STUDY PROTOCOL

Study Protocol of Validation of a Mobile Sound Application for Noise Measurement in The Manufacturing Industry in Klang Valley, Malaysia

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ABSTRACT

Introduction: To prevent occupational noise-induced hearing loss (NIHL), sound level meter (SLM) has been mandated by legislation to measure noise level in the workplace. However, the SLM is expensive and the calibration process is labour-intensive. To look for a cost-effective, convenient, and accurate alternative, this study aims to determine the validity and reliability of the NIOSH sound level application for noise measurement in manufacturing industry in Malaysia. **Methods:** A cross-sectional study is scheduled in September 2024. A manufacturing factory will be purposively chosen, in which 33 noise measurements will be taken by both SLM (as gold standard) and the NIOSH sound level application (installed in an iPhone). Three parameters including average noise level (LAeq), maximum sound level (LMax), and 8-hour time-weighted average (8-hour TWA) will be recorded from each measurement. The effectiveness of the NIOSH sound level application will be evaluated against the SLM via concurrent validity (using Pearson's correlation coefficient) and intra-rater reliability (using intraclass correlation coefficient). **Discussion:** Upon establishing the validity and reliability of the NIOSH sound level application, it is anticipated that it could serve as a valuable alternative to SLMs, which would enhance noise surveillance and potentially reduce the prevalence of occupational NIHL within the manufacturing industry. **Trial Registration:** Ethical approval for the present study has been granted by the Ethics Committee of the National University of Malaysia (JEP-2024-071).
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INTRODUCTION

Hearing loss is defined by the World Health Organization (WHO) as the partial or complete inability to perceive sounds in one or both ears, and it ranges from mild to profound (1). This condition represents a significant global public health concern, impacting a substantial segment of the population. It affects a considerable portion of the global population with approximately 1.57 billion people experiencing hearing loss, and 403.3 million of them having moderate to severe form of hearing loss (2). In Malaysia, the prevalence of hearing loss was estimated at 21.5% (2). Various factors can contribute to this condition, but among the significant ones is none other than prolonged exposure to excessive noise (3).

Noise originates from both natural and human-made sources, such as weather phenomena and traffic (4). However, a substantial proportion of noise is generated from industrial activities, particularly in manufacturing. These include the operation of heavy machinery, metalworking processes, conveyor system, use of power tools, operating heavy motorized vehicles, and usage of large-scale ventilation systems (5).

The incidence of occupational noise-induced hearing loss (NIHL), defined as partial or complete hearing impairment resulting from one's employment, remains elevated, ranging from 11.2% to 58% (6). This issue is more pronounced in developing countries and it was ranked at the second most self-reported occupational illness (7). A recent study conducted locally among palm oil mill workers revealed an overall occupational NIHL prevalence of 50.8% (8), and another local study involving 173 workers in manufacturing factories reported a significant occupational NIHL prevalence of 49.7% (9). These evidences indicate the inadequate detection and management of occupational NIHL at manufacturing industry.

Occupational NIHL has negatively impacted the health and overall well-being of workers. For instance, in noisy environment they have difficulties in understanding spoken words (10), resulting to miscommunication that can affect their safety and overall job performance (6). Psychologically, occupational NIHL can cause frustration and disturb sleeping pattern, leading to decreased productivity of workers (11). On the employers' side, occupational NIHL can cause increment in healthcare costs associated with hearing aids, assistive devices, and potential medical interventions (12). Given the elevated prevalence of occupational NIHL in the manufacturing industry and the substantial effects of this health condition on workers within this industry, it is crucial to identify cost-effective, convenient, and accurate equipment to monitor noise levels in the manufacturing industry to encourage high uptake of noise surveillance and increase workers' awareness towards noise.

Conventionally, a sound level meter (SLM) is a handheld or fixed device used for real-time measurement of noise level in the workplace (13). Despite its significance in measuring noise levels, this device has certain limitations. For instance, it gives imprecise reading in environmental condition like humidity, and it is prone to error when not calibrated properly before using it (14). Additionally, it needs knowledge and skills to use the SLM device (15).

Meanwhile, various mobile sound level applications have been designed for noise measurement, that can be a substitute to SLMs in occupational settings. These applications utilise the built-in microphones in smartphones to capture environmental noise, allowing users to monitor noise levels instantly. Till date, various types of mobile sound level applications such as SPLnFFT app (16), SoundMeter app (16), SLA Lite run (17), and NIOSH SLM app (18) have been developed with many of them offering free access in either Google Play Store and/or Apple Store. These mobile sound level applications offer numerous advantages such as easy accessibility (19), flexibility (20), cost-free (19), and user-friendly (21).

However, one significant limitation of it is their reliance on the quality of internal microphones in smartphones, as the microphone is designed for capturing human voice with sufficient accuracy, not for precise noise level measurements. Some applications, such as the SPLnFFT, which demonstrated accuracy in controlled laboratory settings, performed less reliably in environments with a broader frequency range (22). Most importantly, a majority of mobile sound level applications are lacking of proper validation and reliability in real-world scenarios (20, 22, 23). Given these uncertainties, this study is aimed to identify the most accurate noise measuring mobile applications and its validity and reliability in manufacturing industry, as compared to the SLM.

METHODS

Study design and study location

A cross-sectional study is scheduled to take place in September 2024. The study will involve noise measurement in a manufacturing factory located within the Klang Valley. Although the aim of the present study is only to validate the NIOSH SLM app in measuring noise in a manufacturing setting (i.e., without investigating prevalence of occupational NIHL), the selection of this specific location is owing to the fact that this area reported notable incidence of occupational NIHL and its status as the economic hub of Malaysia. Hence, this helps the investigators to familiarise with this area for future prevalence study using the NIOSH SLM app.

Study population

A manufacturing factory located within the Klang Valley will be selected in the present study if it: (i) Involves at least one manufacturing process using machinery in their production lines; (ii) Operate machineries that expose workers to noise; (iii) Easily accessible by the investigators; (iv) Are willing to cooperate with the investigators; and (v) Consists of at least three departments in the workplace. Nonetheless, manufacturing factories that have recently implemented noise control measures will be excluded as this may mask the true extent of noise exposure.

Sample size estimation

For validity, given the Pearson's correlation coefficient, r = 0.9 (24), power = 80%, confidence interval = 95%, and type I error (a) = 0.05, the sample size required is 7. Meanwhile, for reliability, given the intraclass correlation coefficient, ICC = 0.90 (p1) (25), minimum acceptable ICC (p0) = 0.70 (26), power = 80%, and type I error (a) = 0.05, the sample size required is 23. The sample size of 23 will be inflated by 30% to cater for missing data. Hence, the final sample size estimated is 33. The sample size is calculated using the GitHub online software (27).

Sampling technique

A purposive sampling approach will be employed to select an eligible manufacturing factory for the noise measurement. To achieve this, the investigators will acquire a list of manufacturing factories in Klang Valley using the Federation of Malaysian Manufacturers directories. Each manufacturing factory will be assessed using the aforementioned inclusion and exclusion criteria. The manufacturing factory that fulfills all inclusion criteria will be selected and contacted via phone call. Once the top management of this selected manufacturing factory verbally agrees to participate to the present study, an information booklet explaining the purposes and procedures of the study as well as an informed consent form will be delivered to them via email or postage. Upon returning their written informed consent forms, the investigators will conduct walk-through surveys at that manufacturing factory to identify the number of machineries available in each of the department. A total of 33 noise measurements will be taken at that particular manufacturing factory. To encompass a broad spectrum of noise levels, efforts will be made to measure noise emitted by a variety of machineries in that manufacturing factory.

Study instruments

To compare the effectiveness of the mobile sound level application in noise measurement against the standard SLM, a SLM (The Quest™ SoundPro™ SE-DL Series SLM, model number SP-SE-2-1/3) and an iPhone 12 will be utilised to measure the noise levels. Although newer iPhone models are available in the Malaysian market, they are still not widely used, particularly in manufacturing environments. Hence, iPhone 12 will be a better representation in this setting. Besides this, it is known that Android-based devices are more commonly used among the manufacturing workers. However, since the NIOSH SLM app is not compatible with Android smartphones, the investigators resort to an iPhone instead.

The SLM will be configured to the A- weighting and the data-logged noise levels set at 5- min intervals. The SLM will be calibrated before data collection using a sound calibrator. The selection of the iPhone 12 is influenced by its popularity as one of the widely used brands in Malaysia, and most of mobile sound level applications are exclusively accessible on the iOS platform. The iPhone 12 will be installed with the NIOSH sound level application as this application demonstrated the best performance in noise measuring in the real-world condition (20).

Data collection

The data collection procedures will be carried out with the assistance and monitoring by an industrial hygienist. During data collection, the SLM (i.e., the standard reference) and the iPhone 12 (i.e., test device) will be mounted on separate tripods placed close together, at one meter away from the machineries in the manufacturing factories. To minimise the influence of reflected sound, both devices will be placed at one meter above the floor and at least 0.6 meter away from any walls, whenever possible. The internal microphone of the iPhone 12 is aligned in the same direction as the SLM's microphone.

Both devices will measure the noise level simultaneously, with the differences in start and stop times between both devices within two seconds. The length of each measurement lasted for 10 minutes for each machinery. The average noise level (LAeq), maximum sound level (LMax), and the 8-hour time-weighted average (8-hour TWA) measured by both SLM and iPhone 12 will be recorded respectively. The LAeq is the A-weighted, equivalent continuous sound level, having the same total sound energy as the fluctuating level measured. The 8- hour TWA is a worker's average exposure to noise in an 8-hour work shift.

Data analysis

A descriptive analysis will be performed to describe three noise parameters (i.e., LAeq, LMax, and 8-hour TWA) measured by both mobile sound level application and SLM. The effectiveness of the mobile sound level application will be assessed using concurrent validity, intra-rater reliability, and agreement tests.

Concurrent validity was assessed by calculating the Pearson's correlation coefficient between the noise parameters measured by the mobile sound level application and those measured by the SLM. If the assumption of normality is met (determined using a Shapiro-Wilk test), the concurrent validity of the mobile sound level application will be assessed against the SLM using Pearson's correlation. If the assumption of normality is not met, a Spearman's correlation will be used to analyse the concurrent validity of the mobile sound level application instead. If the Pearson's correlation coefficient, r, is between 0.7 and 1.0, there is a strong correlation between the noise parameters measured by both devices. If r is between 0.4 to 0.70, there is a moderate correlation and if r is less than 0.4, the correlation is weak (28). Concurrent validity of the mobile sound level application was considered acceptable if the correlation with SLM is at least 0.70 (26).

A two-way mixed effects intraclass correlation coefficient (ICC 3,1) will be used to assess the intra-rater reliability of the mobile sound level application. ICC greater than 0.90 indicate excellent reliability, ICC between 0.75 and 0.9 indicate good reliability, ICC between 0.5 and 0.75 indicate moderate reliability, and ICC less than 0.5 are indicative of poor reliability. ICC of at least 0.70 is set as the minimum standard for intra-rater reliability (29).

The agreement in the noise parameters measured by both devices will also be graphically presented using the Bland-Altman plot, in which the mean difference between the two devices (e.g., LAeq measured by SLM – LAeq measured by mobile sound level application) on the y-axis and the mean of the two devices (e.g., LAeq measured by SLM + LAeq measured by mobile sound level application divided by two) on the x-axis (30). If the points are evenly distributed around the line of equality (i.e., zero line), it indicates good agreement between the two devices (30). Consistent pattern above or below the line of equality suggests a systematic bias that needs to be considered. Limits of agreement will also be calculated in the Bland-Altman plot, which represent the range within which 95% of the differences between the devices are expected to fall. These limits are typically calculated as the mean difference x 1.96 times the standard deviation of the differences.

Ethics Approval

Ethical approval for the present study has been granted by the Ethics Committee of the National University of Malaysia (JEP-2024-071). Booklets consisting of information regarding the objectives and procedures of the study will be provided to the top management of the potential manufacturing factories. Informed consent from the top management of the manufacturing factories shall be obtained prior to the study. No information will be collected from the individual workers. While participating manufacturing factories will not receive monetary benefits, their workers will be educated on workplace hearing protection. If the noise level in these factories exceeds the permissible limit (i.e., 85 dB(A)), the top management will be notified and further actions will be discussed. All data collection and analysis procedures will adhere to the principles outlined in the Declaration of Helsinki.

DISCUSSION

It is expected that the NIOSH sound level application (installed in the iPhone 12) will be valid and reliable in measuring noise level in the manufacturing industry, as compared to the SLM. Upon establishing the validity and reliability of the NIOSH sound level application, it is anticipated that it could serve as a valuable alternative to SLMs, which would enhance noise surveillance and potentially reduce the prevalence of occupational NIHL within the manufacturing industry.

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