STUDY PROTOCOL

Work Fatigue Among Air Personnel: Protocol for Fatigue Intervention Program (FIP) and Quasi Experimental Study

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ABSTRACT

Introduction: Work fatigue is common in air and ground crew since they have prolonged working hours. Work fatigue is excessive tiredness and decreased function during or after work. Fatigue can also affect sleep quality. Despite work fatigue causing disproportionately significant psychosocial dangers, limited studies have developed an intervention program. Thus, this study will develop a Fatigue Intervention Program (FIP) and evaluate its effectiveness in reducing air and ground crew fatigue. **Methods:** The FIP was developed after literature review and expert's evaluation. This is a quasi-experimental study to evaluate the effectiveness of FIP. One east Malaysia base will be the intervention arm and one west Malaysia base will be the control arm. Each arm will comprise of 61 participants for a total of N=122. Work fatigue (primary outcome) and sleep quality (secondary outcome) will be evaluated using Multidimensional Fatigue Inventory (MFI) and Pittsburgh Sleep Quality Index (PSQI) questionnaires respectively. Baseline, post-intervention, post one-month, and post three-month assessments will be done for both arms. Data will be described by percentages, frequencies, and mean. Time and group interaction effects will be examined using General Estimating Equation. **Discussion:** Five experts gave a Content Validity Index of 0.90 to 1.00 for relevancy, clarity, adequacy, and agreeability in the evaluation of the FIP. Enrolment will take one month and data collection three months. The FIP is expected to reduce the domains of MFI such as reduced motivation, reduced activity, general, physical and mental fatigue. The FIP is also expected improve the PSQI domains; duration of sleep, days dysfunction due to sleepiness, sleep disturbance, efficiency, latency, and quality. **Trial Registration:** The study has been registered in Thai Clinical Trials Registry with approval number TCTR20221004004.
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INTRODUCTION

Work fatigue is common in aircrew and ground crew since they spend most of their time at work (1). The state of being exceedingly tired, weary, or sleepy is what is referred to as fatigue, and it is a condition that can arise as a result of extended exertion. In addition, the term "work fatigue" refers to an overwhelming sensation of weariness and a lowered functional ability that occurs during and after a day's worth of job activities. This occurs in the setting of the workplace and is known as "work fatigue" (2). Furthermore, fatigue could also affect the sleep quality of the personnel.

Recent years have seen a rise in awareness about the problem of fatigue in the workplace. Previously, the primary focus of workplace concerns was on

the physical working conditions of an organisation (such as the presence of hazardous chemicals, noise, cleanliness, illumination, and physical job overload). However, in recent years, the focus has shifted to the growing number of complaints regarding fatigue in the workplace (3). In a survey that was conducted in 34 European nations in 2012, it was found that 22% of the workforce suffers from problems connected to work-related fatigue (3). Furthermore, it was discovered that between 68 and 91% of American pilots were suffering from fatigue while on the job (4,5). In addition, 65.7% of the working population in the United States of America (USA) reported suffering from health problems that caused them to lose productive time at work due to fatigue (6). Besides that, a study conducted among air crew of the United States Air Force (USAF) revealed that 94% of participants reported experiencing performance impairments as a result of fatigue (7). According to Caldwell et al. (2009), the harmful effects of fatigue have been shown to be a contributing factor in errors and accidents in the aviation industry (8). An additional investigation indicated that 54.5% of workers at a semiconductor factory in Malaysia were experiencing symptoms of weariness (9). The results of a study that was conducted with Malaysian air crew and pilots revealed that 91% of them are concerned about experiencing fatigue during the course of their job. In addition, 86 percent of the respondents in the same poll, or 100 out of 117, stated that they were concerned about the effects of job fatigue on their health (10).

An individual is better able to deal with the demands of their job, which enables them to be more productive and positive while they are at work when they experience little or no fatigue at work as a result of learning techniques to reduce work fatigue from a programme. Furthermore, if work fatigue can be reduced, employees will be able to perform better and will also have higher levels of job satisfaction. This, in turn, will lead to increased performance, which will be to the benefit of the organization as well as the nation (10,11).

Besides that, one of the methods of reducing fatigue is by the practice of deep breathing which is a dynamic approach to body-mind treatments that may be used to treat fatigue, anxiety, depression, exhaustion, stress, burnout, and other psychosomatic conditions (12,13). The activity of breathing involves a contraction of the diaphragm, an expansion of the abdomen, and an extended process of inhaling and exhaling, which decreases the regularity of the respiratory process and elevates blood gases. The mechanism that controls breathing is connected to the autonomic nervous system, which consists of the heart rate and is regulated by the equilibrium of the sympathetic and parasympathetic neural systems (14). When it is taken into the lungs, it causes the cardiovascular centre to suppress vagal outflow, which leads to sympathetic predominance and a rapid heart rate (15). During the process of exhaling, a slower heart rate is produced as a result of the vagal outflow restoration. This method is associated to lowering levels of fatigue (16).

In general, both the air crew and the ground crew are essential members of the workforce for the country's various aviation services. It is absolutely necessary to intervene with the personnel by means of a programme for job fatigue. In addition, to the best of the authors' knowledge, there has been no research conducted in Malaysia on a Fatigue Intervention Program (FIP) to minimise the amount of fatigue experienced by air and ground crew. As a result, the purpose of this study is to establish a Fatigue Intervention Program and measure the program's effectiveness in reducing fatigue among ground crew and air crew.

Overall, the goal of this study is to develop, execute, and determine the effectiveness of the Fatigue Intervention Program (FIP), in reducing work fatigue among both the ground crew and the air crew (air personnel). The specific objectives of this study are firstly to develop and implement a Fatigue Intervention Program (FIP) for the air crew and ground crew. Secondly, to compare the baseline fatigue scores between intervention and comparison group among air personnel and to compare the post-intervention fatigue scores of air personnel between intervention and comparison group. Last but not least, to compare the effectiveness of FIP on the level of fatigue between intervention and comparison group. Besides that, also to compare the effectiveness of FIP on improving sleep quality between intervention and comparison group.

METHODS

Study Design

This study is a quantitative study, and its design is that of a two-arm quasi-experimental study to investigate the enduring intervention effects. In contrast to "true" experiments such as randomized controlled trials (RCTs), quasi-experiments assign treatment based on self-selection or administrator discretion. This study employs discrete and abrupt exogenous study variables, such as fatigue and sleep quality. A quasi-experimental study design is preferable to a randomized controlled trial (RCT), which is conducted at a specific time and with a specific population, for analysis purposes. Furthermore, the quasi-experimental design of this study may increase generalizability and external validity in comparison to a RCT. Furthermore, rapid response solution for fatigue will be evaluated using quasi-experimental techniques due to time and resource limitations. Therefore, a non-randomized intervention design is utilized in this study.

An interventional arm will be assigned to one of the bases, while the control arm will be assigned to the other. The research will be conducted in two stages. The initial stage was to come up with an all-encompassing

Fatigue Intervention Programme (FIP). The next stage will be the execution of the program at the air base, after which the effectiveness of the program in decreasing fatigue among ground crew and pilots will be evaluated.

The first stage was to create the Fatigue Intervention Programme (FIP) to reduce work fatigue. The contents of the first component of the FIP, which is knowledge, were produced based on consultations with subject matter experts and literature review. Besides that, literature review as well as the input based on the discussions with two senior physiotherapists were used for the second component which is the Deep Breathing Exercise. Assets of Deep Breathing Exercise (BE) include its accessibility, low costs, and positive side effects without causing organisational red tape. Besides that, a study conducted by Ghanbari in 2018 showed BE having a large effect size in reducing fatigue (13). BE is also considered a dynamic technique within the realm of body-mind therapies, utilized for the purpose of managing symptoms associated with fatigue (12,13), hence BE was chosen as the form of intervention for reducing work fatigue. The Deep Breathing Exercise component was finalised based on the steps, frequency, duration and methods. One of the physiotherapists is a dean of a Malaysian physiotherapy college and clinical physiotherapist with over 30 years of experience. The other physiotherapist is a lecturer in a Malaysian physiotherapy college and also clinical physiotherapist with 28 years of experience. Before the contents of the components of the FIP were finalised, both of the components were subjected for review and evaluation by a panel of five subject matter experts consisting of occupational health doctors, aviation medicine specialist, mental health specialist, public health specialists, and occupational health programme experts. The first expert is a principal of public health college in Bangalore, India as well as a public health and occupational health physician with over 15 years of experience. The second expert is an associate professor in public health college in Bangalore, India and public health as well an occupational health physician with over 8 years of experience. The third expert is an associate professor in a university in Malaysia with a doctorate study in work fatigue. Last but not least, the subsequent expert is a director of a Malaysian aviation medicine institution, public health and aviation medicine physician with also expertise in mental health with over 20 years of experience in the field. The final expert has a doctorate qualification as well a technical expert and trainer of occupational health programs in a Malaysian based institute for occupational safety and health. Overall, the program module was evaluated by a mixture of International and National experts. The program modules were evaluated on the relevancy, clarity, adequacy and agreeable components.

The second stage of the procedure will consist of a FIP pilot study, implementation, and evaluation of the FIP's effectiveness. The quantitative data will be gathered via self-administered physical questionnaires. Participants must complete a sociodemographic form, a quiz, Multidimensional Fatigue Inventory (MFI) questionnaire, and the Pittsburgh Sleep Quality Index (PSQI) questionnaire. The questionnaires will be administered to participants in the intervention arm during screening at before intervention, after intervention, after 1 month, and after 3 months. In addition, the control arm would receive pamphlets on job fatigue and be assessed at the same time periods as the intervention group. The summary of the phases of the study is depicted in Figure 1. Additionally, the allocation of the participants in the two study arms are depicted in the Consort diagram, Figure 2.

Study Setting

The study will be carried out on a population of ground air crew and pilots in a base from an airbase in both East and West Malaysia. The base in West Malaysia is designated as the intervention group and the other in East Malaysia as the control group. The bases are active 24 hours a day, seven days a week. The interventional and control group are comparable in terms of fatigue level, but have different locations to avoid cross contamination. The comparability of both groups in terms of the fatigue levels will be ascertained by a baseline screening of the fatigue levels. There are administrative personnel, air crew, and ground crew at the bases. Air crew and ground crew comprise the vast majority of the air base's employees. The inclusion criteria for this study will be air crew and ground crew involved in active

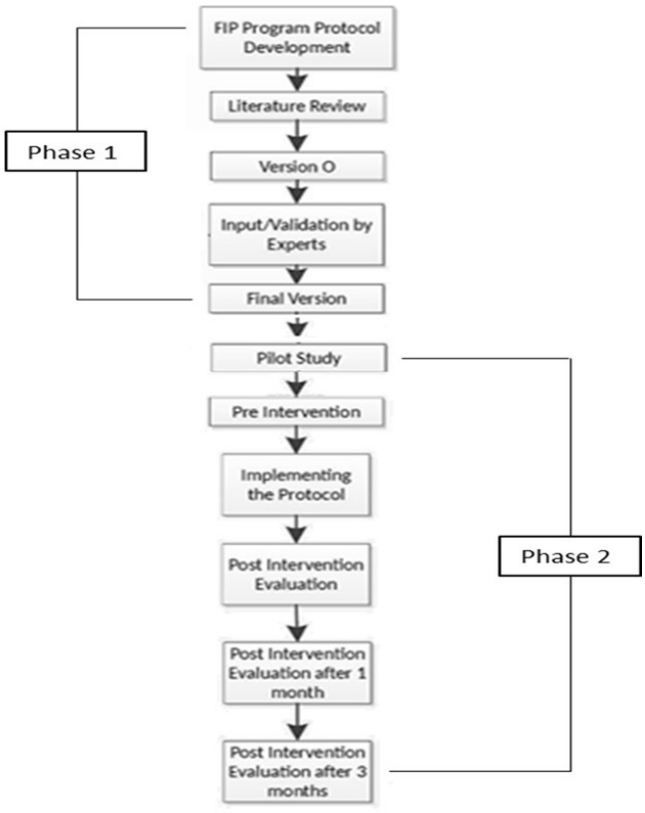

Figure 1: Phases of Fatigue Intervention Program (FIP)

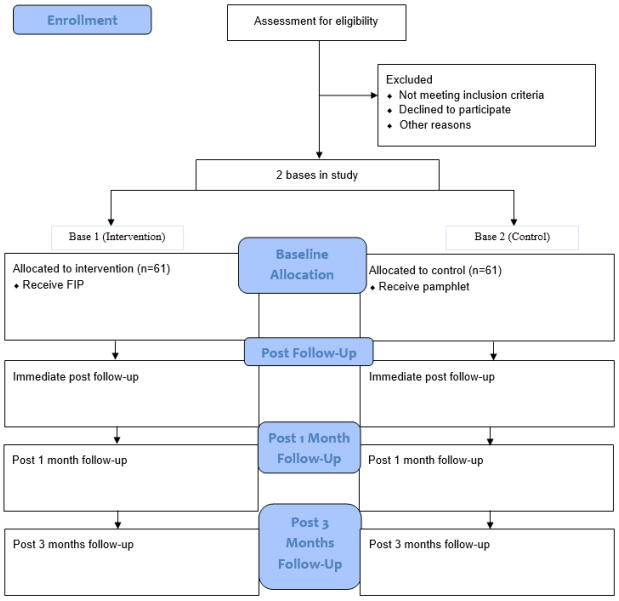

Figure 2: Flow diagram of study

duty while are able to converse in English or Malay language. The exclusion criteria are all administrative personnel, psychiatric diseased workers and pregnant staffs. The duties of ground crew include aircraft loading, unloading, and refueling, servicing, repair, and maintenance, as well as the operating of a variety of service vehicles to support these tasks. The ground crew mustering is also responsible for road ground crew duties, including vehicle dispatch, fleet management, and accident management. Aircrew members have a variety of responsibilities, including working in the air, operating numerous pieces of equipment, and making crucial judgements in difficult environments. Aircrews are ultimately responsible for the safe and efficient fulfilment of a specific assignment. They are responsible for flying the aircraft and executing a variety of other responsibilities. Overall, the air crew and ground crew's job scope complement each other and plays a crucial role as a whole for the continuance of the air services despite the differences in the job scopes. Therefore, the air and ground crew of an East Malaysia air base as a whole will be compared with the air and ground crew of a West Malaysia air base in this study.

A written informed consent will be obtained from all eligible participants. Participation in the study will be entirely voluntary, and participants will have the option to freely withdraw from the study at any point during the course of it. Prior to that, all participants will be handed participant information sheets that will provide information about the study (purpose, procedures, risks, benefits, alternatives to participation).

FIP Program

Participants in the intervention group will come from an air base located in the Klang Valley in Malaysia. The ground and air crew, who have satisfied the inclusion requirements shall be considered qualified to participate in the activities carried out by the research team. Participants from the intervention group will get the intervention in the form of Fatigue Intervention Program (FIP) once. The FIP is composed of two distinct components. The first component (knowledge) is education in the form of a presentation to the crew addressing work fatigue to offer knowledge to the participants on work fatigue, symptoms, indicators, and effects of work fatigue. The demonstration of the Deep Breathing Exercise (BE) makes up the second component (activity) of this intervention. It is required that the participants perform the Deep Breathing Exercise two times each day, every day, for a period of three months. The participants will each receive a video guide, a booklet for self-recording, and a written guide. The participants will be evaluated using the Multidimensional Fatigue Inventory (MFI) to assess the primary outcome, Pittsburgh Sleep Quality Index (PSQI) questionnaire to assess the secondary outcome and quiz to assess the knowledge given at baseline, post intervention, 1st and 3rd month post intervention. The quiz consists of 10 multiple choice questions, each with 4 possible choices.

Enrollment will last approximately one month, followed by three months of data collecting. Overall, the FIP was established through a comprehensive literature review and extensive consultations with experts, resulting in the synthesis and integration of their expert opinions. Publications subjected to peer review will be used to distribute study results to stakeholders at the Institute of Aviation Medicine in Malaysia and throughout the world.

Ethics Approval

The study has approval from the University of Malaya Research Ethics Committee (UMTNC2/UMREC_1811). Consent to participate will be attained from participants prior to completing and submitting the survey responses.

Clinical Trial Registration

The study also has been registered in Thai Clinical Trials Registry with approval number TCTR20221004004.

Outcomes and Measures

Clinical outcomes will be evaluated with paper version of two validated screening instruments, such as the MFI and PSQI questionnaire. The participants will be required to answer the bilingual questionnaires which consists of a compilation of English and Malay versions. The participants are free to answer either the English or Malay versions. The MFI is a questionnaire which has been developed and validated questionnaire to ensure internal consistency and reliability in measuring the primary outcome fatigue (17,18). In addition, the Malay validated version of the MFI will also be used in this study (11). The adaptability of the MFI permits the questionnaire to provide a psychometrically sound assessment of work fatigue in the aviation population

and can enhance the comparability of results across studies of the aviation population (19,20). The MFI-20 is a 20-item self-report tool designed to assess five characteristics of fatigue (general fatigue, physical fatigue, reduced activity, reduced motivation, and mental fatigue) (21). Each question is graded from one to five, and there are five questions per dimension. Consequently, the dimension score spans from 4 to 20 (a higher score indicates more fatigue).

In addition, the secondary outcome of sleep quality will be evaluated using the english and malay validated version of Pittsburgh Sleep Quality Index (PSQI) questionnaire (22,23). PSQI is a self-administered measurement instrument developed by Professor Daniel J. Buysse will be utilised to evaluate sleep quality as a secondary outcome (22). The Pittsburgh Sleep Quality Index (PSQI) is a valuable assessment instrument that has been employed in several aviation studies with comparable validity and reliability (24,25). The nineteen factors are classified into five categories such as sleep length, sleep disturbance, sleep latency, day dysfunction owing to sleepiness, sleep efficiency, overall sleep quality, and sleep medication usage. The scores for each category range from 0 to 3, with 3 representing the highest dysfunction, while the overall score ranges from 0 to 21. A total score greater than 5 indicates poor sleep quality.

Sample Size Estimation

The sample size was obtained using version 3.1.7 of GPower. The sample size was estimated based on the specified objectives. The greatest sample size was chosen based on the sample size calculation for the purpose of determining the effectiveness of exercise in reducing employee job fatigue. Ghanbari's study demonstrating the effect size of the exercise intervention necessary to decrease fatigue was used for the sample size calculation (13).

This study's total sample size was determined to be 30, based on power of 85%, α 0.05, and effect size of 0.70 based on the study by Ghanbari (13). The anticipated attrition rate of 20% yields an estimated total sample size of 36. Given that this is an interventional study and that the ICC for the design effect is 0.02 (26), a total of 61 samples were calculated for each arm, for a grand total of 122.

Statistical Analysis

All analyses will be done using International Business Machines Statistical Package for Social Sciences (IBM SPSS) for Windows, version 28.0. The degree of significance will be set at $p<0.05$. The program module content validation index based on the evaluation by the experts as per Table 1 was done using the Content Validation Index calculation method developed by Professor Mahmoud Danaee (27). Furthermore, upon implementation of the module, the characteristics of the participants in relation to the variables will be described using a descriptive analysis based on percentages, frequencies, and the mean. In addition, the effectiveness of the FIP will be analysed emphasizing on Intention to Treat (ITT) analysis. The Generalized Estimating Equation (GEE) will be utilised to assess the statistical significance of the effects of intervention (time * group) on the fatigue measurement. It will be used to compare the mean response over time between the intervention and control groups.

Table I: Content Validity Index of evaluation of the Program Module Contents

FIP Module Contents	Content Validity Index (CVI)	Kappa
Knowledge session	1.00*R,C	1.00*R,C
Activity session	1.00*A,R,C 0.90*AG	1.00*A,R,C 0.90*AG
Questionnaires	1.00*A,R,C 0.95*AG	1.00*A,R,C 0.95*AG
Quiz	1.00*A,R,C,AG	1.00*A,R,C,AG

*R is Relevancy, C is Clarity, AD is Adequacy and AG is Agreeable

RESULTS

Program Module Content Validation

The evaluation of the protocol by the experts is tabulated as Table I.

DISCUSSION

Expected Findings

Fatigue is a multifactorial condition that leads to disease and loss in production, and it affects a large number of workers worldwide. This study aims to demonstrate a Fatigue intervention program (FIP) that individuals will perform during the work schedule, and to evaluate the effectiveness of this exercises program for fatigue control.

The hypothesis investigated in this study is that the use of a practical, cost-effective, and easily accessible method for delivering an occupational intervention for air personnel who may be suffering job fatigue. It is understood that improving fatigue at work could have a substantial influence on the health, lifestyle, psychological safety, and well-being of air personnel (19,28).

The objective of this study is demonstrating a FIP protocol to be performed at the workplace during the work schedule, and to describe the procedure that will be used to evaluate the effectiveness of this program in fatigue management for air personnel. However, the current study has not been conducted yet and is expected to reduce fatigue in the intervention group compared to the control group. The FIP is expected to reduce 20% to 50% of general, physical and mental

fatigue while improving the motivation and activity by 10% to 30% of the personnel at work. Besides that, the FIP is expected to significantly improve the duration of sleep, sleep latency, sleep efficiency and sleep quality by 10 to 30%. The program is also expected to significantly reduce sleep disturbance and days dysfunctional due to sleepiness by 10 to 30% among the air personnel.

The reduction in fatigue is expected to be consistent with other studies (12,29,30). The estimated reduction in fatigue is further supported as the participants in this study will be practicing deep breathing exercise for three months in comparison to a study finding of fatigue reduction by practicing breathing exercise for four weeks by Tanja et al. in 2019 (30). Besides that, this study findings are also expected to be comparable with the findings of Sutinah and Azhari (2020), who found that conducting deep breathing exercise resulted in a significant reduction in the amount of fatigue experienced by the interventional group in comparison to the control group (12). Furthermore, performing deep breathing exercises at least twice daily also significantly decreased the total mean percent fatigue score in the intervention group compared to the controls (29).

All of these previous study findings support the current study's hypothesis; highlighting a significant difference in the levels of fatigue experienced by the control group and the intervention group as a result of participating in the deep breathing exercise. This could be due to the fact that, deep breathing exercise triggers the parasympathetic nervous system to release noradrenaline (12). This, in turn, slows the heart rate, increases lung expansion, and relaxes the muscles. In addition, breathing raises the amount of oxygen that the body takes in while simultaneously removing excess carbon dioxide (12). This helps the body produce more energy and reduce levels of fatigue (12).

Furthermore, despite fatigue being a highly relevant topic, very few studies have assessed the effect of a fatigue intervention program at the workplace. We expect that this intervention with deep breathing exercise will have high adherence by the air personnel and will reduce the occurrence of fatigue symptoms. We believe that deep breathing exercise can be effective for fatigue reduction and improving sleep quality. The program will bring many benefits to the participants, including good maintenance of health, reduced perception of fatigue, reversal of fatigue, reduction in complaints and pain, improved quality of life, higher productivity, improved mental health, and positive changes in lifestyle. We also expect that the results of this study will contribute significantly to the decision-making capacity of professionals working in the field of occupational health.

Limitations of the Study

Firstly, although validated questionnaires are used to quantify job fatigue, the evaluation is not intended to be diagnostic. The Hawthorne effect is a second potential drawback of this study. The very nature of the persons under study, observation, or investigation might influence them and hence the outcomes. With many follow-up points such as post intervention, post 1 month intervention and post 3 months intervention, this limitation is expected to be reduced. Despite these limitations, this is novel research to establish a programme to address job fatigue among air personnel in Malaysia. This study is also the first study to evaluate the effectiveness of a developed FIP in decreasing job fatigue among air personnel in Malaysia. The findings would be of interest to policymakers, particularly those in the occupational health sector.

CONCLUSION

This study will assess the effectiveness of a developed FIP in decreasing job fatigue among air personnel. The research will have a substantial impact on the management of job fatigue among air personnel. If the results are positive, the FIP can be advocated as a technique to reduce job fatigue among Malaysian and foreign aviation personnel. The study outcome will also compliment policy decision-making for health care resource allocation in support of the occupational health sector. Furthermore, the evidence from conducting this study may be used by the aviation organizations as the 24/7 nature of aviation means that fatigue will always be a consideration in accident investigations. The organizations and policy makers could make evidence-based decisions from the future findings of this study as a part of their fatigue regulatory framework to ensure air personnel operate safely by making use of the program to manage fatigue among their air personnels.

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