Effectiveness of an Educational Program in Preventing Noise Induced Hearing Loss in a Textile Factory Workers, Khon Kaen, Thailand

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Executive summary

Background: Noise induced hearing Loss (NIHL) is the most common occupational hazard and a very serious problem among rapidly growing industry. Nowadays there is still high prevalence of NIHL in certain industries, which is likely to be a gross underestimate of the true magnitude of the problem. Though hearing conservative program (HCP) has been accepted to be effective in preventing NIHL among developed countries for many years but there are still some arguments of its effectiveness. Failures of the HCP might often be traced to a lack of education and training. In order to combat both practically effective educational pattern for preventing NIHL and methodological flaws from previous studies, the aim of this study was to evaluate the effectiveness of an educational program in preventing NIHL.

Material and Methods: Textile factories were matched on the basis of characteristics related to the primary outcome measurement (noise exposure) and randomly allocated to the treatment factory (with educational program) and control factory (no educational program). Eligible subjects included workers who were exposed to a continuous noise level more than 85 decibel (db)for at least 8 hours in each working day. Demographic data, history taking, physical examination and audiometric data were carried out for each worker. Hearing measured pure tone thresholds for air conduction, which were obtained at 250, 500, 1000, 2000, 4000 and 8000 Hz. We could not find any room in the factories which was quiet enough for testing, thus only the adjusted audiogram was able to be used in this study. Intervention was applied in the treatment factory. The ultimate outcome (audiogram) was carried out at the end of the study and analyzed by comparing the mean of its difference between before and after study in both factories as well as comparing the number of workers who suffered from hearing loss classified according to significant threshold shift criteria. We estimated the rate difference of hearing loss and its 95% confidence interval using normal approximation to binomial distribution. Significance level was set at 0.05. All are two-tailed tests. Using STATA statistical software to perform the analysis.

Results: There was small difference figures between two factories as well as loss to follow up groups in term of age, sex, educational level and duration of exposure to loud noise. There was also no significant difference between the two factories in level of noise at high-risk stations (91.4, 91.4 db) and testing rooms (52.6, 50.0 db) as well as baseline conversational hearing level (21.5, 18.8 db). About seventy percent of workers in treatment factory used earplug regularly compared to fifty percent of workers in the control factory at the end of first month after intervention. The mean of hearing difference which changed from baseline was higher in control factory than treatment factory at all frequencies [0.51(p=0.01), 0.17(p=0.44), 0.61(p=0.01), 1.30(p<0.01), 3.03(p<0.01) and 0.04(p=0.93) respectively]. When classified hearing loss according to significant thresholds shift (STS) criteria or baseline hearing, the result shown rate of hearing loss in treatment factory was 22.3% whereas it was 27.2% in control factory. Thus the rate in control factory was 4.9% higher than those of treatment factory (95%CI:-13.6% to 40.0%) The 95%CI difference was within the range that was considered to be no difference. Thus the difference was not statistically significant (p-value = 0.282) The unadjusted odds ratio was 0.9 (95%CI:0.6% to 1.6%). The odds ratio adjusted for age, sex and duration of noise exposure was 0.8 (95%CI:0.5% to 1.4%) which was consistent with the similar data of baseline characteristics in both factories.

Conclusions: The incidence rate of hearing loss in control factory was 4.9% higher than those of treatment factory. The difference was not statistically significant (p-value = 0.282). These results recommend further big enough and well-controlled study before concluding that the intervention is not effective. Because the difference was meaningful figure in term of investment although a rather short study period we still recommended these program for those who have responsibility to preventing noise induced hearing loss. They were not only capable in practices but enable maintains in the long time without any obstacles from both factory and resource. With the good cooperation from an administrative manager of the factory and through serial contacts with workers, finally we believed that the personnel and the workers could establish an effective HCP in their responsible area without difficulty.

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Chapter 1
Introduction

Noise Induced Hearing Loss (NIHL) is the most common occupational hazard and a very serious problem among rapidly growing industry (Paparella 1991; Cummings 1993) . It can disturb not only physical and mental health but also the awareness of safety monitoring sound and loss of jobs and incomes. Finally there will be an increase in a number of disabled hearing persons especially in working groups that will affect the overall economic and health situation of the country (Hinchcliffe 1967; Glorig 1979; Rop 1979; Dobie 1981). Nowadays there are still high prevalence of NIHL in many industries. Moreover,there is likely to be a gross underestimate of the true magnitude of disease from many survey studies (Sulkowski, Starzynski et al. 1981; Brian 1989; Chavalitsakulchai, Kawakami et al. 1989; Adera, Donahue et al. 1993; Dobie 1993; Division of Occupational Health 1994; Roster 1994; Siripantananugul 1995; Irwin 1997; Lusk 1997; Hong, Chen et al. 1998; Reilly, Rosenman et al. 1998; Suthammasa 1998; Wu, Liou et al. 1998). It is now realized that the cost of NIHL is much greater than what had been estimated (Brian 1989; Dobie 1993; Tour 1995; Laracy 1996). Many efforts have been made to control and prevent this condition. The one that had been wildly accepted and mandatory in many countries is the Hearing Conservative Program (HCP). It had been introduced by the Occupational Safety and Health Administration (OSHA) many decades ago. Details of the HCP was given in Chapter 2.

Though the HCP has been reported to be effective in developed countries (Lane, Dobie et al. 1985; Reynolds, Royster et al. 1990; Lee-Feldstein 1993), there were still some arguments about such findings. In 1995, the U.S. and Canadian Military reported the result of annual audiogram after applying strict HCP. The data showed that most subjects appreciated the potential benefit of wearing hearing protectors in HCP but still found a high incidence of NIHL (29% per year or more) after implementing the HCP. The acceptable level of NIHL of less than 15% has never been reported anywhere (Adera, Donahue et al. 1993; Wolgemuth 1995; Callow 1998). A number of studies suggested that the lacking of effectiveness could be due to the fact that some components of the HCP were weak, some suggested other methods to strengthen it (Phoon 1994; Wolgemuth 1995; Irwin 1997; Lusk 1997). It is believed that educational component is one of the most important among many components of the HCP.Many authors agreed that the failure of the HCP might be due to lacking of practical education and training (Leinster, Baum et al. 1994; Dobie 1995; Pelausa, Abel et al. 1995). Only a few research focused exclusively on it such as conducted to deal with or search for more an effective educational and training program (Hetu, Getty et al. 1994; Malchaire 2000) Their result was found later that the application was not established in other areas.

Compared to other countries, Thailand had relatively more problem of NIHL (Division of Occupational Health 1994; Siripantananugul 1995). Reduction of NIHL starts with the fundamental understanding of HCP. Without the HCP, we would never find meaningful solution to prevent NIHL. The HCP has not been established in majority of Thai factories even one part of it such as audiometry or supplying earplugs for all high-risk workers. Even though empirical evidence suggested that these might be difficult to implement it in our current setting, the proposed educational part is possible to do. Finally, its effectiveness needs to be demonstrated before recommending its use too. This study was conducted to assess the effectiveness of the HCP, which focused mainly on education program.

Chapter 2

Related findings

This chapter presents results from comprehensive literature review. There are two main sections to describe the literature related to this study. The first partrelated to magnitude of the NIHL problem and the second related to efforts to solve it. Here, the Hearing Conservative Program (HCP) is the main emphasis.

2.1 Magnitude of the problem

Table 2.1 summarized findings of studies related to noise survey, prevalence and magnitude of NIHL. The revealed numbers varied widely according to type of factory, noise level in factory either in work place or testing room, individual workers including resting ear stage before test performing, standard of all equipments and quantification of personnel.

Table 2.1 Summary of findings from related literatures regarding magnitude of the problem

Authors (year), Place	Study design	Main findings
Sulkowski (1981), Poland	Survey occupational disease throughout Poland	• NIHL was most frequent among all occupational disease and its incidence rate was more than 16 new cases annually per 100,000 workers
Alleyne (1987), Canada	Cost analysis on NIHL claimed workers(1979-1983)	• Annual increase of 20.4 % for NIHL claims and the cost per claim was US$ 14,106
Callow (1988), London	Survey of 299 Territorial Army servicemen (1983-1985)	• Prevalence of 3, 4 & 6 kHz average of 30 dB loss or more was11.4 % in left ear (CI: 7.8-15) and 10.5 % in right ear (CI: 7.0-14) of servicemen • Strong tendency for NIHL to increase with the length of service

Authors (year), Place	Study design	Main findings
Chavalitsakul-chai (1989), Thailand	Survey of 1,611 workers in textile factories	• Average noise level was 101.3 dB(SD 2.7) • Significantly NIHL workers in textile factories than other factories • Concerning personal noise protective devices, 38.6% of the workers never used them. It was concluded that hearing loss status in the workers of the mill was serious.
Tilahun (1993), USA	Assessing of 599 workers with likelihood of developing NIHL relative to 93 reference workers (9 years retrospectively)	• Study workers were three times more likely to develop NIHL in contrast to reference workers (RRMH= 3.0;CI: 1.8-5.2) This adjusted value was essentially unaltered from the crude value (RR: 3.0 vs.2.8)
Rosler (1994), Sweden	Reviewed 11 investigations dealing with NIHL during long term exposure	• Despite the great diversity in the character and level of the noise, the compilation showed the hearing loss in the range of 3 to 8 kHz are similar to all investigations; however, at 1 kHz and 2 kHz the differences in the character of the noise are apparent in a wide spread between the different studies.
Division of Occupational Health, Ministry of Public Health (1994), Thailand	Survey of 1,191 workers in 14 types of industries (1990-1993)	• Noise Induced Hearing Loss (NIHL) varied from 4.6-68.9 % of workers. Type of factories which have hearing loss in more than 30 % of workers were textile factories, metallic producing factories and Military repairing unit.
Siripantananu-gul (1994), Thailand	Survey of 122 workers in 15 textile factories	• NIHL was detected in 55.7 % of workers and noise in work place ranged from 98-116 dB with an average of 106.3 dB(SD 6.3)
Lynne (1996), Hong Kong	Report article in newspaper	• More than 180 workers have sought compensation from Hong Kong's Occupational Deafness Compensation Board since it was set up in 1995An estimated 60,000 workers are exposed to hazardous noise.
Lusk (1997), USA	Review many articles and concluded the method to control noise	• Proposed a surveillance system and prevention of NIHL

Authors (year), Place	Study design	Main findings
Hong (1998), Korea	Cross sectional studied with 255 noise exposed and 195 non-noise exposed	• Significant difference in prevalence of NIHL between two groups($p<0.05$) • About 60 % of noise exposed workers wear ear plugs
Reilly (1998), USA	Surveillance system among Michigan workers	• 1,378 workers had NIHL and 46 % of them were not provided regular hearing testing • From over all 43 companies, 23 companies had high noise level and 17 of those had incomplete or no HCP
Wu (1998), Taiwan	Survey of 9,463 workers who work in various place of Taiwan	• NIHL was found in 34.0 % of workers (mild degree 19%, severe degree 14%) • NIHL was higher in construction (38 %), ship building/repairing (19 %) and weapon manufacturing (13 %)
Division of Occupational Health, Ministry of Public Health (1998),Thailand	Review articles and concluded the method to control noise	• Proposed a guideline for surveillance and prevention of NIHL
Suthamasa (1998),Thailand	Review articles and proposed the method to control noise	• Proposed a surveillance system and prevention of NIHL

2.2 Efforts attempted to solve the problem : the HCP

HCP had been introduced by Occupational Safety and Health Administration (OSHA) for many decades. It is required when a time-weighted average (TWA) exposure more than 85 dB (decibel) exists. It is now mandatory in many countries. If this is not accomplished, the employer will be considered to be at fault (Glorig 1979; Osguthorpe 1991; Dobie 1993). According to HCP, the managers were responsible for controlling loud noise, beginning with engineering (noise source and path) or administrative control. These are usually not functioning due to several reasons such as more cost to pay for new machine or building noise barrier for worker, lack of union rule, difficult to rotate worker to other stations, time consuming and interrupted process of production. If this control measure failed, then the hearing protective devices to high-risk workers should be applied.

In order to understand the HCP, it can be categorized as follow:

1. Hearing conservation policy and responsibilities.
2. Noise monitoring, noise survey and measurement, time exposure study and noise exposure assessment.
3. Noise control: administrative control, engineering control and hearing protective devices (earplug, earmuff etc.).
4. Hearing monitoring audiometry, consulting and referral system.
5. Educational training and motivation.
6. Record keeping: documentation, notification and audit.

Dobie (Dobie 1995)found several studies suggested that HCP could prevent NIHL but none of these were conclusive. He found that there was no randomized controlled trial or most of them suffered from the following shortcomings: failure to match treatment and control groups, failure to control for audiometric learning effects such as inclusion of workers who had already worked for a long time without hearing protection before performing audiometry. Meanwhile many authors agreed that the failure of the HCP might often be traced to a lack of education and training (Leinster, Baum et al. 1994; Dobie 1995; Pelausa, Abel et al. 1995) . Only a few previous studies have been conducted or attempted to deal with or search more for a real practical point or more effective educational and training. Reynolds (Reynolds, Royster et al. 1990) introduced a new work-shift criterion, which had no impact on the effectiveness of HCP to use instead of old criteria. Finally, these were not imitated in many countries because of the administrative problems. Malchaire (Malchaire 2000) proposed a method that could be used by the workers themselves first, and then, in later stages, call in the assistance of specialist to identify more complex solution and medical surveillance. But his strategies were not clear enough to be repeated by other studies such as timing, monitoring, management, maintenance, media instruction etc. They only proposed strategies in many aspects for possible success in control noise.

Table 2.2 summarized findings of studies related to assessment and comparing an effectiveness of HCP, current management of HCP and many efforts attempted to solve the problem.

Table 2.2 Summary of findings from related literatures regarding efforts to solve the problem

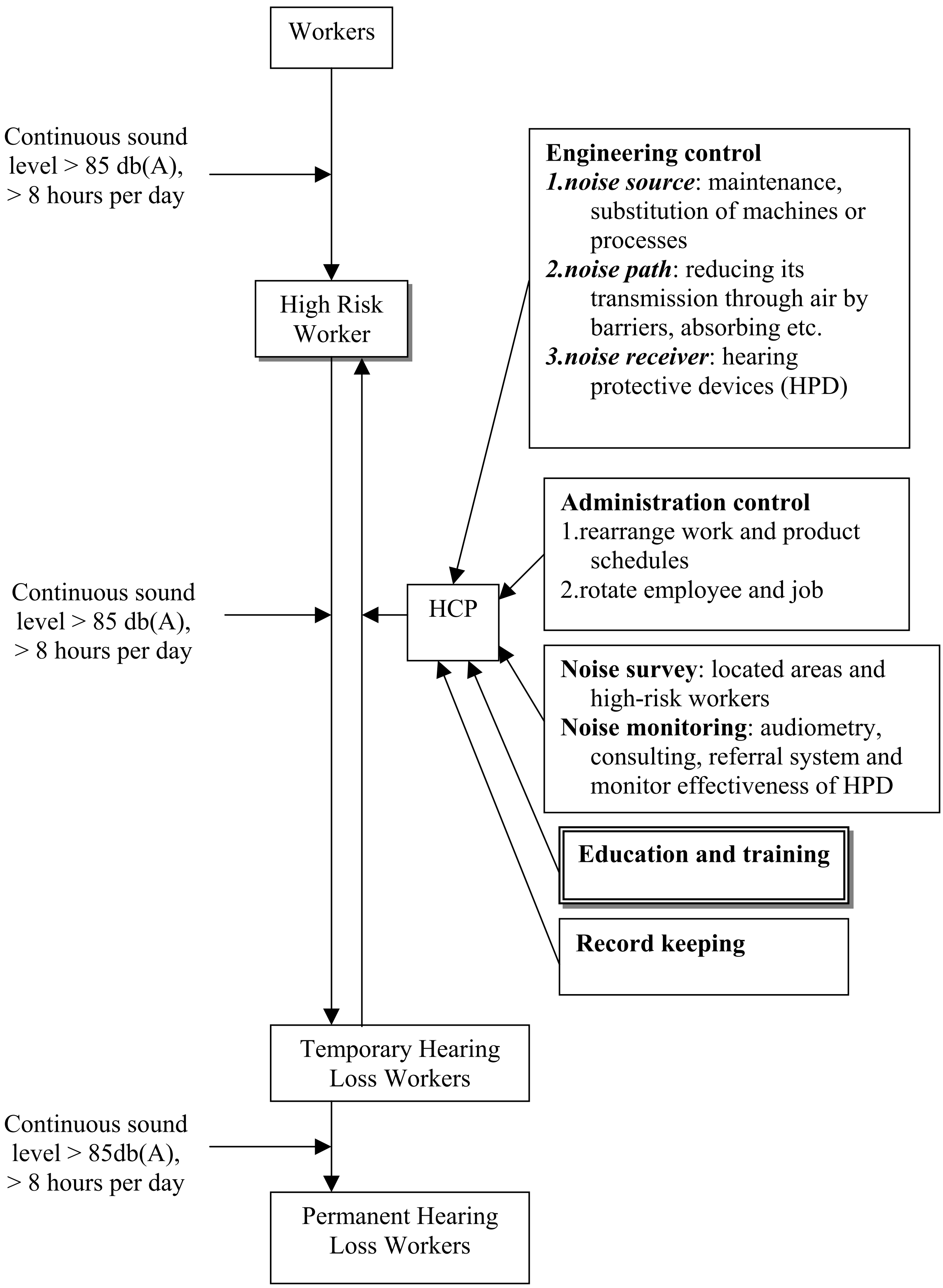
Authors (year), Place	Study design	Main findings
Lane (1985), USA	Review many articles and proposed a new criteria for STS	• Proposed a new STS. Revision of baselines after an STS occurs is recommended.
Reynolds (1990), USA	Survey of ADBA method and comparing of the time-shift	• The introduction of the 12-hr work shift has had no impact on the effectiveness of the HCP. In evaluating the three HPDs in use at the facility (3-M foam earplug, E-A-R foam earplug, and Bilsom Soft earplug), it was found that they all offered effective protection from noise at all audiometric test frequencies (0.5 to 6 kHz) except 0.5 kHz. All three HPDs exhibited TTS at 0.5 kHz with the TTS measured significant at the p less than 0.05 level for the E-A-R and 3-M wearer groups.
Lee-Feldstein, (1993), USA	Five years follow up study in an automobile company	• Noise exposure ranged from104-110 dB(A) among five study locations, the average hearing loss at 2,000-4,000 Hz in the worst-loss ear ranged from 3.4 to 6.2 dB over the follow-up period. In comparison to a control group of nonnoise-exposed employees, hearing conservation programs at four of the five locations were judged to be effective.
Adera (1993), USA	Assessed the DANS method for evaluating HCP by comparing it against a standard method	• The epidemiological method found a 130% increased risk of NIHL (relative risk = 2.3, 95% confidence interval = 0.8 to 6.5). Workers who were excluded from analyses for failing to comply with the DANS criteria were found to be at significantly increased risk of NIHL (relative risk = 9.1, 95% confidence interval = 3.4 to 24.2). These data indicated that the DANS method may overestimate the effectiveness of hearing conservation programs and systematically exclude workers at high risk of hearing loss from analyses.

Authors (year), Place	Study design	Main findings
Phoon (1994), Singapore	Proposed a method to control NIHL	• The statutory medical examinations helped to highlight the problem of the noise hazard. Individual companies were able to monitor the noise problem in their workplaces, using the audiometry results to supplement the noise assessments. Susceptible workers can be identified and followed up more closely, and health education intensified.
Leinster (1994), U.K.	Survey of 48 organization, 10 of these as case studies	• Workers reactions to noise tended to be passive and neither managers nor the workforce were conscious of the noise hazard. This was the case even where some managers were committed to good industrial housekeeping and accident prevention. As effective hearing conservation program requires three management attributes: leadership from senior management, the ability of middle management (particularly in production and engineering) to put hearing conservation measures into practice, and specialist technical knowledge of noise and of the legislation. The study pointed to the need for more education and motivation of senior managers as the priority in improving standards of hearing conservation and noise control.
Raymond (1994), Canada	Content analysis using a phenomenological attitudes towards NIHL	• Description the perception of workers to the problem of NIHL
Wolgemuth (1995), USA	Data of audiograms were collected from 12,492 medical records (1987-1990)	• The incidence of Significant Threshold Shift (STS) was still high (29%) and low follow up audiogram compliance(62%) after applying HCP in U.S. Navy • Checklists used to evaluate HCP compliance were not highly correlated with STS incidence.
Pelausa (1995), Canada	Prospective evaluation of HCP 134 subjects for 3 years	• While subjects appreciated the potential benefit of wearing hearing protectors, instructions on their proper use and education on the hazards of noise exposure were poor. • The results suggested methods to strengthen the existing scheme for hearing conservation to further minimize risk.

Authors (year), Place	Study design	Main findings
Dobie (1995), USA	Review published articles dealed with HCP	• From the author viewed, no randomized clinical trial has been reported among those of articles. One or more of the following shortcomings are showed: failure to match treatment and control groups for age, nonoccupational noise exposure, and/or prior hearing loss; failure to control for audiometric learning effects No single study offered convincing evidence on the efficacy of occupational HCP, primarily due to methodological flaws.
Simpson(1998), USA	Prospective study, follow up investigation of audiogram results	• These findings did not support notions that ANSI S12.13 outcomes clearly provide indirect measures of TTS. HCP managers should exercise extreme caution in interpreting ANSI S12.13 outcomes to rate overall program performance hearing loss in the populations involved.
Malchaire (2000), Belgium	Proposed strategy for prevention and control of NIHL	• The proposed strategy enriched the assessment procedure that is usually recommended by providing for one preliminary stage used by the people directly concerned. It explicitly recognizes (a) the competence of the workers and management about their working conditions and (b) that knowledge and measurements of acoustics are not an absolute prerequisite for solving-at least partly-noise problems. It attempts to organize in sequence and optimize the cooperation between the workers, the occupational health specialists, and the experts in acoustics.

In summary, NIHL is an important occupational problem in Thailand. There is an existing well-established preventive measure but it has never been implemented here in Thailand. Several difficulties of implementing the HCP in other countries have been intensively reviewed. Its educational component is the focal point for strengthening due to its practicality and feasibility. But there is no conclusive evidence about its effectiveness. A well designed study to evaluate this program before applying to all Thai workers is, therefore, essential. Figure 2.1 presents relationship among selected issues mentioned above and indicates where the research question is.

Figure 2.1 Conceptual framework of NIHL and HCP



Chapter 3
Subjects and Methods

This chapter provides details of methodology of the study. It describes the nature of the study design, subject selection, data collection, details of the intervention, and statistical methods.

3.1 Design

This was a randomized controlled trial. Two textile factories were selected according to their similarity of noise level in worker stations and all other characteristics, which were described in the next section. They were then randomly allocated to the treatment factory (participate in educational program) and control factory (no educational program). The study was conducted between June 1999 and October 2000. The scheme showing an overview of the design was presented in Figure 3.1.

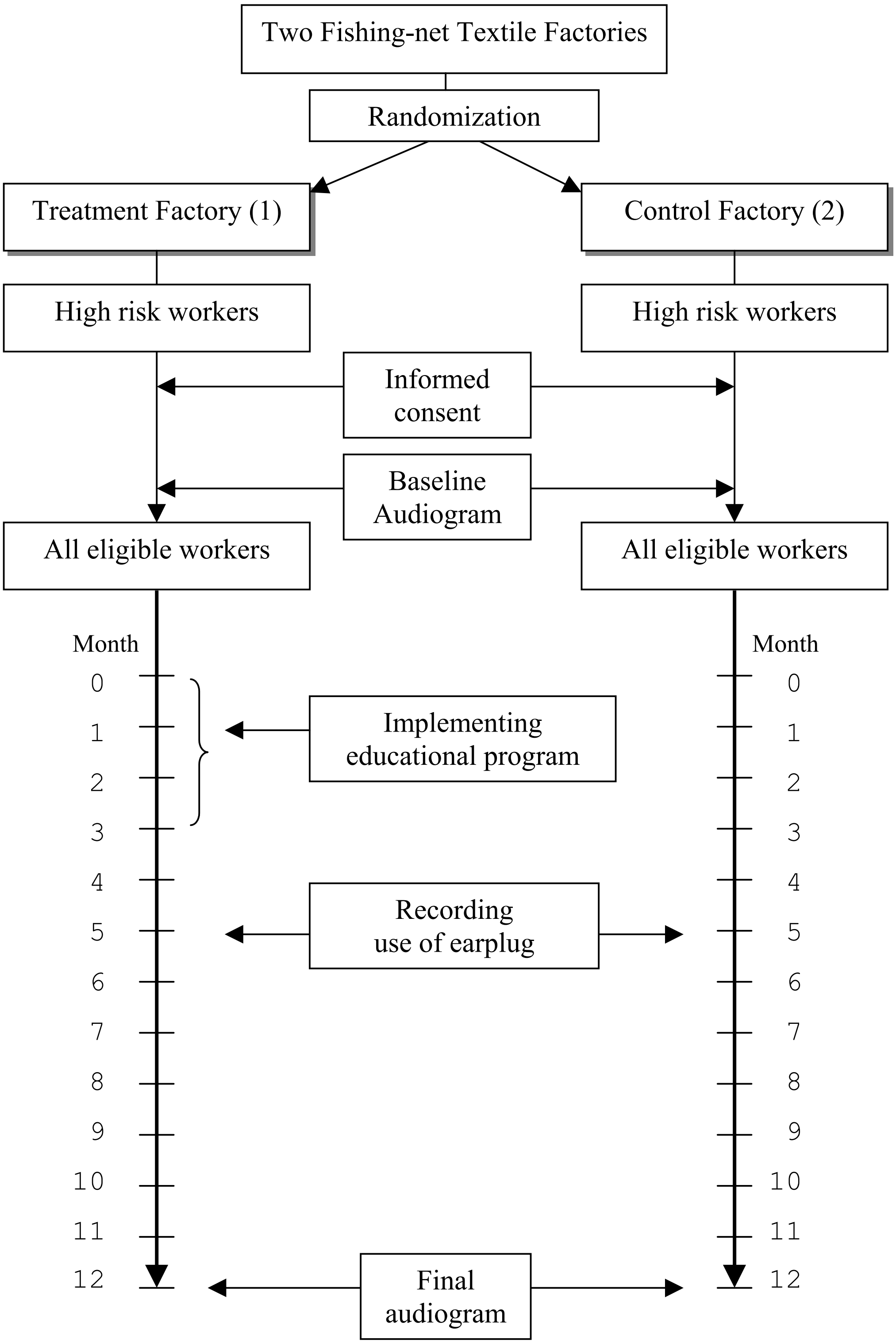
3.2 Subjects selection

The study was conducted at the two large textile factories that produced the same products (fishing net). They were similar with regard to the plant size, number of workers, and level of noise. They are located in the same province but far from each other. The first site was Dachapanich Fishing Net Factory located in northern Khon Kaen. The second one was Khon Kaen Fishing Net Factory which located in southern Khon Kaen.

Mapping noise or noise survey was conducted by using sound pressure level meter to measuring noise at all employee's work stations and all possible quiet rooms for audiometric test in each fishing net factory.

For workers selection, all workers in stations that had a noise level above 85 dB (A) from noise survey were eligible to be recruited in both factories. Inclusion criteria included workers who were exposed to a continuous noise level of more than 85 dB (A) for at least 8 hours in each working day. Exclusion criteria included unilateral deaf workers, chronic middle ear infection, as their infection would interfere with audiometry and hearing protective device (HPD) use. Subjects with ear anomalies that could not use HPD and those who concurrently used of medication such as intravenous form of aminoglycoside, furosemide, cisplatin, oral form of aspirin more than 1.9 g/d and quinolone were also excluded.

Figure 3.1 Overall design of study



3.3 Data collection

Demographic characteristics of the workers were collected by interview using structured questionnaires. Physical examination, especially otologic examination including ear canal toilet before audiometric, were carried out for each worker. In order to avoid the temporary thresholds shift, the workers were requested to take a full rest and not allowed exposing high noise level for at least 8-14 hours before audiogram test in the morning of the following day. Without the interruption of manufacturing process, the audiometry was done only from 7.00-7.30 am before they entered to work places. Pure tone thresholds for air conduction were obtained at 250, 500, 1000, 2000, 4000 and 8000 Hz, after correcting for reliability and validity of the equipment. We used the audiometer (Digital audiometer FONIX) which was measured by the qualified technician under supervise of otolaryngologist before the beginning of the study. We could not find any room in the factories for audiometry testing because most of the rooms in all industrial areas had a noise level of greater than the maximum background sound pressure level for audiogram testing room which defined by OSHA or ANSI (Dobie 1993) It was finally decided to use the conference or nursing room in each factory where the noise level was the lowest in the factory and corrected audiogram data comparing audiogram of the normal hearing personnel. We deducted 10 dB at frequency 250, 500 Hz and 5 dB at frequency 1000-8000 Hz from the crude audiogram. Only the adjusted audiogram could be used in this study. Earplugs were introduced and taught how to use them for each worker in both factories.

3.4 Intervention

In order to understand program arrangement, we first explained the process of working in factory. Normally, the factory divided workers in three groups (A, B and C) approximately 40-45 workers per group and divided work-time according to work-shift [8 hours morning(7.30 am-3.30 pm), evening (3.30 pm-11.30 pm) and midnight (11.30 pm-7.30 am)] in a day.

	Morning	Evening	Midnight
First week	Group A	Group B	Group C
Second week	Group B	Group C	Group A
Third week	Group C	Group A	Group B

Then rotated the group of workers to other work-shift time in every Monday morning.

Fourth week Group A Group B Group C

Thus we will meet Group A again in fourth week which we conducted the second part (content) of educational program with them that mean we had to repeat the intervention to cover all groups. The suitable time of workers, factory and personnel for conducted program was 3.30-4.00 pm, Monday. This was the duration after the workers finished their work-shift. The educational program composed of 5 parts, each part took 30 minutes to finish. Monday morning 7.00 am-7.30 am was the suitable time for conducting audiogram before they expose to environmental noise in work places. Occupational nurse, health education personnel, and otolaryngologist performed the educational program. The intervention was held at the conference room for nearly two months. See details of intervention in Table 3.4

Table 3.4 Intervention program

Treatment program	Activities and main content	Time (Minutes)	Media
1	Introduction	10	Guideline in
	Objective of the intervention program	10	preventing
	Elected the representative of worker in each group	10	loud noise
2	Lecture: occupational hearing loss and how to prevent	10	Slide
	Open discussion for individual perception in noise exposure	20	Poster
3	Lecture: effect of noise on hearing and hazard of loud noise	15	VDO
	Group process "how to encourage ear plug use in each group"	15	Open discussion
4	Demonstrate how to use and care ear plug	10	Earplug
	Practiced ear plug using	10	Earmuff
	Open discussion "problem of ear plug use"	10	
5	Role of worker for motivation and compliance use of ear plug	5	
	How to record data in check list	5	
	Conclusion of the intervention program 1-4	10	
	Open discussion "method to prevent hearing loss in the future"	10	

3.5 Outcome measurement

Intermediate outcome or percent of earplug use from checklist, a recording of used or not used earplug during work-time in each day by themselves. The result was assessed by average of uses from individual workers after intervention. The ultimate outcome (audiogram) were carried out and analyzed by comparing mean of hearing difference between before and after study as well as comparing the number of workers who suffered from hearing loss classified according to significant threshold shift criteria.

This study required repeated performing in data collection, intervention and outcome measurement. To be sure all procedures were the same standard, all personnels (1 otolaryngologist, 2 occupational nurses, 1 health educationist and 1 qualified technician.) were trained before starting the study. All equipment was calibrated before the study. All media and content instruction in intervention were identical in each performing.

For possible noise exposure outside workplace, the objective of study was explained to the administrators and workers at the beginning of study including the essential to be a complete follow up of this study also. With the randomization process and matching factories as well as restricted criteria, we believed that the confounder would distribute equally in both groups.

Significant threshold shift (STS) in either ear was defined according to baseline audiogram (Dobie 1981)

- If baseline audiogram is normal (all frequency thresholds<25 dB), STS is defined if there is 20 dB or greater increase at any frequency other than 500 Hz in either ear.
- If baseline audiogram is abnormal(any frequency threshold exceeding 25 dB, STS is defined if there is 10 dB(A) or greater at 1000 or 2000 Hz or 15 dB(A) or greater at 3000 or 4000 Hz or 20 dB(A) or greater at 6000 or 8000 Hz
- If baseline audiogram is abnormal (average thresholds >25 dB(A) at 1000, 2000 and 3000 Hz) STS is defined if there is 10 dB(A) change at any frequency other than 500 Hz.

3.6 Statistical analysis

Sample size calculation was based upon the previous data (Wolgemuth 1995) which indicated that the incident rate of NIHL among industrial workers with the HCP was 29%. It was planned that the study had 80% power to detect a difference of 15%. By allowing an α-error of 5% with two-sided test, we needed at least 132 workers in each group. It was necessary to add more number of workers because all factories workers had tend to change or quit their job easily. We expected the rate of loss to follow up to be 20% thus we need sample size at least 158 workers for each factory. For data analysis, the categorical variables (e.g., sex, educational level, etc.) were presented as percentage. The continuous variables (e.g., age, history of noise exposure, noise level in stations, noise level in testing rooms, and audiogram) were calculated for mean, standard deviation, median and range.

We estimated the rate difference of hearing loss between the two-comparison factories, together with its 95% confidence interval using normal approximation to binomial distribution. Significance level was set at 0.05. All tests were two-tailed. All analyses were done using STATA.

Chapter 4
Results

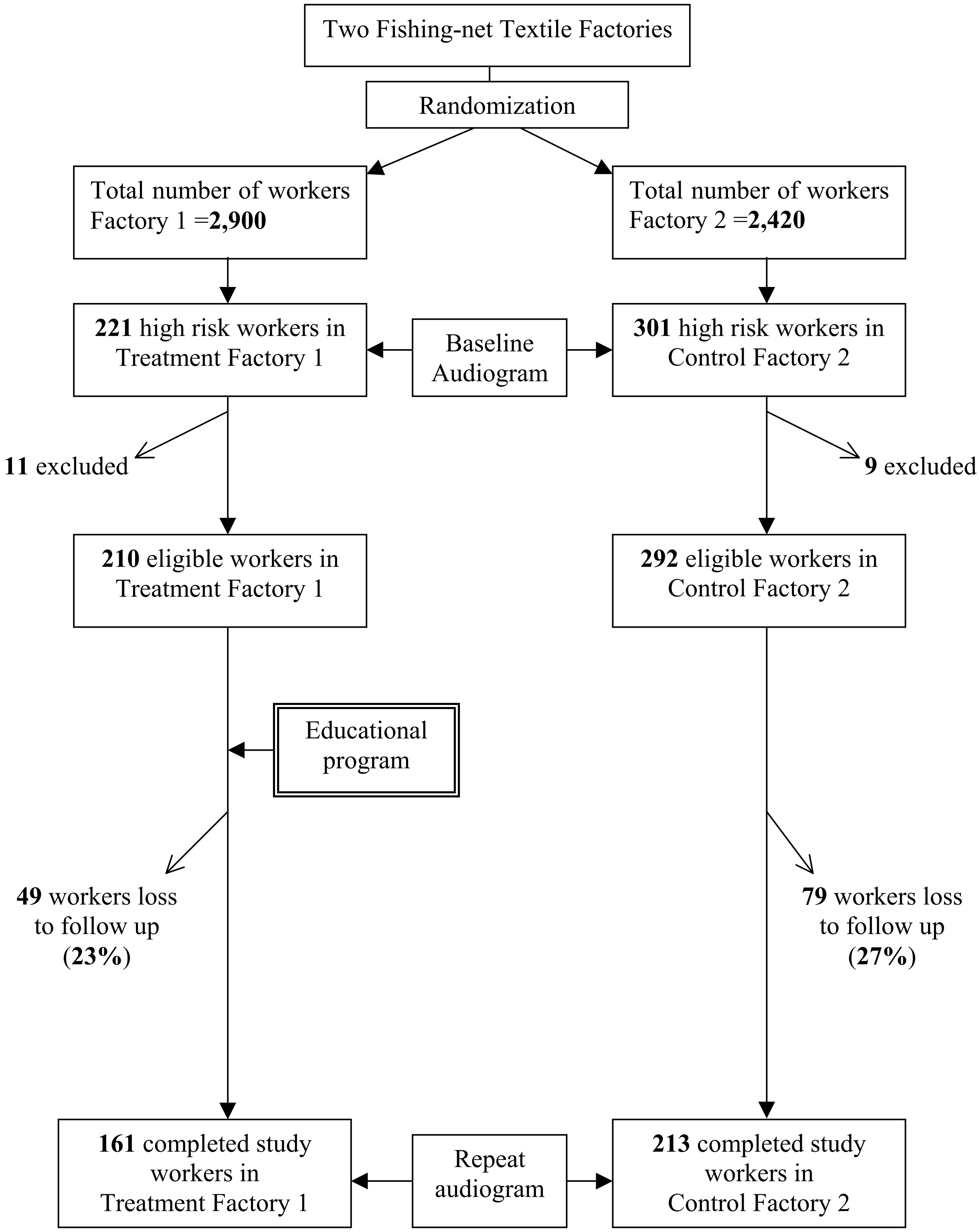
The results were divided into 3 parts, the first part showed all figures of study samples from the beginning to the end of the study and how to recruit it properly. The second part demonstrated baseline characteristics, baseline hearing level of the study workers and noise level in environment. The last revealed the effectiveness of the intervention program for both intermediate (ear plug use) and ultimate (hearing level) outcomes.

4.1 Study samples

Number of factories and workers were recruited into the study and followed until the end of the study was shown in Figure 4.1. The two large fishing net factories, the Dachapanich Fishing Net Factory (Factory 1) and the Khon Kaen Fishing Net Factory (Factory 2), were randomly allocated to either the experiment or the control factory. As a result, Factory 1 was the treatment factory and Factory 2 was the control factory. Initially, numbers of high-risk workers were 221 workers in factory 1 and 301 workers in factory 2. According to exclusion criteria, the eligible workers were 210 workers in factory 1 and 292 workers in factory 2. Number and percent of loss to follow up in factory 1 was 49 workers (23.3%) and 79 workers (27%) in factory 2. Finally, the numbers of complete study workers were 161 workers in factory 1 and 213 workers in factory 2. There had were only two major reasons to loss to follow up; planning for further study or get married.

The administrator persuaded all workers to attend for all class of intervention and most of them also preferr to join in-group activities.

Figure 4.1 Study samples



4.2 Baseline characteristics

4.2.1 General characteristics of the study workers

The average ages of workers in the treatment factory were more slightly higher than the control factory for both complete and loss to follow up group (28.6 v.s. 28.3 and 26.6 v.s. 24.5 years old). Compatible with the longer period of noise exposure (33 months and 28 months) but loss follow up group in control factory had less noise exposure time than other groups (11 months). With the lesser history of noise exposure time, the workers tend to quit their job than other groups too. Female: male ratio in treatment factory was 4: 1 and 9: 1 in control factory. More than eighty percent of all workers were graduated from junior school or less.

In overall basic characteristics, treatment factory were similar to the control factory as well as loss follows up group.

Table 4.2.1 General characteristics of the study workers in factory 1, factory 2 and loss to follow-up group (Factory 1 = Treatment Factory, Factory 2 = Control Factory)

Variable	Complete study group		Loss follow up group	
	Factory1 (n=161)	Factory 2 (n=213)	Factory 1 (n=49)	Factory 2 (n=79)
Age(year)				
Mean(SD)	28.6(6.8)	26.6(6.1)	28.3(7.0)	24.5(5.4)
Median(min:max)	29(17:52)	27(17:40)	27(18:45)	24(17:39)
Sex				
female:male	4.2:1	9.1:1	3.9:1	35:1
Education (%)				
Preliminary	70	61	63	58
Junior school	19	28	22	33
High school	10	10	14	7
Above all	1	1	1	2
Duration of previous noise exposure (month)				
Mean (SD)	33.8(33.7)	28.6(34.4)	33.0(36.3)	11.3(21.0)
Median(min:max)	19(1:120)	19(1:170)	14(1:110)	4(1:120)

4.2.2 Noise level in environment

Average of noise level in every high risk stations of both factories were close approximately value (91.4 db) as well as in the testing room (52.6 db and 50.0 db)

Table 4.2.2 Noise level in environment

Noise level in environment	Factory 1	Factory 2
Noise in high risk station (dB)		
Mean (SD)	91.4(4.8)	91.4(4.6)
Median (min:max)	90(87:100)	93(86:97)
Noise in testing room (dB)		
Mean(SD)	52.6(0.5)	50.0(1.0)
Median(min:max)	53(52:53)	50(49:51)

4.2.3 Baseline hearing level

Average of baseline hearing both left and right sided of workers in treatment factory were slightly greater than control factory for all frequencies level (19.2 db to 24.7 db and 15.6 db to 21.9 db).

Table 4.2.3 Average of left and right side baseline hearing level (decibel).

Frequency (Hz)	Complete study group		Loss follow up group	
	Factory 1 (n=161)	Factory 2 (n=213)	Factory 1 (n=49)	Factory 1 (n=79)
250	24.7(3.6)	21.9(2.3)	23.5(3.3)	21.2(2.9)
500	21.9(4.3)	19.8(2.3)	20.9(4.0)	19.1(2.9)
1000	20.3(5.9)	17.3(2.7)	18.3(3.2)	16.6(3.0)
2000	19.2(7.6)	15.6(3.8)	16.8(3.7)	14.6(4.2)
4000	20.9(11.6)	16.3(6.2)	15.7(5.4)	14.4(4.8)
8000	19.8(12.2)	16.2(7.2)	14.5(4.9)	12.7(5.7)

4.3 Intermediate and ultimate outcome

4.3.1 Intermediate outcome

Percent of earplug used from checklist, a recording of used or not used earplug during work-time in each day for one month, after applied intervention. Using ear plug more than 90% of their work time was more common in treatment factory (73.6% versus 52.6%).

Table 4.3.1 Intermediate outcome, percent of earplug use from checklist after applied intervention.

Percent of ear plug uses	Factory 1 (n=198)	Factory 2 (n=262)
100	20.7	22.9
90-99	53.0	29.7
80-89	19.7	28.2
<80	6.5	19.0

4.3.2 Ultimate outcome

Workers in control factory had a mean of difference, an average of the final hearing level extracted from baseline hearing level of workers, greater than workers in treatment factory (0.51,0.17,0.16,1.30,3.03 and 0.04 db).

Table 4.3.2.1 Test of mean of different (after-before) between treatment and control factory.

Frequency	Factory1 (n=161)	Factory2 (n=213)	Difference (F2-F1)	95%CI	p-value
250	1.19	1.71	0.51	-0.9 to -0.09	0.01
500	1.77	1.94	0.17	-0.6 to 0.2	0.44
1000	1.78	2.32	0.61	-1.1 to -0.1	0.01
2000	3.05	4.42	1.30	-2.0 to -0.6	<0.01
4000	5.10	8.14	3.03	-4.1 to -1.9	<0.01
8000	6.94	6.98	0.04	-1.0 to 0.9	0.93

When classified hearing loss according to significant thresholds shift (STS) criteria or baseline hearing, the result showed that the rate of hearing loss in treatment factory was 22.3% versus 27.2% in control factory. Thus the rate in control factory was 4.8% higher than those of treatment factory (95%CI:-13.6% to 40.0%) The 95%CI difference was within the range that was considered to be no difference. This difference was not statistically significant (p-value = 0.282).

Table 4.3.2.2 Hearing loss classified according to significant threshold shift (STS).

Hearing loss	Factory 1 % (n=161)	Factory 2 % (n=213)	Different	95%CI	p-value
Right and Left side	3.7	7.5	3.8	-0.8 to 8.3	0.124
Right or Left side	18.6	19.7	1.1	-6.9 to 9.1	0.792
Total Hearing loss worker	22.3	27.2	4.8	-13.6 to 40.0	0.289

Adjusted analysis for potential confounders (age, sex and duration of noise exposure) using logistic regression. The unadjusted odd ratio was 0.9 (95%CI:0.6% to 1.6%). The odds ratio adjusted for age, sex and duration of noise exposure was 0.8 (95%CI:0.5% to 1.4%) which was consistent with the similar data of baseline characteristics in both factories.

Chapter 5
Discussion

Summary of results: There was small different figures between two factories as well as loss to follow up group for age, sex, educational level, level of noise and duration of exposed to loud noise. Averages of baseline hearing level of workers in intervention factory were slightly higher than control factory for all frequencies level (19.2 db to 24.7 db and 15.6 db to 21.9 db). After intervention, about seventy percent of workers in treatment factory used ear plug regularly when compared with only fifty percent of workers in control factory. Probably it would alter behavior of workers to increase use of earplug in spite of a short time. The mean of difference hearing level which changing from baseline was higher in control factory at all frequencies although some figure did not reach statistically significant difference. Finally, percent of hearing loss workers classified according to significant thresholds shift (STS) criteria showed the incidence of hearing loss in treatment factory was 22.3% versus27.2% in control factory. Thus the incidence in control factory was 4.9% higher than those of treatment factory (95%CI:-13.6% to 40.0%) The 95%CI difference was within the range that was considered to be no difference. This difference was not statistically significant (p-value = 0.282). The unadjusted odds ratio was 0.9 (95%CI:0.6% to 1.6%). The odd ratio adjusted for age, sex and duration of noise exposure was 0.8 (95%CI:0.5% to 1.4%) which was consistent with the similar data of baseline characteristics in both factories.

Related to other studies: Most of previous studies did not deal with educational program. Only a few has been conducted or attempted to deal with a real practical point or more effective educational and training. Reynolds introduced a new work-shift criterion, which showed no impact on the effectiveness of HCP to use instead of old criteria. Finally, this strategy could not imitated in many countries because of administrative problems. Adera introduced DANS method for evaluating HCP by compared with a standard method but the results was not satisfied. Malchaire proposed a method that could be used by the workers themselves first, and then, in later stages, call for the assistance of specialist to identify more complex solution and medical surveillance. But his strategies was not clear enough to be repeated by other studies such as timing, monitoring, management, maintenance, media instruction etc. They only proposed strategies in many aspects for possible succeess for controling noise. Our study was similar to Leinster's study in that the leadership and the ability to implement HCP into practice as well as technical knowledge from senior management were required.

Strength and limitation: The strengths of this study were primarily evaluating the effectiveness of HCP by randomized control trial, standard measurement and personnel, corrected and collected in proper way which based on scientific and knowledge of the field, explicit criteria and finally proposed a practically effective educational program to overcome NIHL. Limitation of this study was the small number of factories because we did not had enough resource to do more than 2 factories. There was no statistically significant difference in hearing loss because it is difficult to detect changing in one year study but the difference was meaningful figure in term of investment. With the young age, the workers tended to quit their job before the end of study. We had a drop out rate 23% in treatment factory and 27% in control factory. The most common reasons were they planned to further study or get married. Notwithstanding drop out rate so high, no striking difference in basic characteristics between the complete study and the loss to follow up group. These facts were confirmed by adjusted analysis.

Conclusions: The incidence rate of hearing loss in control factory was 4.9% higher than those of treatment factory. The difference was not statistically significant (p-value = 0.282). These results recommend further big enough and well-controlled study before concluding that the intervention is not effective. Because the difference was meaningful figure in term of investment although a rather short study period we still recommended these program for those who have responsibility to preventing noise induced hearing loss. It was not only capable in practices but enable maintains in the long time without any obstacles from both factory and personnel. With the good cooperation between an administrative manager of the factory and through serial contacts with workers, finally we believed that the personnel and the workers could establish an effective HCP in their responsible area without difficulty.

Chapter 6
Recommendations

Recommendation for policy: Thailand has been launched the law for noise control in industries from the Ministry of Interior since 1978 which has only a half page comparing with thirteen pages of OSHA and neither the content of scientific issues nor the real practices has ever been standardized. For instance, a continuous sound level of 85 dB considered to be a maximum acceptable safe level within 8 hours and HCP must be applied in that area for many decades in developed countries. But a sound level of 91 dB has persisted used as a maximum accepted safe level and we have never mentioned about HCP in our law. Ministry of Industry, Ministry of Labor and Ministry of Public Health should revise the law and made a real act for noise control. All noisemaking industries must follow every step and has a clear policy for their HCP.

Recommendation for Health Provider: In 1998, the Division of Occupational Health provided an adequate equipment for noise monitor, survey and trained nurses with a short course training to be an occupational nurse for all regional and general hospital of Ministry of Public Health. With the advent of the equipment, the authorities expected the hospitals could apply HCP to Thai factories by the year 2000. In fact, there is very few factories known about this policy because the health provider also did not know how to apply in a real field. HCP can apply in many situations depending on each feasibility and judgment. For example, it is difficult to find a room, which quiet enough for performing audiometry. The adjusted audiometry result could be used instead. In this study, we used all material that had already been distributed to all hospitals and occupational nurses were also the main persons in conducting all procedures in factory. The health provider should be a key man to know how to use it, give counseling, training, evaluating, extended with low cost of services, quality control, strictly follow noise law and properly refer abnormal hearing workers as well as motivate them to wear earplug or earmuff.

Recommendation for workers: Failure HCP results from lack of knowledge, awareness and proper training for wearing earplug or earmuff in preventing noise induced hearing loss. With the young age and rather low education level, workers tend to ignore their health thus they need intensely encourage of knowledge and awareness. One of most effective encouragement way was the earplug using by their friends and managers too.

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Appendix

Data collection form

DATE…………..

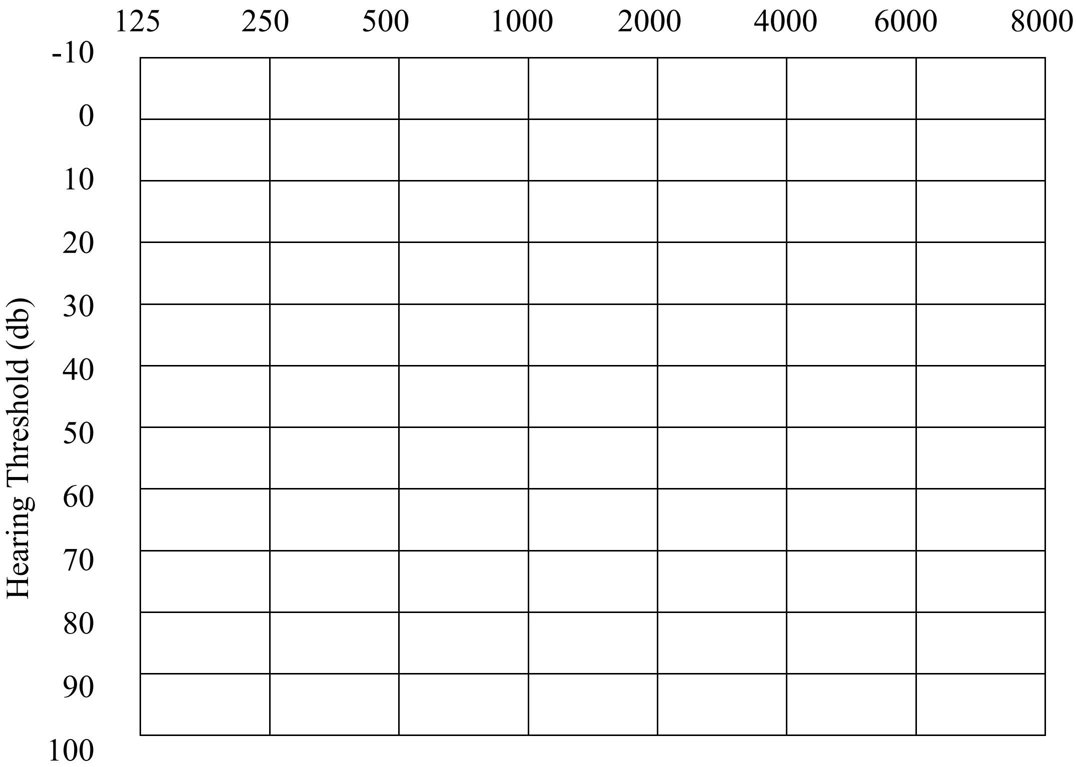
FACTORY……….

ID……….

DATA	CODE
1.Name	Name
2.Sex 1) Female 2) Male	Sex ( )
3.Age (year)	Age ( )
4.Address	Address
5.How long did you expose loud noise? (month)	Expose ( )
6.Did you had next history? 1)Otorreah 2)Vertigo 3)Diabetes 4)Hyperytension 5)Mumps 6)Syphilis 7)Tinnitus 8)Drug for malaria, diuretic, aminoglycoside 9)other	History ( )
7.Did you were earplug during work-time? 1)Yes 2)No	Use ( )
8.If you did not use earplug, why? 1) Don't know how to use it 2) Pain 3) Annoyance 4) Dirty 5) Broken earplug 5) Other	Reason ( )
9. Otoscopic finding after cleaning ear canal. 1) Normal both ear 2) Perforation either ear 3) Atelectasis either ear 4) Other	Finding ( )
10.Body weight (kilogram)	BW ( )
11.Height (centimeter)	Height ( )
12.Systolic/Diastolic Blood pressure (mmHg)	BP ( ) ( )

Audiometric Evaluation

First Pure Tone Audiometry



Second Pure Tone Audiometry