

STUDY PROTOCOL

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Prevalence and risk factors of long covid and its associated adverse work outcomes among workers in the manufacturing sector in Malaysia – a mixed-methods study protocol

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Abstract

Background The manufacturing sector in Malaysia has been severely impacted by the COVID-19 pandemic. This is further exacerbated by Long COVID-19 symptoms among the manufacturing workers, which are proven to influence work performance and quality of life. Of note, there is currently a lack of knowledge regarding the burden of Long COVID-19 in the Malaysian manufacturing sector. As such, our study aims to investigate the prevalence and risk factors of Long COVID-19 symptoms among the manufacturing workers, and subsequently assess the prevalence and risk factors of adverse work outcomes among the workers with Long Covid-19 symptoms.

Methods This is an exploratory mixed-methods study. In phase 1 (qualitative phase), three groups of participants (i.e., clinicians, employers, and workers) will be invited to participate to focus group discussions (FGDs) until thematic saturation. The aim of the FGDs is to explore the understanding, experience, and potential risk factors of Long Covid-19 among manufacturing workers. Findings from the FGDs will be analysed thematically. Themes generated from the FGDs will be used to generate items in a new questionnaire. The newly developed questionnaire will be validated using a fuzzy Delphi study, which will also be conducted among clinicians, employers, and workers. Phase 2 is a cross-sectional study that will be conducted among manufacturing workers across all states in Malaysia to identify the prevalence and risk factors of Long COVID-19, as well as the prevalence and risk factors of adverse work outcomes among workers with Long COVID-19. A multistage cluster sampling will be used to collect data from 4500 manufacturing workers in Malaysia. Logistic regression will be performed to determine the association between risk factors with both Long COVID-19 and adverse work outcomes.

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Conclusion Once the prevalence and risk factors of Long COVID and its associated adverse work outcome are identified, timely support and effective interventions could be provided to manufacturing workers to maintain their health and productivity.

Ethical considerations Ethical approval has been granted by the Research Ethics Committee of the National University of Malaysia (JEP-2023-607) and the Medical Research and Ethics Committee (MREC) Malaysia (NMRR ID-23-03310-H3E).

Keywords Long COVID-19, Work outcomes, Manufacturing, Workplace

Background

Malaysia encountered the initial wave of the COVID-19 pandemic in January 2020 [1]. Subsequent waves led to clusters of infections, especially within workplaces, which comprised over half (55.6%) of the 3495 identified clusters between 2020 and 2021 [2]. Particularly concerning was the manufacturing sector, a crucial contributor to Malaysia's gross domestic product (GDP) and job market, which accounted for half of these workplace clusters. Notably, the acute phase of COVID-19 not only disrupted operations in this sector but also posed a long-term threat due to the potential transition to Long COVID-19.

Long COVID-19 is defined by the World Health Organization (WHO) as symptoms persisting for at least two months in individuals with a history of probable or confirmed SARS-CoV-2 infection [3]. It has been reported to affect a significant proportion of the population, with prevalence ranging from 17.3 to 53.7% across various studies [4–11]. Particularly, data from the Ministry of Health (MOH) Malaysia indicated that 65.9% of acute COVID-19 patients were suffering from Long-Covid-19 syndrome [12]. On the other hand, a recent meta-analysis of consisted of mainly healthcare workers reported a lower prevalence of Long COVID-19 at 12.6% [13]. Not only that there was an inconsistency in the prevalence estimate between the general population and working population, the information on the burden of Long COVID-19 specifically in the manufacturing sector is also lacking due to the absence of occupational details in national databases like MySejahtera. Another reason for the lack of prevalence data is due to the focus of MOH's e-Covid notification system that solely focus on acute infections. Worst still, it remains unclear whether prolonged exposure to various substances at the manufacturing settings (e.g., chemicals, dust, and heavy metals) and work stress could increase the risk of developing Long COVID-19.

According to previous literature, the symptoms of Long COVID-19 encompass a range of issues affecting various organs and functions, including fatigue, dyspnoea, and cognitive impairment [14], along with adverse effects on mental well-being such as anxiety and depression [8]. Additionally, gastrointestinal problems, sensory

disturbances, and other persistent discomforts have been reported [6, 10, 11, 15], leading to a diminished quality of life in both physical and mental aspects compared to those without symptoms [9]. Although there is a lack of literature regarding the impact of Long COVID-19 on manufacturing workers specifically, a recent systematic review reported that workers (in general) with Long COVID-19 suffered from fatigue, headache, loss of taste, loss of smell, shortness of breath, difficulty in concentration, depression, and anxiety [16]. According to the previous systematic search and meta-analysis of the research team, it was found that almost one in four (38%) of the workers in general sector suffered from Long COVID-19, experiencing 43 symptoms in total [17]. Subsequently, if workers have existing occupational diseases (such as occupational asthma and occupational stress) or highly exposed to occupational hazards (such as chemicals, psychosocial stress, noise, etc.) at workplace, these Long COVID-19 symptoms are likely to be exacerbated, making them harder to recover [18]. Consequently, they may struggle to return to work and restore pre-pandemic levels of work quality and productivity [19, 20].

If the above challenges persist, Malaysia's economy will be heavily impacted, given that the manufacturing sector's GDP in the country amounted to RM93,369 million in 2024, which translates to 4.7% contribution of the country's GDP [21]. These underscore the urgent need to investigate the burden and impacts of Long COVID-19 on the work outcomes of the manufacturing workers.

Based on these rationales, our study has three objectives. Firstly, we seek to assess the prevalence of Long COVID-19 symptoms among workers in manufacturing sector in Malaysia. Secondly, we aim to identify the risk factors that lead to Long COVID-19 among these workers. Thirdly, we will investigate the adverse work outcomes due to Long COVID-19 among manufacturing workers.

Methods

This is an exploratory mixed-methods study. Phase 1 consists of qualitative interviews among subject matter experts to determine the field-specific definitions of Long COVID-19, signs and symptoms of Long COVID-19, potential risk factors for Long COVID-19, as well as

potential adverse work outcomes of Long COVID-19. This information will be used to generate a questionnaire to be used in Phase 2 of the study. Meanwhile, Phase 2 is a cross-sectional study to investigate the prevalence of Long COVID-19, risk factors of Long COVID-19, and adverse work outcomes of Long COVID-19 among manufacturing workers in Malaysia.

An exploratory mixed-methods approach is justified for this study because it combines the strengths of both qualitative and quantitative methods to provide a comprehensive understanding of the research problem. In the context of Long COVID-19, where the topic is relatively new and underexplored, qualitative methods (e.g., focus group discussions) are crucial for identifying emerging themes, risk factors, and experiences directly from stakeholders such as workers, clinicians, and employers. These insights help inform the design of a relevant and context-specific questionnaire.

The subsequent quantitative phase (cross-sectional survey) allows for the generalisation of findings to a larger population by statistically determining the prevalence, risk factors, and adverse work outcomes of Long COVID-19. This combination of qualitative exploration followed by quantitative measurement enables a deeper understanding of the issue while ensuring the findings are applicable at a broader level.

According to the socioecological model, health is affected by the interaction between the individual, interpersonal, organisational, community, and public policy. Adapting this model into the context of workplace illness, we propose that Long COVID-19 will be affected by three risk factors, namely the work factor, individual factor, and clinical characteristics of acute COVID-19 infection. On the other hand, Long COVID-19 might result in adverse work outcomes towards work quality of life, work productivity, and safety at work, moderated by organisational factor and personal factor. These relationships are illustrated in the conceptual framework in Fig. 1 below.

Phase 1

Phase 1 is composed of focus group discussions (FGDs) and Fuzzy Delphi Method (FDM). These processes are aimed to develop and validate a questionnaire, which will be used to measure our study objectives in Phase 2.

Focus group discussions

FGDs will be conducted in June 2024. It will involve three groups of panels, namely clinicians, employers, and workers. Clinicians will be invited among the academicians of various specialties at a local university hospital as well as from the Ministry of Health Malaysia facilities. Clinicians will be recruited via purposive and snowballing sampling (i.e., they will be invited based on their experience in treating Long COVID-19 patients). The investigators will send invitation to these clinicians via email.

Similarly, the employers will be recruited via purposive and snowballing sampling from various factories in Klang Valley. The investigators will send invitation to these employers via phone calls. For the workers, we will also recruit them via purposive and snowballing sampling from various factories in Klang Valley. The investigators will send invitation to these workers via phone calls. The clinicians, employers, and workers will undergo separate FGD sessions. The roles, representatives, and inclusion criteria of the clinicians, employers, and workers are provided in Appendix 1.

Prior to the FGDs, all participants will be required to read the participants' information sheet and sign the informed consent, both in physical booklets. An interview schedule is developed to guide the FGDs (Appendix 2). The comments or inputs from all panels of the FGDs will be recorded using a voice recorder. No videography will be taken at all times. Each FGD session will last less than three hours. We will repeat the FGDs until thematic saturation. We will allocate five participants in each FGD session.

The audio recording will be de-identified, and there will be no mention of personal identifying information such as names, identification number, etc. during the FGDs. The audio recording is for transcription purposes

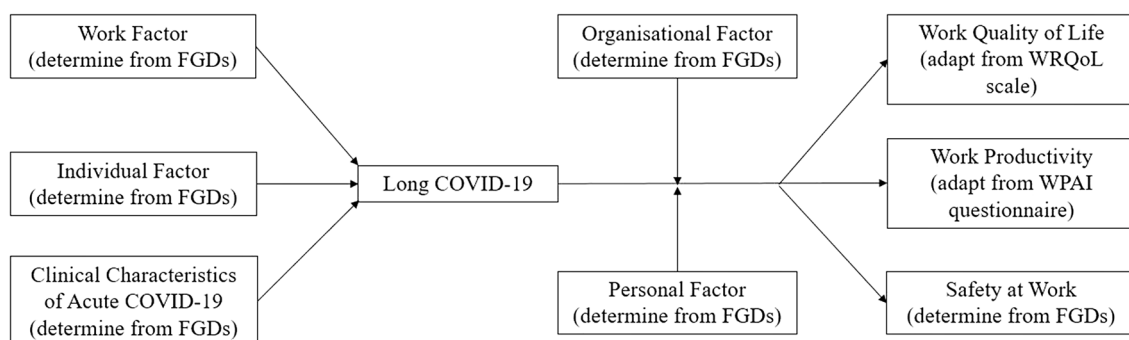


Fig. 1 The conceptual framework of the study

and will not be copied or sent to any other individual or used for any other purpose. After transcription, the audio recording will be disposed of securely. Analysis will be done using Atlas Ti. software.

To familiarise with the qualitative data, the researchers will thoroughly read the data to grasp its content and note initial thoughts. Following this, the researchers will engage in an inductive coding, systematically assigning codes to meaningful segments of the data that represent various aspects related to the research question. Once the inductive coding is complete, the codes will be reviewed and grouped into subthemes that capture important patterns within the data. Then several subthemes will be grouped into overarching themes. These identified themes will then undergo a review and refinement process to ensure they accurately represent the data, which may involve merging, splitting, or redefining the themes. After finalising the themes, they will be clearly defined and named to capture their essence, and the results will be reported with supporting quotes to illustrate how the themes address the research question.

To ensure inter-coder reliability during this process, coders (investigators) will receive training to understand the coding framework and the use of Atlas.ti. A detailed coding framework will be developed to guide the coding process, reducing ambiguity. Additionally, pilot coding sessions will be conducted on a small sample of data to refine the coding framework and ensure a common understanding among coders. Inter-coder agreement will be assessed using statistical measures such as Cohen's Kappa to evaluate the level of consistency between coders. Any coding discrepancies will be addressed through consensus meetings, where discussions will help refine the coding scheme as needed. Periodic reassessments will also be conducted throughout the analysis to maintain high inter-coder reliability and consistency.

The findings from FGDs conducted with three different groups of panels will result in the identification of subthemes and overarching themes. These themes will then be operationalised into specific items to form a questionnaire. Following this, the validity of these items will be assessed through a Fuzzy Delphi Method.

Fuzzy delphi method

A Fuzzy Delphi Method (FDM) will be used to obtain consensus and validation on the items generated from the previously described FGDs. It will be conducted in July 2024. Similar to the FGDs, three groups of panels (i.e., clinicians, employers, and workers) will be sampled using purposive and snowballing sampling.

Collection of data will be performed electronically whereby identified panels will be invited through email or WhatsApp. There will be two rounds of FDM. The first round will consist of experienced panels whereby

questionnaire with the items generated from FGDs will be critically appraised. The experienced panels will need to rate the relevance of each item using a 5-point Likert scale (ranging from 1 – “not at all relevant” to 5 – “highly relevant”). They are also allowed to add related items according to their knowledge and experience.

The second round of FDM will consist of expert panels. Expert panels are defined as those who represent renowned organisations. The findings of the first round of FDM and the revised questionnaire will be provided to these expert panels. Similarly, these expert panels will need to rate the relevance of each item using a 5-point Likert scale (ranging from 1 – “not at all relevant” to 5 – “highly relevant”). They are also allowed to add related items according to their knowledge and experience. The findings of the second round of FDM will be used in the finalisation of items in the questionnaire, which will be used in the cross-sectional study in Phase 2.

Each FDM will involve two key processes: Triangular Fuzzy Numbers (TFN) and the Defuzzification process [22]. Finally, the acceptability of each item will be assessed based on three criteria: (i) the threshold value, with $d\text{-construct} \leq 0.219$, (ii) expert agreement on the evaluated items must be $\geq 75\%$, and (iii) the ranking of each item [22].

Phase 2

Phase 2 of the study consists of a face validation, pilot study, followed by the actual cross-sectional study to determine the four objectives mentioned above.

Face validation

A face validation will be carried out in August 2024 to evaluate the questionnaire's formatting, readability, and language clarity. At least five workers will be randomly recruited to assess whether the items in the questionnaire accurately represent the constructs being measured, as well as to provide feedback on the overall questionnaire design. Any difficulties or confusion encountered by the workers will be documented and relayed to the principal investigator for necessary revisions. The time taken to complete the questionnaire will also be monitored.

Pilot study

The pilot study will commence in August 2024, tentatively. A total of 30 workers will be randomly selected from a manufacturing company in Negeri Sembilan, Malaysia. For selection, each manufacturing company listed in the Federation of Manufacturing Malaysia (FMM) directory will be assigned a number. A factory will then be selected randomly using a random number generator. The selected company will be contacted via phone call. Should the company agree to participate to the study, informed consent form will be provided. The

Table 1 Inclusion and exclusion criteria for workers in pilot study

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> • All diagnosed and documented COVID-19 in e-Covid or MySejahtera from January 2022 until December 2023. • Malaysian and legal non-Malaysian worker. • Working at least 6 months prior to the acute phase of COVID-19 as pre- COVID-19 working exposure is part of the variables investigated for association with Long COVID-19 and work outcome (as baseline comparison). 	<ul style="list-style-type: none"> • Unable to be contacted for workers who had resigned or terminated. • Temporary workers. • Pregnant women during data collection or during acute phase of COVID-19. • Workers who refuse to participate to the study.

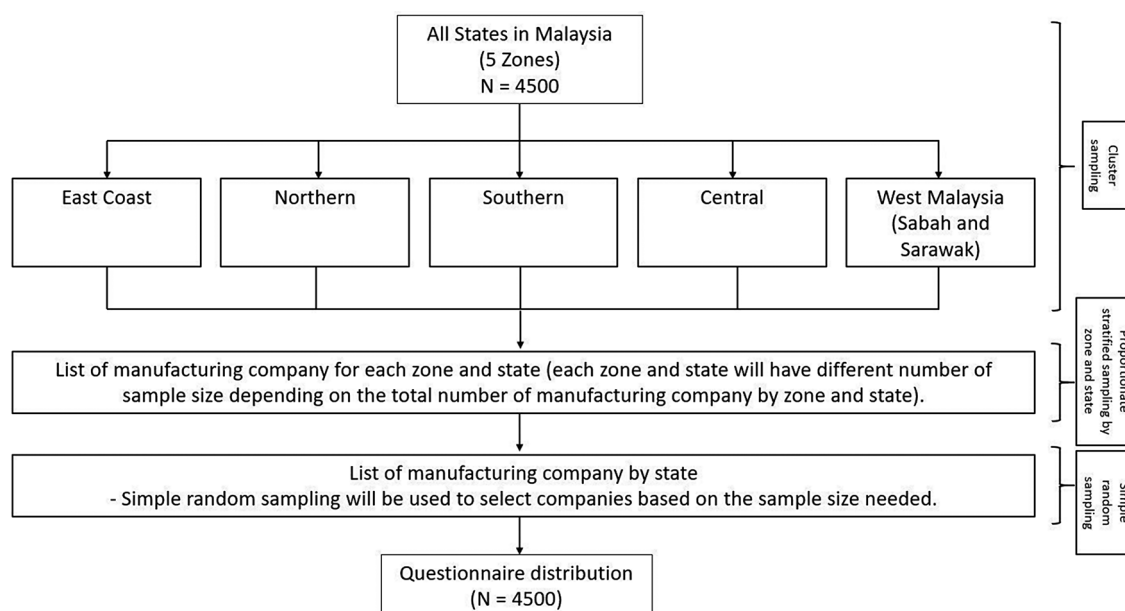


Fig. 2 Sampling method and data collection flow

30 workers invited for the pilot study must adhere to the inclusion and exclusion criteria listed in Table 1 below.

Cross-sectional study

The cross-sectional study will take place from August 2024 to April 2025 across Malaysia’s five geographical zones (i.e., East Coast, Northern, Southern, Central, and East Malaysia) (Fig. 1). The target population comprises workers from manufacturing companies listed in the FMM directory, with eligibility criteria matching those outlined in the pilot study (Table 1).

Workers will be selected through a multistage sampling approach. Initially, a cluster sampling will take place within each zone based on the total number of manufacturing companies. Subsequently, a proportionate stratified sampling method will be utilised to select workers from states within each zone. Finally, a simple random sampling will be employed to select one or two manufacturing companies per state.

With a precision level of 0.05, confidence level of 95%, design effect of 2, and a Long COVID-19 prevalence of 30%, the minimum sample size needed is 900 for each zone [23]. Consequently, the total sample size across all

five zones would amount to 4500 (Fig. 2). This sample size is estimated using the Kish’s formula [24].

The outcome of Phase 1 will be utilised to create a set of validated questionnaires, which will function as tools to assess the prevalence and risk factors associated with Long COVID-19, as well as the risk factors of adverse work outcomes resulting from Long COVID-19. Additionally, two existing validated questionnaires, namely the Malay version Work-Related Quality of Life (WRQoL) Scale [25] and the Work Productivity and Activity Impairment (WPAI) Questionnaire [26], will be incorporated. The WPAI will be translated from English language to Malay language. Permission to use both of these existing questionnaires has been obtained from their developers.

Researchers will visit selected manufacturing companies across the five zones. These companies will be asked to provide a list of workers who have been diagnosed and documented with acute COVID-19. With the cooperation of the management, researchers will gather these selected workers in a designated room within the management office. Each worker will be screened for eligibility based on the abovementioned criteria (Table 1).

If eligible, they will receive a briefing on the study objectives, instructions for questionnaire administration, and their rights before consenting to participate. Those who are ineligible or decline to participate will be thanked and allowed to return to work. Before the survey begins, informed consent will be obtained from participating workers. Participants will be encouraged to complete the questionnaire with the assistance of the investigators, and ample time will be provided to ensure high-quality data collection. Throughout the study, anonymity and confidentiality of participants will be maintained. To minimise disruption to workplace operations, only 1–2 workers will be asked to complete the questionnaire at a time.

In Phase 2, the prevalence of Long COVID-19 will be presented in percentage. Binary logistic regression will be utilised to ascertain the association between risk factors (e.g., clinical characteristics of acute COVID-19, individual factors, work factors, organisational factors, and personal factors) and Long COVID-19 symptoms as well as the association between Long COVID-19 symptoms and adverse work outcomes. Moderating effect such as organisational factor and personal factor of the workers on Long COVID-19 symptoms will be examined using Andrew Hayes Process Macro in SPSS version 28. Potential confounders will also be controlled using multiple logistic regression.

Ethical considerations

Ethical approval has been granted by the Research Ethics Committee of the National University of Malaysia (JEP-2023-607) and the Medical Research and Ethics Committee (MREC) of the Ministry of Health Malaysia (NMRR ID-23-03310-H3E).

Discussion

Long COVID-19 significantly impacts both quality of life and work capacity, leading to challenges for many workers in returning to their jobs due to health concerns [19]. However, understanding Long COVID-19 remains complex due to variations in its definition, symptoms, and effects on work observed across different studies [11, 27, 28]. To fill the gap in literature, we will conduct a research to identify prevalence and risk factors of Long COVID-19 and its associated adverse work outcomes. It is hoped that the findings of the study will provide insight to employers, policymakers, and stakeholders on the extent of the issue in the industry and guide the implementation of preventive measures to mitigate risks related to safety, health, and work quality of life, ultimately enhancing work productivity.

Strengths and limitations

To our knowledge, this is the first nationwide study that investigate Long COVID-19 among manufacturing

workers. To ensure the logistic feasibility and quality of data from the 4500 workers across five regions in Malaysia, we will recruit at least 10 enumerators to assist in data collection in the current study. These enumerators will be trained via a workshop once the study commence. Following the workshop, they will visit each factory in a group of five and interview the workers (one-to-one) using the physical questionnaire. We anticipate completing one interview within 30 min and completing one region within three weeks.

One of the potential limitations of the current study is the utilisation of a purposive sampling to select the workers with previous acute COVID-19 infection, which might lead to selection bias (i.e., workers with healthy work practice respond to our study invitation). To avoid the selection bias, efforts will be made to include a range of employers from various types of manufacturing sectors (e.g., electronics, textiles, machinery) and different company sizes (small, medium, and large enterprises). Besides this, workers will be selected from a variety of roles and exposure levels within the manufacturing sector to ensure that the sample reflects a wide range of working conditions. This approach will involve including workers in both high-risk (machine operators and maintenance staff) and low-risk positions (administrative staff and managers). By incorporating perspectives from different job roles, the analysis will better represent the diversity of experiences within the industry.

Another limitation is concerning the use of FDM over the classical Delphi method because of time and cost constrain. For instance, the findings from the FDM are based on the opinions of a selected group of experts, which may limit the generalisability of the results to a broader population. To enhance generalisability, we aimed to invite a diverse group of expert panels, representing different clinical disciplines and backgrounds. Furthermore, to minimise consensus bias, the FDM will remain anonymous to ensure that experts' responses are not influenced by others.

Although the questionnaires will be administered with the assistance of investigators or enumerators at the factory, the possibility of recall bias cannot be overlooked. This is because workers may have difficulty remembering the precise duration and symptoms of their acute COVID-19, potentially leading to inaccuracies in diagnosing Long COVID-19. To minimise this risk, we will instruct workers to refer to their MySejahtera app (which contains a digital record of their COVID-19 history) to verify the exact duration and symptoms of their acute COVID-19 illness.

Study implications

The findings of the study could significantly inform policy decisions at both the company and national levels. At

the company level, insights into the prevalence and risk factors of Long COVID-19 could lead to the development of more supportive workplace policies, such as enhanced sick leave provisions, reasonable accommodations for affected employees, and improved health and safety standards. By adopting these measures, companies can foster a healthier work environment, boost employee morale, and maintain productivity, ultimately benefiting both the workforce and the country's GDP.

At the national level, the study's findings can guide public health initiatives and labour policies aimed at addressing the broader impact of Long COVID-19 on the workforce. Policymakers such as the Ministry of Human Resource Malaysia could use this data to advocate for comprehensive health programs, create funding for workplace safety improvements, and establish national guidelines for managing long-term health conditions within the labour force with Long COVID-19. By addressing these issues on a national scale, governments can enhance worker protection, promote public health, and contribute to economic resilience in the face of ongoing health challenges.

Recommendations for future study

The findings from the current study, including the prevalence, risk factors, and adverse work outcomes associated with Long COVID-19, will enhance understanding of this health condition. These insights could inform future research aimed at evaluating the effectiveness of physical rehabilitation, mental health support, and workplace adjustments in alleviating Long COVID-19 symptoms.

Conclusion

Once the prevalence and risk factors of Long COVID-19 and its associated adverse work outcome are identified, the extent of the problem regarding Long COVID-19 among workers in the manufacturing sector will be better understood by employers, policymakers, and stakeholders.

Specifically, the findings from this study could inform workplace policies by promoting more flexible sick leave options, allowing extended recovery time for workers affected by Long COVID-19. Employers may also implement reasonable accommodations, such as modified work schedules or lighter duties, to support workers with ongoing symptoms. Additionally, workplace safety standards could be enhanced by addressing identified risk factors, improving ventilation, enforcing stricter PPE protocols, and offering routine health screenings and treatment. Lastly, the study could encourage the integration of mental health support services, ensuring a more comprehensive approach to worker well-being and long-term productivity.

Acknowledgements

We would like to thank the Director of National Institute of Occupational Safety and Health (NIOSH) Malaysia, for their grant and permission to publish this article. As specified in the terms of reference, the study will focus exclusively on manufacturing workers.

Author contributions

HMY, MAMN, AAR and RD conceptualised and designed the study. SQY, HMY and AMN conducted the literature search and data extraction. SQY, AMN, OH, and NMT performed the statistical analysis. SQY, ZM, NCM, FHM, MIAS, and MHS drafted the initial manuscript. All authors contributed to the interpretation of results, critically revised the manuscript for important intellectual content, and approved the final version for publication.

Funding

This work was supported by the National Institute of Occupational Safety and Health (NIOSH) Malaysia [grant number: UKMP-S230424] to [HMY].

Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Ethical approval has been granted by the Research Ethics Committee of the National University of Malaysia (JEP-2023-607) and the Medical Research and Ethics Committee (MREC) of the Ministry of Health Malaysia (NMRR ID-23-03310-H3E). All participants are required to provide written informed consent prior to their participation. No personal identification will be collected throughout the study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Received: 3 September 2024 / Accepted: 18 November 2024

Published online: 25 November 2024

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