed. The group difference at 6000 Hz approached significance ($P = .054$) in the direction of less hearing loss in the intervention group (38% with loss of ≥10 dB, compared with 50% in the control group). When it was included as a covariate in this model, smoking (ever or never) was significantly related to the 6000-Hz outcome ($P = .002$ [smokers had more hearing loss]) and increased the apparent significance of the intervention effect ($P = .024$; odds ratio: 0.62). Adjustment for smoking did not result in significant intervention effects at other frequencies.

The standard threshold shift indicator showed no suggestion of group differences ($P = .847$) (Table 2). Similarly, no significant group differences were observed with hearing summary measures (Table 2). Means adjusted for design and gender were very similar according to group for the low- and high-frequency averages and the bulge depth statistic.

DISCUSSION

General Interpretation

Major findings that emerged from this 16-year follow-up study from a cluster-randomized trial were that (1) participants who were assigned randomly to the hearing conservation intervention reported more-frequent use of hearing protection, compared with control subjects, although this was limited to 2 contexts (agricultural work and gunfire), and (2) the educational intervention had no convincing effect on early NIHL, as assessed with objective audiometric measures. Long-term increases in the use of hearing protection devices in the intervention group, compared with the

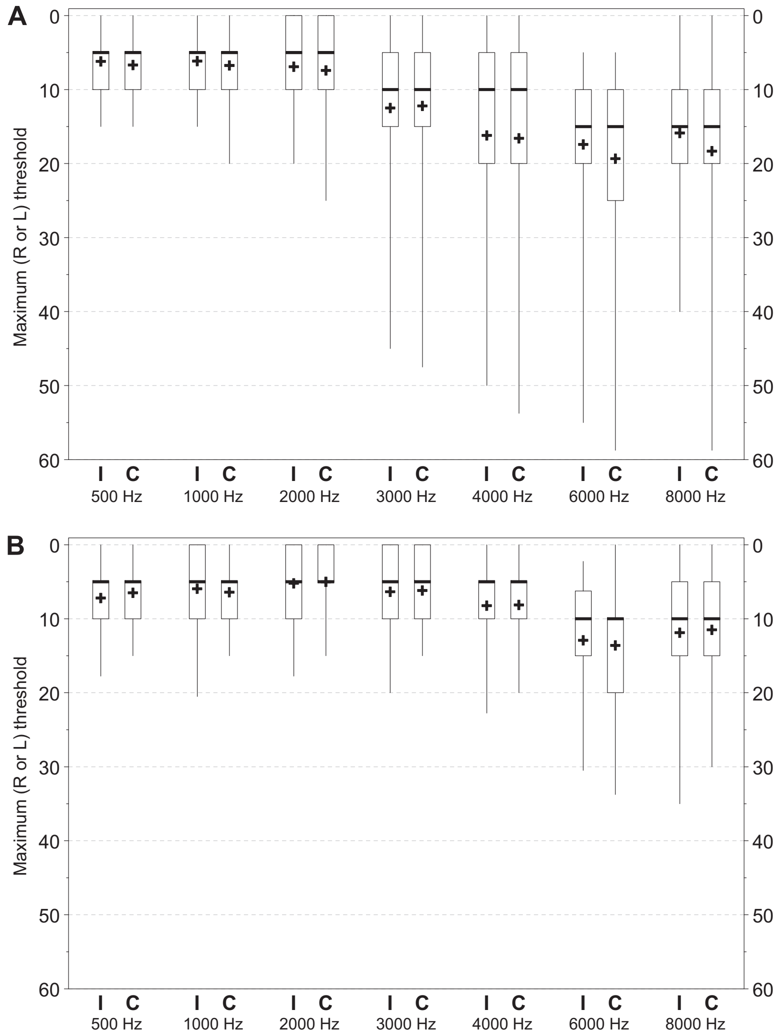

FIGURE 2
Current audiometric test results according to randomized group: A, males ($n = 139$ [intervention group] and 104 [control group]); B, females ($n = 48$ [intervention group] and 64 [control group]). Boxes extend from the 25th percentiles to the 75th percentiles with black lines at the medians and plus signs at the means. Vertical lines extend to the 5th and 95th percentiles. I indicates intervention; C, control; L, left; R, right.

control group, were demonstrated. However, the increased use of hearing protection during noisy agricultural activities was still quite low (25.9%) and similar to rates reported for the general farm population.[14] Even if findings are real, such effects may not be adequate to prevent NIHL. The observed increase in the use of hearing protection would still have resulted in substantial exposures to potentially damaging noise, because rates of use in numerous noisy occupational and recreational contexts also were low.

The lack of any convincing effect of the intervention on the audiometric test results for this cohort is noteworthy. Although there was some indication of an effect at a single high frequency (6000 Hz), this yielded significance only with adjustment for smoking history and was not supported by data at other frequencies, as required *a priori* in our trial protocol for definitive evidence. Studies have shown associations of smoking with hearing,[15,16] but those reports involved older subjects, and there is a strong potential for confounding of the effects of smoking by other important factors (gender, age, or occupation). Nevertheless, by documenting important changes in hearing acuity at high frequencies in a young cohort over time, this study provides objective evidence that a well-organized educational intervention by itself may be of limited effectiveness in preventing NIHL. Therefore, other approaches to prevention require consideration.

Internal Validity

Threats to internal validity in the 16-year follow-up study include possible selection bias attributable to loss to follow-up. However, recruitment rates were equivalent for the study arms (intervention: 53%; control: 51%); all 34 schools in the original trial were represented. In addition, comparisons of results for participants at 3 years who were or were not lost to follow-up over 16 years showed no differences between groups. Subjects who did not participate were similar according to study arm with respect to key baseline factors, including living and working on farms, using hearing protection, having exposure to firearms, and having a family history of hearing loss (analyses not shown), which further indicates that our results are free from substantial selection biases.

There is a possibility that important effects of the intervention might have been missed. This trial was 85% powered *a priori* to detect a substantial difference in hearing loss, defined as a change in the standard threshold shift of $\geq$10 dB, between the intervention and control groups. Recruitment targets were 205 subjects per arm and, although those targets were not met, a conservative value was used for the ICC (0.06 compared with an observed value of 0.02). On the basis of the latter ICC, a similar level of power would re-

TABLE 2 Analyses of Audiometric Changes from Baseline to 16-Year Follow-up Assessments for Intervention and Control Groups

	Loss		(95% CI)	*P*	ICC
	Control	Intervention			
Individual audiometric frequencies[a]	Proportion with >= 10 dB from baseline		Odds ratio		
500 Hz	9.8	12.0	1.01 (0.53–1.93)	0.963	0.11
1000 Hz	23.1	26.9	1.03 (0.66–1.63)	0.886	0.03
2000 Hz	16.4	25.1	1.35 (0.76–2.41)	0.296	0.08
3000 Hz	28.6	25.1	0.92 (0.53–1.60)	0.763	0.06
4000 Hz	40.5	38.5	1.00 (0.60–1.68)	0.990	0.05
6000 Hz	50.1	37.6	0.67 (0.45–1.01)	0.054	0.02
8000 Hz[b]			0.96 (0.64–1.44)	0.849	0.00
Standard threshold shift[c]	14.6	13.8	0.94 (0.46–1.89)	0.847	0.003
Audiometric summary measures[d]	Adjusted mean dB		Difference, Mean dB[e]		
Low-frequency average	4.7	4.9	−0.19 (−1.12 to 0.83)	0.686	0.03
High-frequency average	9.4	9.2	0.21 (−1.20 to 1.79)	0.773	0.02
Bulge depth	4.0	4.4	−0.34 (−1.74 to 1.14)	0.632	0.04

The study was performed in Wisconsin. The original study period was 1992–1996, and the follow-up period was 2009 –2010. Results were adjusted for age and gender. School was modeled as a random effect. CI indicates confidence interval.

[a] Statistical results were obtained with an ordinal logistic regression model. The control group was modeled as the reference group. Audiometric responses are ordinal, and the proportional odds assumption implies that the intervention effect on the odds is the same for each level of response.

[b] No baseline data were available. Results at 16 years were compared with no adjustment for baseline.

[c] Statistical results were obtained with a binary logistic regression model.

[d] Statistical results were obtained with a linear regression model.

[e] Control minus intervention values. Negative differences indicate less hearing loss in the control group.

quire 127 participants in each arm of the trial. These targets were exceeded, and thus the study was powered adequately to detect the originally postulated effect.

External Validity

The rural high school students in this trial originally worked in agriculture, but many entered other occupations between 1996 and 2010. Therefore, these findings likely are generalizable to populations with cultural and exposure experiences similar to those of the study participants. Findings may not be generalizable to other cohorts and contexts.

Strengths and Limitations

Few randomized controlled trials of the efficacy of educational initiatives for prevention of NIHL in young populations exist and, to best of our knowledge, this is the only randomized trial with long-term follow-up assessment conducted with adolescents who were into adulthood. The intervention was based on strong educational and behavioral theory and was optimal according to that theory. Outcome assessments were based on objective clinical assessments and standard audiometric measures, and a rigorous approach was used to locate and to recruit participants 16 years after the intervention.

In terms of limitations, although audiologists were not aware of the study arm assignment of participants, some unblinding was inevitable during the clinical consultation, although this was unlikely to lead to differential errors in audiometric assessments because of reliance on objective measures. Follow-up audiometric testing was conducted in a clinical setting, whereas the original testing was conducted in a mobile unit, but the earphone types, calibration methods, permissible ambient noise levels, and test techniques for determining thresholds were the same. Any differences between the clinical and mobile settings would be expected to affect the intervention and control groups equally. In addition, lack of blinding of study participants might have led to differential reporting of the use of hearing protection devices in the intervention group, because of social desirability. Finally, effects of the intervention in preventing NIHL might have been diluted because the original trial was developed in an agricultural context. It is possible that many participants experienced damaging noise in other occupational and recreational contexts, and they might not have translated their learning to the other settings.

Implications

Our findings suggest that this comprehensive, well-designed, well-executed intervention aimed at educating rural high school students about hearing conservation was of limited effectiveness in preventing early NIHL. This is particularly notable because this was an early intervention in the lives of these young people and, theoretically, such early interventions should be efficacious. There is a need for creative solutions to protect young people from major sources of noise in both occupational and recreational settings. Potential solutions should focus on environmental modifications and regulations to control noise emissions, because educational solutions on their own may fail to protect many young people from NIHL.

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