Research Proposal

Study title	"Comparative Efficacy of Earplug Usage Instruction : A Randomized Trial of Video-Based and Paper-Based Instruction"
Acronym of the Study	Earplug Usage Training
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Name of the Research Funding Source	Faculty of Medicine Research Fund, Chiang Mai University
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PROJECT SUMMARY/ABSTRACT

1. A brief background of the project

This study aims to compare the effectiveness of two training methods—video-based and paper-based training—in promoting the proper use of earplugs among personnel at Maharaj Nakorn Chiang Mai Hospital . Additionally, the study will assess participants' satisfaction with the training methods to evaluate their acceptability and practicality.

Noise-induced hearing loss (NIHL) is a preventable yet widespread occupational health issue, particularly in environments where workers are regularly exposed to high levels of continuous or impulse noise. Professions in industries such as manufacturing, construction, and music are especially at risk, as noise levels often exceed safe thresholds. Earplugs are one of the most commonly used forms of personal protective equipment (PPE) to prevent hearing damage . Despite their availability, proper earplug use remains inconsistent, leading to inadequate protection and an increased risk of NIHL. This study seeks to investigate the effectiveness of two different training approaches—video-based training and paper-based training—to promote proper earplug usage and ultimately reduce the risk of hearing loss among healthcare workers.

The integration of video-based training has shown promise in improving learning outcomes in various healthcare settings, offering a more engaging and accessible way to communicate important health information . By comparing this approach to more traditional paper-based methods, the study aims to identify which training modality most effectively supports correct and consistent earplug usage.

In addition to effectiveness, the study will explore participant satisfaction with the training methods, including aspects such as ease of understanding, engagement, and perceived usefulness. Understanding how participants feel about the training will provide valuable insights into which method is more likely to be adopted and sustained in a real-world setting.

Ultimately, the findings from this research will provide valuable insights into the role of different training methods in promoting hearing health and enhancing occupational safety for personnel at Maharaj Nakorn Chiang Mai Hospital.

Objectives, or hypotheses

Primary Objective:

- To compare the effectiveness of earplug usage between video-based and paper-based instruction.

Secondary Objectives:

- To compare retention of effectiveness of earplug usage at 1 week between the two instruction methods

In this study, 'effectiveness ' refers specifically to the accuracy of earplug insertion skill as assessed by a standardized observational checklist.

1. **The research design and methodology (action steps) to be used**

- **research design** : a parallel-group randomized controlled trial
- **target population or patients :**

  The study will be conducted at Maharaj Nakorn Chiang Mai Hospital, Faculty of Medicine, Chiang Mai University. Participants will be hospital personnel working in noise-exposed environments, such as engineering units, kitchen staff, and laundry units.

- **research methodology :** parallel-group randomized controlled trial
- **outcome measures/ endpoints :**

  1. Primary Outcome :

The primary outcome is earplug insertion skill, defined as the participant's ability to correctly perform earplug insertion.

- Skill will be assessed using a standardized 20-point observational checklist (10 points per ear), covering key steps such as hand hygiene, earplug preparation, insertion technique, and fit verification. Each item will be scored as correct or incorrect.

Participants will be asked to demonstrate earplug insertion, and performance will be evaluated by trained assessors blinded to group allocation.

2. Secondary Outcomes : retention of earplug insertion skill at 1 week post-intervention, assessed using the same checklist and procedure.

- **data analysis and statistical methods :**

Data Collection Plan

Outcome assessors and data analysts will be blinded to group allocation to minimize detection and assessment bias.

Statistical Analysis Plan

- Descriptive statistics will be used to summarize participant characteristics.
- For the primary outcome, post-training earplug insertion scores will be compared between groups using an independent t-test (or Mann–Whitney U test if data are not normally distributed).
- For the secondary outcome, a two-way mixed ANOVA (group × time) or linear mixed-effects model will be used to assess within-group changes over time (baseline, immediate post-training, and 1-week follow-up) and between-group differences across time points.

Statistical significance will be set at $p < 0.05$.

4. The significance of the proposed research and relevance to public health

Noise-induced hearing loss (NIHL) remains a significant, yet preventable, occupational health issue globally and in Thailand. Despite the availability of personal protective equipment (PPE) such as earplugs, improper usage diminishes their effectiveness, leaving workers vulnerable to long-term auditory damage. In healthcare environments such as Maharaj Nakorn Chiang Mai Hospital, staff may be intermittently exposed to harmful noise levels—particularly in certain departments (e.g., General Maintenance Department, laundry unit)—making proper hearing protection an important concern.

This research is significant because it addresses a key gap: ensuring not only access to earplugs but also the correct and consistent use of them through effective training methods. While traditional paper-based training is often used, it may not be as engaging or practical for modern healthcare workers. On the other hand, video-based training has emerged as a potentially more dynamic and accessible method, especially in time-constrained or multilingual environments.

By conducting a comparative trial, this study goes beyond merely evaluating knowledge acquisition; it focuses on actual behavioral outcomes—the correct application of earplugs. It also explores participant satisfaction and acceptability, which are crucial for the sustainability and scalability of occupational health interventions.

From a public health perspective, the findings can:

- Inform institutional policies on PPE training in hospitals and other high-risk workplaces.
- Improve occupational safety and reduce the long-term healthcare costs associated with hearing loss.
- Support evidence-based education strategies that can be adapted across various settings and industries.
- Enhance the effectiveness of hearing conservation programs by identifying the most practical training modalities.

Ultimately, the study contributes to broader public health goals by promoting safer workplace environments, preventing disability, and improving workers' quality of life. The results may also be generalizable to other occupational groups beyond healthcare, reinforcing the cross-sector importance of proper PPE training.

Research Proposal Details

1. Title of the study

“Comparative Efficacy of Earplug Usage Instruction : A Randomized Trial of Video-Based and Paper-Based Instruction”

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Pending submission for the Faculty of Medicine Research Fund, Chiang Mai University

5. Background and rationale

Noise-induced hearing loss (NIHL) is a significant yet preventable occupational health issue, particularly in environments where individuals are exposed to loud, continuous, or impulsive noises (Daniel, 2007; WHO, 2015). NIHL occurs when exposure to loud sounds damages the hair cells in the cochlea, which do not regenerate, leading to permanent hearing impairment (Sliwinska-Kowalska & Davis, 2012). Continuous exposure to noise levels above 85 decibels (dB) can cause gradual hearing loss, while sudden, intense sounds exceeding 120 dB, such as gunshots or explosions, can result in immediate damage (Liberman, 2017). Over time, cumulative exposure to hazardous noise levels can lead to irreversible hearing loss, tinnitus, and other auditory complications (NIDCD, 2021).

Risk of NIHL is particularly high among workers in industries such as manufacturing, construction, mining, and music, where noise levels often exceed safe thresholds (Daniel, 2007;). The National Institute for Occupational Safety and Health (NIOSH) estimates that 22 million workers in the United States are exposed to hazardous noise levels annually, underscoring the need for effective hearing conservation strategies (NIOSH, 2021). Globally, approximately 1.1 billion young people are at risk of NIHL due to unsafe listening practices, including exposure to loud music through headphones (WHO, 2015). The consequences of NIHL extend beyond hearing impairment, often leading to communication difficulties, social isolation, reduced quality of life, and increased risks of mental health issues such as depression and anxiety (Shukla A ,et al.,2020).

Hearing protectors are essential tools in mitigating the risk of NIHL, and they come in various forms, each with unique advantages and limitations. The most common types include earmuffs, earplugs, and dual-protection systems, which combine both earmuffs and earplugs for enhanced noise attenuation.

Earmuffs consist of hard plastic cups with cushioned seals and sound-absorbing linings, held over the ears by a tensioned headband (over or behind the head)[SK4] . They are easy to wear and visibly noticeable, making compliance easier to monitor. Some models are designed to mount directly onto helmets, improving fit and performance, though compatibility with head sizes may vary (OSHwiki, 2023).

Earplugs , on the other hand, are worn in or over the ear canal to seal it. They can be attached to cords or bands for convenience. While earplugs are less intrusive and unaffected by other headgear, they can be tricky to insert correctly, requiring clean hands for fitting, which makes them less suitable for dirty environments. Custom-molded earplugs offer easier fit and higher attenuation but require proper fitting and regular testing to ensure effectiveness (OSHwiki, 2023). Custom-molded earplugs, offering higher attenuation, are often preferred by workers

who require long-term, continuous protection (Verbeek et al., 2014), But less available and more expensive.

Dual-protection systems combine earmuffs and earplugs to provide higher noise attenuation. However, the combined attenuation levels must be tested, as they cannot be predicted from individual performance data alone. Specialized hearing protectors may also include electronic features for communication, adjustable attenuation, or mechanical filters to provide a flat frequency response (OSHwiki, 2023).

No single hearing protector suits all users, so offering a variety of options is essential. Workers should be provided with both earmuffs and earplugs in different sizes and styles, allowing them to choose based on comfort, ease of fitting, and the ability to hear and work safely. Comfort is a key factor, as protectors should not cause physical discomfort during long use or make users self-conscious about their appearance, especially in public-facing roles. Ease of fitting is another critical consideration, particularly for earplugs, which can be challenging for users with narrow or crooked ear canals. Training and a range of options, including custom-molded earplugs, can help address these challenges (OSHwiki, 2023).

Earplugs are one of the most commonly used forms of hearing protection, offering a practical and cost-effective solution to reduce noise exposure (Salmani Nodoushan et al., 2014) . The effectiveness of earplugs in preventing NIHL depends on their ability to attenuate sound effectively, the quality of their fit, and proper usage by the individual (Berger, 2000). Properly fitted earplugs remain effective over time, but attenuation may decrease slightly during a work shift. Training and protection adequacy should account for potential attenuation changes (Gong et al., 2023).

However, the protective capacity of earplugs can be compromised if they are not worn correctly. Improper insertion or inconsistent use can significantly reduce their effectiveness, leaving workers vulnerable to hearing damage (Bergman et al., 2013).

Research consistently demonstrates that workers who are trained to use earplugs properly have a lower risk of hearing loss compared to those who are not (Salmani Nodoushan et al., 2014). For example, a study by Takada et al. (2020) found that training significantly improved the proper fit and usage of earplugs, with post-training evaluations showing a statistically significant increase in pass rates for proper insertion.

Given the critical role of proper earplug usage in preventing NIHL, training programs are an essential component of hearing conservation initiatives. These programs often involve demonstrating the correct way to insert earplugs, explaining when and how often they should be used, and providing feedback on proper fit (Takada et al., 2020). Studies have shown that individual training can significantly increase both the usage rate and the proper use of hearing protection devices. For instance, Tsukada and Sakakibara (2008) reported that the percentage of workers achieving sufficient noise attenuation (≥25 dB) increased from 46% before training to 72% immediately afterward, with effects persisting two months post-intervention.
Despite the proven benefits of training, challenges remain. Bergman et al. (2013) found that only 57% of participants used earplugs correctly even after receiving training, highlighting the need for more effective and engaging training methods. Traditional paper-based instructions have been widely used, but emerging evidence suggests that video-based training may offer advantages in terms of engagement, retention, and practical application of skills (Murphy et al., 2011). Video-based training can provide visual and auditory demonstrations, which may be more effective in conveying the correct techniques for earplug insertion and usage compared to static, text-based instructions.

The effectiveness of different training methods has been explored in several studies. Murphy et al. (2011) evaluated the impact of written, video, and one-on-one training on earplug attenuation and found that while group averages for attenuation were not statistically significant between video and written instructions, one-on-one training yielded significantly greater results. This suggests that interactive and personalized training methods may be more effective than

passive approaches. However, the study also highlighted the potential of video-based training as a scalable and cost-effective alternative to individual training.

Similarly, Takada et al. (2020) demonstrated that training interventions significantly improved the proper use of earplugs, with post-training evaluations showing a statistically significant increase in pass rates for proper insertion. These findings underscore the importance of training in enhancing the effectiveness of hearing protection devices and suggest that innovative training methods, such as video-based instruction, could play a key role in improving outcomes.

NIHL remains a significant public health issue, with substantial personal, social, and economic consequences. Earplugs and other hearing protectors are critical tools in preventing NIHL, but their effectiveness depends on proper usage, consistent application, and comprehensive training programs. While traditional paper-based training methods have been widely used, emerging evidence suggests that video-based training may offer advantages in terms of engagement, retention, and practical application of skills.

keywords: ear plugs, noise induced hearing loss, video-based instruction, paper-based instruction, instruction method, hearing protection device

6. The objectives of the trial or study, its hypotheses or research questions, its assumptions, and its variables

6.1 primary objective: To compare the effectiveness of earplug usage between video-based and paper-based instruction

6.2 secondary objective:

- To compare retention of earplug insertion skill at 1 week between the two instruction methods

6.3 Hypotheses / Research Questions

Null Hypothesis (H_0):

There is no significant difference in retention of earplug insertion skill between

participants trained using video-based and paper-based methods, either immediately or at 1-week follow-up.

Alternative Hypothesis (H_1):

There is a significant difference in retention of earplug insertion skill between the two training methods at immediate or 1-week follow-up.

Research Questions:

1. Which training method (video-based or paper-based) is more effective in improving earplug insertion skill immediately after training?

2. Is the improvement in earplug insertion skill sustained at 1 week following the intervention?

6.4 Study Assumptions

- All participants start with a comparable baseline in earplug usage skill.
- Both training formats deliver equivalent content, differing only in mode of delivery.
- The checklist used for assessing skill is standardized, valid, and reliable.
- Participants will not receive additional training or practice during the follow-up week.

6.5 Study Variables

Type	Variable Name	Description
Independent	Training method	Video-based vs paper-based
Dependent	Earplug usage skill	Score from standardized checklist (0–20 total)
Control	Training content	Identical across both groups
Time points	Assessment time	Immediately post-training and 1-week follow-up
Covariates (optional)	Age, department, prior earplug use	For subgroup/exploratory analysis (if included)

7. Study type : parallel-group randomized controlled trial

8. Study population

8.1. source of participants

Participants will be recruited from personnel who currently have noise exposure while working at Maharaj Nakorn Chiang Mai Hospital, Faculty of Medicine, Chiang Mai University, during the year 2026.

8.2. number of participants and sample size calculation

Sample size calculation for primary objective: To compare the effectiveness of earplug usage between video-based and paper-based instruction

The required sample size was calculated using Satterthwaite's two-sample t-test for unequal variances. Based on pilot data, the mean earplug usage score was 17.2 for participants trained with video-based instruction (SD = 1.0954), and 13.75 for those trained with paper-based instruction (SD = 2.63), resulting in an expected mean difference (Δ) of 3.45. To achieve 95% power with a two-tailed alpha level of 0.05, the estimated effect size (Cohen's d) was calculated using the pooled standard deviation. Using this effect size, the minimum required sample size was determined to be **11 participants per group (22 in total).**

Sample Size Calculation for Secondary Objectives

- **To compare the retention of effectiveness of earplug usage at 1 week between the two instruction methods**

  This objective compares two dependent means for a paired-matched study.

$$n = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 \sigma^2}{\Delta^2}$$

- **Paper group:** Based on a pilot study with a mean score of 13.75±2.63, assuming a 10% expected difference post-intervention, a 95% confidence level (α=0.05), and 80% power (β=0.2), the required sample size is **29 participants**.

- **Video group:** Based on a pilot study with a mean score of 17.2±1.09, assuming a 10% expected difference post-intervention, a 95% confidence level (α=0.05), and 80% power (β=0.2), the required sample size is **4 participants**.

Reference: Chow, S.-C., Shao, J., & Wang, H. (2003). *Sample Size Calculations in Clinical Research* (2nd ed.). Chapman & Hall/CRC., p. 51.

Analysis: Pre- and post-intervention scores will be compared within each group using a **paired t-test** (mean and standard deviation) or a **Wilcoxon signed-rank test** (median and interquartile range).

Based on the primary and secondary objectives of the study, the largest required sample size was derived from the secondary objective, which **required 29 participants per group. Therefore, a total of 58 participants (29 per group) will be recruited.**

To account for an anticipated data loss or dropout rate of 10%, the final target sample size was increased to **64 participants.**

8.3. Eligibility criteria

Inclusion criteria

Personnel aged 20–60 years old who report regular works in areas perceived as noisy department based on data from Health promotion unit Faculty of Medicine, Chiang Mai University (there are maintenance department 17 person , laundry department 48 person , kitchen department 78 person) while working at Maharaj Nakorn Chiang Mai Hospital, Faculty of Medicine, Chiang Mai University, during the year 2026. Willing and able to participate in the study throughout its duration.

Exclusion criteria

1. Individuals with active ear infections.
2. Individuals with ear canal stenosis that limit to insert the earplug.
3. Individuals with visual or auditory impairment that limit to read or see the instruction

4. who have limitation to use their hands to insert the ear plug.

8.4. withdrawal criteria

This study presents minimal risk to participants. However, the following conditions may result in early termination:

- A participant withdraws consent at any time.
- discomfort, minor irritation, or allergic reactions to the earplugs
- Any changes in ear anatomy or otological symptoms (such as ear infections or conditions affecting the ear) during the study period.
- Disruptions that make continued data collection infeasible (e.g., major policy changes, staffing issues).

8.5. The expected duration of subject participation 1 week

9. study design : a parallel-group randomized controlled trial

10. methods

1. **Instructional materials:** The video and hand flip instruction, and checklist or scoring rubric of the evaluation form will be created. The contents will be standardized by 3 experts to ensure similar, corrected and effective content.

   Each training method will take approximately 5 minutes.

   Both instructional materials will cover the same content, including:

   - How to properly insert earplugs
   - How to check if earplugs are properly fitted
   - Safety precautions and common mistakes

2. **Recruitment and Informed Consent:** Participants (adults aged 20-60 years) will be recruited from Noise-exposed units Maharaj Nakorn Chiang Mai Hospital . Eligible participants will be provided with an informed consent form explaining the study purpose, procedures, risks, and benefits. Consent will be obtained before participation.

3. **Randomization:** Participants will be randomly assigned in a 1:1 ratio to either the video-based training group or the paper-based training group using computer-generated random numbers (Block of 4). Group allocation will be concealed using sealed opaque envelopes.
4. **Data Collection:** During each assessment, participants will be asked to demonstrate proper earplug usage, and their accuracy will be scored by the researcher using a standardized check list . The assessor and the analyzer will be blinded.

Study Methods

Pre-Training Assessment

- Participants complete a baseline demographic questionnaire
- Assess baseline skill using an earplug insertion checklist (observer-rated)

Training Intervention

- Group A: Receives video-based instruction
- Group B: Receives paper-based instruction
- Participants will be allowed to practice earplug insertion immediately after receiving the instruction before being assessed.

Immediate Post-Training Assessment

- Reassess practical skill with the same checklist

Follow-up Assessment (1 Week Post-Training)

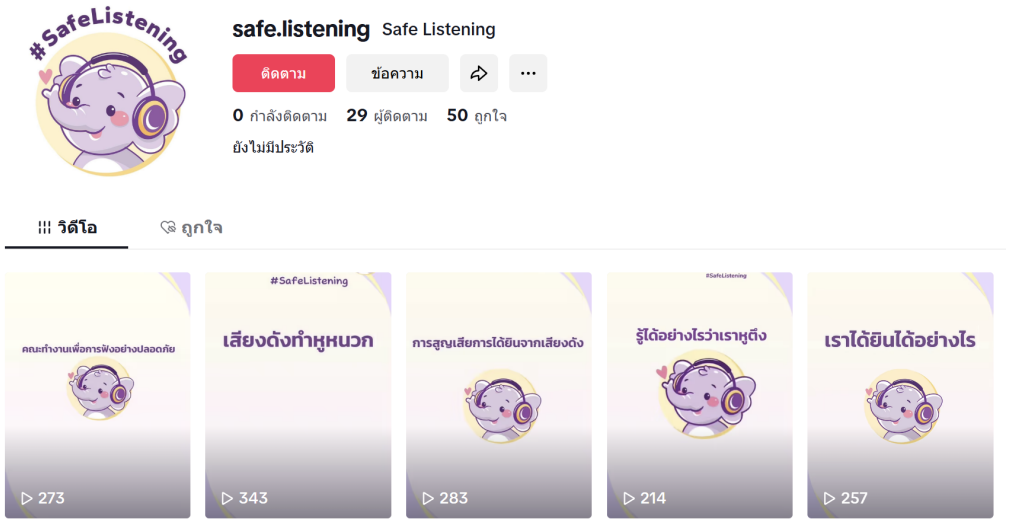
- Reassess skill using the same tools
- Data collection will be scheduled at 1-week window

Additional Details: Intervention and Skill Assessment Tool

The instructional materials used in this study include two formats: video-based and paper-based instruction. Both formats were developed to deliver identical educational content regarding proper earplug usage. The video-based module consists of a 5-minute narrated demonstration featuring visual and auditory guidance on the following steps: hand hygiene,

checking earplugs, proper rolling technique, ear canal opening, insertion method, adjustment, and verification of fit. The paper-based module features an illustrated step-by-step infographic with brief written instructions that mirror the video content.

The research team will develop the contents of both formats. After the paper-based materials have been finished, the VDO-based material will be produced. A promotion campaign will be announced to recruit the VDO clips from CMU medical students in the CMU Medical student Organization (CMSO) Facebook Page. A criterion for selecting the best VDO clips aligned with the paper-based content will be awarded. The winner's VDO clips will be posted in the #SafeListening TikTok channel (https://www.tiktok.com/@safe.listening?_t=8jQcqkJnqoj&_r=1).



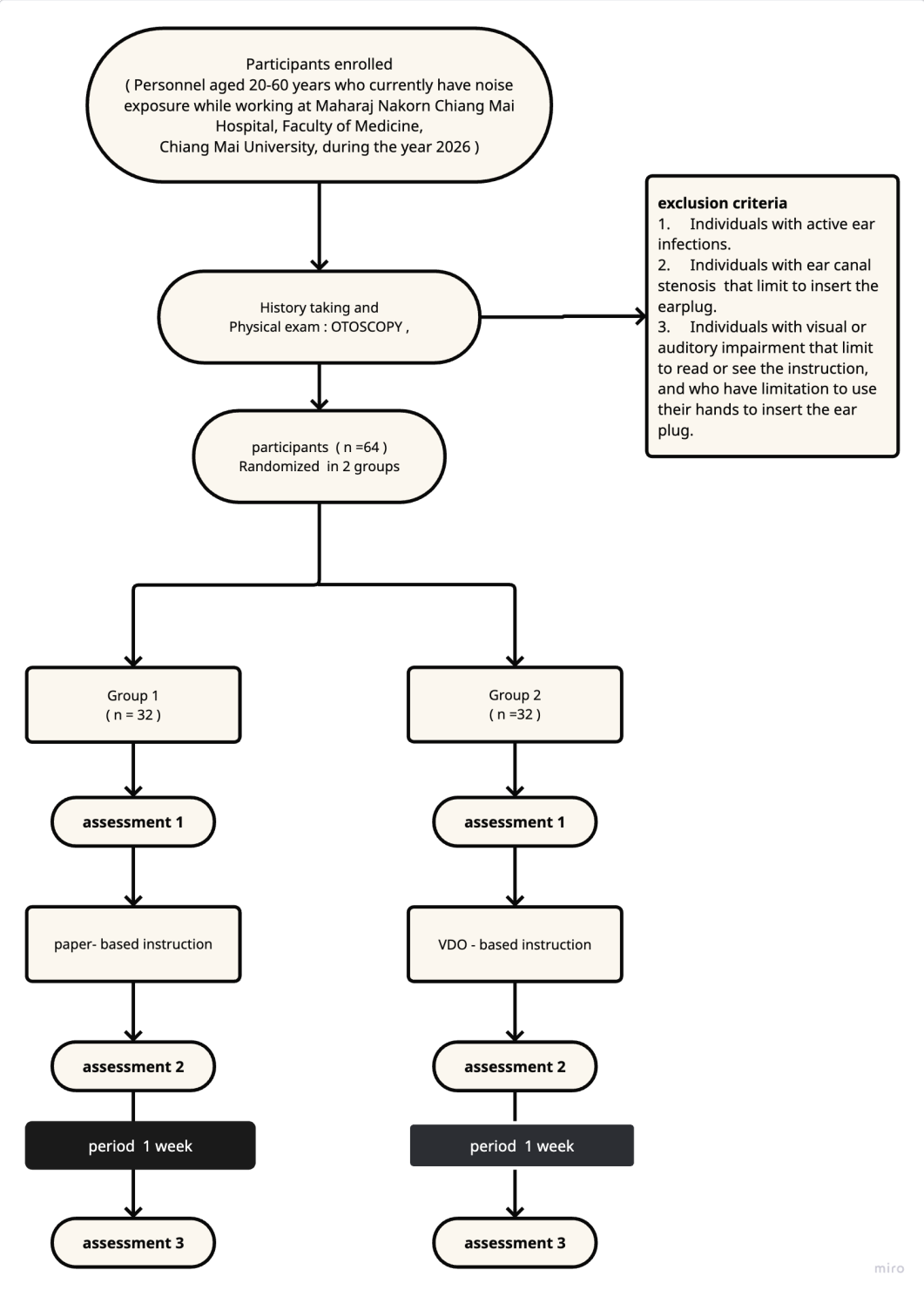
The materials of paper and VDO will be reviewed and revised through a pilot test conducted with hospital personnels, after which minor modifications were made to ensure clarity and accuracy. Content validity will be evaluated using the Content Validity Index (CVI), with an average S-CVI of 0.83 (Yusoff MSB, 2019), which indicates high agreement among experts on the relevance and accuracy of the materials.

The earplug insertion skill was assessed using a standardized 10-item observational checklist based on WHO and NIOSH guidelines. This checklist evaluates critical steps such as

hand hygiene, earplug preparation, correct insertion technique for both ears, and verification of proper fit. Each item is rated as correct or incorrect, with a total score of 0–10 points per ear (total 20 points per personel)

The checklist will be developed by the research team six experts in otolaryngology, occupational health, and research methodology will validate the checklist. Content validity was established through the calculation of the Item-Level Content Validity Index (I-CVI), with each item scoring ≥ 0.80. The Scale-Level Content Validity Index (S-CVI/Ave) will be calculated to achieve at least 0.83 (Yusoff MSB 2019). Inter-rater reliability will be assessed during the initial 10% of observations using Cohen's kappa, targeting a kappa value of ≥ 0.75.

Flow chart


Participants enrolled
(Personnel aged 20-60 years who currently have noise exposure while working at Maharaj Nakorn Chiang Mai Hospital, Faculty of Medicine,
Chiang Mai University, during the year 2026)
History taking and
Physical exam : OTOSCOPY ,
exclusion criteria
1. Individuals with active ear infections.
2. Individuals with ear canal stenosis that limit to insert the earplug.
3. Individuals with visual or auditory impairment that limit to read or see the instruction, and who have limitation to use their hands to insert the ear plug.
participants (n =64)
Randomized in 2 groups
Group 1
(n = 32)
Group 2
(n =32)
assessment 1
assessment 1
paper- based instruction
VDO - based instruction
assessment 2
assessment 2
period 1 week
period 1 week
assessment 3
assessment 3
miro

11. Plans for data collection and statistical analysis; stopping rule or premature termination of research, if applicable

Data Collection Plan

- **Data Collection Instruments**

Demographic Form:

Includes age, sex, occupation, department/unit, education level, and prior experience with earplug use.

- **Earplug Insertion Checklist (Skill Assessment):**

  A standardized 20-point observational checklist used to assess proper insertion of earplugs (left and right ear).

  - Administered at baseline, immediately post-training, and 1-week follow-up.

Data Collection Timeline

Time Point	Collected Data
Pre-training(baseline)	Demographics Earplug insertion skill assessment
Post-training	Earplug insertion skill re assessment
1-Week Follow-Up	Earplug insertion skill retention assessment

Data Collectors

- Trained research assistants (blinded to group allocation) will perform the skill assessments using the standardized checklist.
- Outcome assessors and data analysts will be blinded to group allocation to minimize assessment bias.

Data Management

- Each participant will be assigned a unique ID code to ensure confidentiality.
- All data will be entered into a secured, password-protected database.

- Double-entry and random audits will be conducted to ensure accuracy.

Statistical Analysis Plan

Data Management and Soft ware : All collected data will be entered into a secure, password-protected spreadsheet and verified by two independent researchers. Statistical analysis will be performed using STATA. Significance will be set at $p < 0.05$ (two-tailed).

Descriptive Statistics

- Continuous variables (e.g., checklist scores) will be summarized as means and standard deviations (SD) or medians and interquartile ranges (IQR), depending on data distribution.
- Categorical variables (e.g., gender, prior experience) will be reported as frequencies and percentages.

Primary Outcome Analysis : To compare the immediate earplug insertion skill between video-based and paper-based instruction groups:

- An independent t-test (or Mann–Whitney U test if data are not normally distributed) will be used to compare post-training checklist scores between groups.

Secondary Outcome Analyses

1. Earplug Insertion Skill Retention at 1 Week:
    - A two-way mixed ANOVA (group × time) will be conducted to assess within-group changes across time points (baseline, immediate post-training, and 1-week follow-up) and between-group differences over time.
    - If model assumptions are violated, a linear mixed-effects model will be applied as an alternative.
2. Exploratory Analysis of Predictive Factors:
    - Multiple linear regression will be used to assess whether age, education level, or prior earplug use experience significantly predict post-training earplug insertion skill scores.

- Interaction terms may be included to explore potential moderator effects.

12. References :

1.Basner M, Babisch W, Davis A, Brink M, Clark C, Janssen S, Stansfeld S. Auditory and non-auditory effects of noise on health. Lancet . 2014 Apr 12;383(9925):1325-1332. doi: 10.1016/S0140-6736(13)61613-X. Epub 2013 Oct 30. PMID: 24183105; PMCID: PMC3988259.

2. Berger, E. H. (2000). Hearing protection devices. In E. H. Berger, L. H. Royster, J. D. Royster, D. P. Driscoll, & M. Layne (Eds.), The Noise Manual (5th ed.). Fairfax, VA: AIHA Press.

3. Brueck, E. (n.d.).Hearing protection. OSHwiki. Retrieved January 29, 2025, from https://oshwiki.osha.europa.eu/en/themes/hearing-protection

4. Centers for Disease Control and Prevention [Internet]. Washington, DC: DHHS, CDC. [updated 2024; cited 2025]. Noise and hearing loss prevention; [about 1 screen]. Available from www.cdc.gov/niosh/topics/noise/about.html (Accessed 29 January 2025).

5.Chow, S.-C., Shao, J., & Wang, H. (2003). *Sample Size Calculations in Clinical Research* (2nd ed.). Chapman & Hall/CRC., p. 51.

6.Cory Portnuff, Stacy Claycomb. Hearing protection use in recreational music exposure: A review and analysis of the literature. Available from https://cdn.who.int/media/docs/default-source/documents/health-topics/deafness-and-hearing-loss/monograph-on-hearing-protection-use-in-music-venues.pdf?sfvrsn=a6b008e5_5. Accessed January 24, 2025.

7. Daniel E. Noise and hearing loss: a review. J Sch Health. 2007;77(5):225–31.

8. Gong W, Murphy WJ, Meinke DK, Feng HA, Stephenson MR. Evaluating Earplug Performance over a 2-Hour Work Period with a Fit-Test System. Semin Hear. 2023 Jun 1;44(4):470-484. doi: 10.1055/s-0043-1769586. PMID: 37818150; PMCID: PMC10562054.

9. Liberman MC. Noise-induced and age-related hearing loss: new perspectives and potential therapies. F1000Res . 2017 Jun 16;6:927. doi: 10.12688/f1000research.11310.1. PMID: 28690836; PMCID: PMC5482333.

10. Murphy WJ, Stephenson MR, Byrne DC, Witt B, Duran J. Effects of training on hearing protector attenuation. Noise Health. 2011 Mar-Apr;13(51):132-41. doi: 10.4103/1463-1741.77215. PMID: 21368438.

11. NIDCD, 2021. Noise-induced hearing loss. Available from https://www.nidcd.nih.gov/health/noise-induced-hearing-loss. Accessed January 24, 2025.

12. Salmani Nodoushan M, Mehrparvar AH, Torab Jahromi M, Safaei S, Mollasadeghi A. Training in using earplugs or using earplugs with a higher than necessary noise reduction rating? A randomized clinical trial. Int J Occup Environ Med. 2014 Oct;5(4):187-93. PMID: 25270008; PMCID: PMC7767610.

13. Shukla A, Harper M, Pedersen E, Goman A, Suen JJ, Price C, Applebaum J, Hoyer M, Lin FR, Reed NS. Hearing Loss, Loneliness, and Social Isolation: A Systematic Review. Otolaryngol Head Neck Surg. 2020 May;162(5):622-633. doi: 10.1177/0194599820910377. Epub 2020 Mar 10. PMID: 32151193; PMCID: PMC8292986.

14. Sliwinska-Kowalska M, Davis A. Noise-induced hearing loss. Noise Health. 2012 Nov-Dec;14(61):274-80. doi: 10.4103/1463-1741.104893. PMID: 23257577.

15. Takada MM, Rocha CH, Neves-Lobo IF, Moreira RR, Samelli AG.Training in the proper use of earplugs: An objective evaluation.Work. 2020;65(2):401-407. doi: 10.3233/WOR-203092. PMID: 32007983.

16. Tsukada T, Sakakibara H.A trail of individual education for hearing protection with an instrument that measures the noise attenuation effect of wearing earplugs. Ind Health. 2008 Aug;46(4):393-6. doi: 10.2486/indhealth.46.393. PMID: 18716388.

17. WHO, 2015.Make Listening Safe. World Health Organization; 2015. Available from https://cdn.who.int/media/docs/default-source/documents/health-topics/deafness-and-hearing-loss/mls-brochure-english-2021.pdf?sfvrsn=bf19b448_5, (accessed December 29, 2024).

18. Yusoff MSB. ABC of content validation and content validity index calculation. Education in Medicine Journal. 2019;11(2):49–54. https://doi.org/10.21315/eimj2019.11.2.6

13. Gantt chart

Gantt chart December 2024 - August 2026

Research Duration	Calendar (month/year)	Study procedure	Result
-	December 2024 - November 2025	Design the and establish data collection methods Submit proposal to Research Ethics committee	Acquire a data collection method along with a suitable questionnaire
1st month	December 2025	Responses to the comments from the Research Ethics committee Design and create the checklist, paper-based, and VDO- based instructions	Approval from Research Ethics committee First draft of the checklist, paper-based, and VDO-based instructions
2nd month	January 2026	Conducting a meeting with research team. Recruit experts' opinion on the checklist, paper-based, and VDO- based instructions Modification of the materials according to the experts	Acquire operational strategies Ready-to-use checklist, , paper-based, and VDO-based instructions
3rd month	February 2026	Publicize project information to recruit targeted groups to join the project.	Acquire engagement targeted groups for project participation

4^{th}-7^{th} month	April -July 2026	Distribution of consent forms and proceeding following the study flow. Collect data	Acquire participant data collection . Acquire the collection and analysis of data
8^{th} – 12^{th} month	August-December 2026	Data analysis Summarize and write a full research report for publication	Acquire the results and research have been presented or published

14. total budget and details

"Comparative Efficacy of Earplug Usage Instruction : A Randomized Trial of Video-Based and Paper-Based Instruction"

Date: March 6, 2026

	Unit Price (THB)	Quantity	Amount (THB)
1 Personnel Cost			0
Participant compensation (visit fee 100 THB × 2 visits)	200	64	12800
Expert reviewer fee (evaluating video and paper instructional materials)	500	6	3000
Development of instructional materials (paper and video)	2000	1	2000
Data analysis fee	1000	1	1000
2. Equipment Cost			0
3. Supplies			0
Instructional material documents	1	500	500
Earplugs (6 THB/pair × 2 times × 64 participants)	6	176	1056
4. Miscellaneous Cost			0
Research report preparation fee	3000	1	3000
Grand Total (THB)			**23356**

Total Estimated Budget: 23356 THB

15. Ethical issues and considerations

(1.) Justification for the study, its significance :

Noise-induced hearing loss (NIHL) is a common but preventable occupational health problem, especially in high-noise environments. Hospital personnel working in areas such as engineering, laundry, and transportation may be exposed to sound levels that put them at risk.

Despite the availability of earplugs, improper use reduces their effectiveness and fails to protect hearing as intended. This study seeks to compare two methods of earplug usage training—video-based and paper-based—in order to identify the more effective and acceptable approach. Findings will guide the development of future training protocols and help protect the hearing health of hospital workers, thereby contributing to occupational safety and sustainablilty of safe listening behavior.

(2.) Regulatory and Ethical Compliance :

This research will be conducted in accordance with the Declaration of Helsinki, the International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) guidelines, and relevant national ethics regulations. Ethical approval will be obtained from the Research Ethics Committee of the Faculty of Medicine, Chiang Mai University, prior to data collection. All research activities, including participant recruitment, informed consent, data collection, and data handling, will be conducted with strict adherence to confidentiality and data protection protocols.

(3.) Informed consent and participant recruitment :

Participation in this study is entirely voluntary. All participants will be clearly informed about the study's objectives, procedures, duration, potential risks and discomforts, benefits, and their right to withdraw at any time without penalty or consequences. This information will be provided both in writing and verbally before obtaining signed informed consent. Participants will be recruited from departments within Maharaj Nakorn Chiang Mai Hospital with known noise exposure. A modest compensation (100 THB per visit for 2 visits, 200 THB in total) will be offered to those who complete the study procedures in full.

(4.) Risks of participants as a result of participation in a research study

- **Safety Monitoring Plan:**
    - **Risk Assessment**

Potential risks associated with earplug usage include:

• Physical discomfort: Earplugs may cause discomfort, pain, or irritation if used incorrectly.

• Ear injury or infection: Incorrect use of earplugs (e.g., improper insertion, contamination) could lead to ear injuries or infections.

• Allergic reactions: Participants could have an allergic reaction to the material of the earplugs.

• Psychological discomfort: Some participants may feel anxious about using earplugs, particularly if they are not familiar with them.

- **Monitoring Procedures**

- Pre-screening:
  - All participants will undergo a pre-screening process to ensure they meet the inclusion and exclusion criteria. For example, participants with active ear infections, ear conditions (like auricular stenosis), or cognitive impairments will be excluded.
  - Participants will be asked about any known allergies to earplug materials before participation.
- Ongoing Monitoring:
  - Immediate observation after each training session: Participants will be observed for any signs of discomfort or adverse reactions (e.g., redness, swelling, pain in the ear area). During post-training assessments participants will be asked if they experienced any discomfort, pain, or adverse effects related to earplug use.
- **Adverse Events (AE) and Serious Adverse Events (SAE) Reporting**
  - Adverse Event (AE): Any undesirable experience associated with the use of earplugs that is not necessarily serious but still noteworthy, such as mild discomfort, minor irritation, or allergic reactions.

- Serious Adverse Event (SAE): Any event that could result in significant harm, such as severe ear infection or a major allergic reaction.
- Reporting Process: If any AE or SAE occurs, the event must be documented, and immediate medical attention should be provided if necessary.
    - Minor AEs (e.g., mild ear discomfort): Participants will be instructed to stop using earplugs if discomfort occurs. Any discomfort will be recorded, and participants will be provided with contact information for further support.
    - Serious AEs (e.g., ear infections, hearing problems): Any serious adverse events will be reported to the ethics committee and medical personnel. The participant will be immediately referred for medical evaluation and treatment. The study may also be paused if a serious adverse event is linked to the study.

Follow-up Plan for Safety Monitoring

- Immediate Follow-up: Participants will be contacted after the training session to ensure no immediate adverse effects were experienced (e.g., within 24 hours).
- Ongoing Safety Checks: Participants will be encouraged to report any issues related to earplug use at any time throughout the study. The study team will provide a contact number for inquiries.

Medical Oversight

• A qualified healthcare professional (e.g., an ENT specialist or a medical doctor) will be available to address any medical issues that arise during the study.

• The healthcare professional will be notified immediately in the event of any serious adverse events (SAEs) and will assist in determining the appropriate course of action.

Data Safety Monitoring Board (DSMB)

Not available.

Anticipated benefits to research participants or society :

1. Benefits to Participants

Participants in this study may gain immediate personal benefit through improved understanding and practical skills in correctly using earplugs. This knowledge can directly contribute to better protection of their hearing health in noisy work environments. Additionally, they will have the opportunity to engage in a structured training experience that may raise awareness about noise hazards and proper preventive measures. Participants who complete the study will also receive 2 pairs of earplugs, a modest financial compensation, acknowledging their time and involvement.

2. Benefits to Society and the Healthcare System

The findings of this study will inform the development of more effective and engaging hearing protection training programs for healthcare workers and other occupational groups exposed to hazardous noise. By identifying which educational modality—video-based or paper-based—is more effective and well-received, the study can help institutions design cost-effective, and sustainable training solutions. This has the potential to improve occupational safety practices, safe listening behavior, reduce the incidence of preventable hearing loss, and ultimately enhance quality of life and productivity in the workforce.

5) Plan for Recording, Reporting, and Managing Adverse Events

This study is categorized as **minimal risk**, as it involves non-invasive training on proper earplug use without medical procedures or interventions. Nevertheless, in compliance with ethical standards for human research, the following plan is established to monitor, record, report, and manage any potential adverse events (AEs) :

5.1.) Monitoring and Recording of Adverse Events

- The research team will closely observe participants during all training sessions and actively inquire about any discomfort or unusual symptoms.
- Potential adverse events may include mild ear discomfort, irritation, a sensation of fullness, or temporary hearing changes while using earplugs.
- All events will be documented using a standardized adverse event log, which will include the date, time, description, severity, and management steps taken.

5.2.) Reporting of Adverse Events

- Minor or expected adverse events will be included in the final study report.
- In the event of unexpected or serious adverse events, the research team will notify the Research Ethics Committee, Faculty of Medicine, Chiang Mai University within **7 days**, as per institutional guidelines.

5.3) Management and Response

- If a participant experiences discomfort, the training session will be paused immediately and symptoms assessed.
- If needed, the participant will be referred to an otolaryngologist (ENT specialist) for further evaluation and care.
- Participants may withdraw from the study at any time without penalty if they feel unwell or uncomfortable.

Selection of Research Participants : Participants will be recruited from personnel who currently have noise exposure while working at Maharaj Nakorn Chiang Mai Hospital, Faculty of Medicine, Chiang Mai University, during the year 2026.

6) Care for the Welfare of Research Participants: Insurance Plan for Research-Related Injury, Compensation for Research-Related Injury, and/or Medical Treatment for Research-Related Injury

- A qualified healthcare professional (an ENT specialist doctor) will be available to address any medical issues that arise during the study.

- Participants are entitled to receive specialized healthcare as a fundamental aspect of their rights.

7) Statement of readiness of study site, equipment, and personnel to ensure participant safety during the research

Informed Consent and Participant Education

• Participants will be thoroughly informed about the potential risks associated with earplug use during the informed consent process.

• informed consent will include a description of possible side effects (e.g., discomfort, ear irritation, allergic reactions).

• Participants will also be educated on proper earplug usage, and any signs of adverse effects (such as discomfort or infection) will be outlined.

• Participants will be given clear instructions on how to stop using the earplugs if they experience discomfort or pain and how to seek medical help if needed.

Reimbursement for travel and meal costs incurred by participants attending scheduled study visits with the investigator

Participants will not receive any payment for participating in this study.

However, they will be remunerated with amounts 100 THB per visit, total 200 THB for 2 visits.

(7) Community consideration

This study does not impact the community directly ; instead, it increases awareness and promotes accuracy of ear plugs usage behavior among research participants, with a focus on advancing sustainability in improving hearing health.

(8) Confidentiality

Personal identifiers in the data will be securely stored and not disclosed to unrelated individuals.

(9) Post-Study Plan

- **Post-study care**

After the project ends, participants can directly consult with experts for advice and receive effective and correct advice, with specialists available to provide guidance and efficient care.

- **Collection of biospecimens and/or data for future studies**

The data will be kept and destroyed after the completion of the research study and two years after the research findings have been published in a journal.

- **Publication and data sharing policy**

1. Research Output Publication: The research findings will be published in formats accessible to the public, including academic articles and other relevant media.

2. Data Sharing: Research-related data will be made publicly available, prioritizing the protection of participants' privacy.

3. Consent Agreements: Research participants will be required to sign data usage consent agreements to ensure clarity and alignment with the data sharing policy.

4. Confidentiality Protection: Personal identifiers in the data will be securely stored and not disclosed to unrelated individuals.

5. Funding Acknowledgment: Clear identification of funding sources will be provided in the dissemination of research outcomes.

Research registration The protocol will be registered in the https://www.thaiclinicaltrials.org/