EFFECT OF SLEEP HEALTH EDUCATION ON THE SLEEP QUALITY OF HEALTHCARE WORKERS IN HEALTH CLINICS: STUDY PROTOCOL

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ABSTRACT

Background: Healthcare workers (HCW) are susceptible to develop poor sleep quality. Those with poor sleep quality are more likely to experience adverse effects on their health and work performance. Sleep health education could be beneficial to improve their sleep quality.

Materials and Methods: All eligible HCW from the participating clusters (health clinics) will be recruited. A minimum of 210 participants will be required in the two arm, parallel, cluster randomised trial. Five clusters will be randomly allocated into either intervention group or control group respectively. Intervention group will be given sleep health education whereas control group will be given pre-existing occupational health module on mercury spillage management.

Result: The panel of subject experts will be consulted to develop the intervention module. For implementation, the intervention modules will be given to the participants from each group accordingly. For evaluation, sleep quality will be measured based on self-administered questionnaires at baseline and three months post intervention. Data analysis will be done by using Statistical Package for the Social Sciences (SPSS) version 25. Intention to treat analysis will be done with the level of significance set at 0.05 and confidence level at 95%. For bivariate analyses, chi square and logistic regression will be used for categorical variables whereas linear regression for continuous variables. For multivariate analysis, Generalized estimating equations (GEE) will be used to adjust for the clustering effect.

Conclusion: Sleep health education, particularly on sleep hygiene practice is essential to improve HCW’s sleep quality.

Keywords: study protocol, sleep health education, sleep quality, healthcare workers
1.0 Introduction

1.1 Background

In general, any acute or chronic sleep problems could be collectively known as poor sleep quality (Irish, Kline, Gunn, Buysse & Hall, 2015). The poor sleep quality can be quantified by sleep latency more than 30 minutes, sleep efficiency less than 85%, wake up more than 30 minutes during sleep or total sleep duration less than 6.5 hours (Mollayeva et al., 2015). Although the symptoms are often subclinical, workers with poor sleep quality are at risks of other serious medical conditions and all-cause mortality (Irish et al., 2015). In Australia, sleep disorders were considered as higher risk factor to other health conditions as compared to alcohol abuse or unsafe sex (Hillman, Murphy, Antic, & Pezullo, 2006).

HCW refer to all people “engaged in the promotion, protection or improvement of the health of the population” (Poz, Kinfu, Drager & Kunjumen, 2007). The sleep quality of HCW tends to be affected by their intensive workload, medical disputes with colleagues, heavy responsibilities in caring for patients round the clock, workplace violence by patients, routine yet unique duties in managing diseases, traumas and death as well as the resulting mental stress (Han, Yuan, Zhang & Fu, 2016). One fifth of the general population suffers from poor sleep quality whereas the proportion is about one third in working adults (Czeisler, 2015; Han et al., 2016). In Malaysia, the prevalence of poor sleep quality among hospital nurses were 57.8% (Nazatul, Salmy, Moy & Nabila, 2008).

Poor sleep quality would impair a person’s attention, neurobehavioural performance, mood and cognition (Czeisler, 2015). Disrupted sleep among HCW would lead to building up of sleep inertia, which can be manifested as inability to recall events upon waking up, reduced alertness, slow information processing and poor judgment. The efficiency of clinical tasks carried out by them would also be affected, thus compromise the quality of patient care. With insufficient sleep recovery subsequently, the vicious cycle of poor sleep quality and workplace errors sets off (Owens, 2007). HCW’s work performance would eventually drop due to poor sleep quality.

Study had shown that both sleep knowledge and sleep hygiene practice were positively correlated with the participants’ sleep quality (Gallasch & Gradisar, 2007). Neglect of sleep quality due to work or maladaptive sleep hygiene practice may predispose HCW to various adverse health outcomes (Peach et al., 2016; Nakada, Sugimoto, Kadotani & Yamada, 2018). While the use of medications may be helpful as a short term measure, the non-pharmacological methods would be ideal for a long term solution to promote better sleep quality (Kakinuma et al., 2010; Kaku et al., 2012; Morimoto et al., 2016).

Since HCW are prone to develop poor sleep quality, interventions to improve and maintain their sleep habits becomes very crucial (Kaku et al., 2012). In Malaysia, only one prevalence study on HCW’s sleep quality was done in a public hospital but no interventional study had been conducted so far (Nazatul et al, 2008). Elsewhere, the effectiveness of sleep health education program on the sleep quality of different working groups had been studied across the regions with promising results (Nishinoue et al., 2012; Poulsen, Sharpley, Bauman, Henderson & Poulsen, 2015; Nakada et al., 2018). Whilst most studies conducted were
specific to hospital based HCW, there was none to the authors’ knowledge which had explored the effect of sleep health education on the clinic based HCW’s sleep quality (Sarid, Berger & Segal-Engelchin, 2010; Carter, Dyer & Mikan, 2013; Poulsen et al., 2015).

1.2 Research question

As prevention is better than cure, the researcher intends to explore the effect of primary prevention strategy like sleep health education on the HCW’s sleep quality between and within groups at baseline and three months post intervention.

1.3 Objectives

This study aims to determine the prevalence of poor sleep quality among HCW, as well as to develop, implement and evaluate the effectiveness of sleep health education on the sleep quality of the HCW working in government health clinics.

1.4 Theoretical framework for sleep health education

Health Belief Model (HBM) is commonly used for prediction of preventive health behaviours, sick role behaviours and for clinical use (Conner & Norman, 2005). HBM contains six constructs, namely perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy, and cues to action which helps to predict the action taken by people to prevent medical conditions (Taylor et al., 2006). Once an individual perceives that he is more susceptible to an adverse health outcome, perceives that this outcome could have more serious consequences, and that the benefits of the action would outweigh the barriers, then he is more likely to engage in changing his health behaviour to minimize the risks (Glanz, Rimer & Viswanath, 2008). Study had shown 34% of the sleep behavior change can be explained by the HBM (Knowlden & Sharma, 2014).

2.0 Materials and Methods

2.1 Study location

The study will be conducted in Gombak district, the third most populated district in Selangor state with 706,200 (12.2%) residents living in the district. Gombak District Health Office (PKDG) has established ten government health clinics to cater the health needs of the local community. The range of healthcare services includes outpatient management of acute illness and chronic diseases, antenatal and postnatal care, immunization, family planning, medical screening, minor surgeries, and hospital referral for inpatient management. From 2010 to 2017, PKDG had reported a substantial increment in the total number of outpatient visits by 55.3%, which was from 658,580 patients to 1,022,731 patients annually (Selangor State Health Department {JKNS}, 2015; JKNS, 2019).
2.2 Study design

A parallel, single blind, cluster randomized trial (CRT) study will be conducted in view of its feasibility consideration for logistic arrangement and prevention of data contamination during the study period. The clusters refer to the health clinics within the district. There will be two arms for this study, namely intervention group and control group. Simple randomization method will be used to allocate equal numbers of participating clusters into group. The result of randomization will not be informed to the clusters and the participants in order to ensure allocation concealment. The intervention group will be given sleep health education whereas the control group will be given seminar on handling of mercury spillage in healthcare facilities based on existing occupational health module. Single blinding technique will be applied in which the respondents are unaware of the outcome assessment throughout the study period in order to avoid respondents’ bias.

2.3 Study population

There are 671 staff working in health clinics in Gombak district which comprises of medical doctors, pharmacists, assistant medical officers, staff nurses, community nurses, nursing aides, radiographer, medical laboratory technicians, and health attendants.

Any eligible HCW working in any of the government health clinics within Gombak district will be invited to join this study. The eligibility criteria are set to include those who are Malaysia citizen and have at least one year of working experience in the current health clinics, but those who receive medical treatment for any mental illnesses will be excluded.

2.4 Recruitment of study population

The researcher will send in a formal request to the state health department for permission on the conduct of this study. After that, a meeting with the district health officer will be arranged to brief him on the study’s objectives, interventions involved, flow of study and the potential benefits. Next, another meeting will be held with the respective person in charge from the ten health clinics available, namely Klinik Kesihatan (KK) AU2, KK Batu 8, KK Batu Arang, KK Gombak Setia, KK Hulu Kelang, KK Kuang, KK Rawang, KK Selayang Baru, KK Sungai Buloh and KK Taman Ehsan. The implementation details will be discussed with them to encourage the enrolment of the health clinics. The name lists of the HCW working in each health clinic will also be collected during the meeting.

Upon completion of cluster enrolment, the respondent’s information sheet will be disseminated to the individual HCW within the participating clusters to provide details of the study. HCW who are interested to enrol into the study will have to submit a consent form. Each participants will be reimbursed RM20 for their time spent throughout the study period. In addition, meals will prepared for the participants who attend the intervention program.

2.5 Sample size estimation

In view of the limited clusters available in Gombak district, the cluster size per arm has been pre-determined as five. The sample size estimation is based on formula used for CRT with a fixed number of cluster but unequal cluster size (Hemming, Girling, Sitch, Marsh & Lilford,
2011; Hemming, Eldridge, Forbes, Weijer & Taljaard, 2017). The value of intracluster correlation coefficient (ICC) is 0.02 based on study by Martinson, Murray, Jeffery & Hennrikus (1999). The values for difference in treatment means and standard deviation used are 1.66 and 2.32 respectively in the formula (Lee, Gay & Alsten, 2014). After the consideration of 20% attrition rate, at least 101 participants are required per arm. In another word, each cluster needs to recruit at least 21 participants and the minimum total sample size would be 210 participants for ten clusters.

![Flow diagram of participant’s recruitment](image)

**Figure 1:** Flow diagram of participant’s recruitment
2.6 Data collection

The study instrument is a self-administered questionnaire which is written in both English and Malay languages. The questionnaire has five sections, namely Section A: Sociodemographic characteristics, Section B: Employment characteristics, Section C: Sleep quality, Section D: Sleep hygiene practice, and Section E: Perception towards sleep quality and its intervention.

For Section C on “Sleep quality”, the questions are adapted from Pittsburgh Sleep Quality Index (PSQI) based on study by Buysse, Reynolds, Monk, Berman & Kupfer (1989). Permission to use both the English and Malay version of PSQI has been obtained from the author, Professor Buysse. This adapted questionnaire is a standardized, structured, validated and pre-tested questionnaire.

For Section D on “Sleep hygiene practice”, the questions are adapted from Sleep Hygiene Practice Scale (SHPS) based on study by Yang, Lin, Hsu & Cheng (2010). Permission to use SHPS has been obtained from the author, Professor Chien-Ming Yang. For Section E on “Perception towards sleep quality and its intervention”, the formulation of questions is based on the major constructs of HBM (Conner & Norman, 2005).

2.7 Data analysis

Univariate analysis will be used to summarise the characteristics of both the dependent variables (DV) and independent variables (IV) at baseline. For descriptive characteristics of the respondents, numerical data will be presented by using frequency, mean, median, standard deviation and interquartile range (IQR); whereas categorical data will be presented in terms of proportion and percentage. Data normality will be checked mainly by the appearance of bell shaped curve on histogram, followed by other normality tests such as Kolmogorov-Smirnov test and Shapiro-Wilk test.

Intention to treat analysis will be done in which last observation carried forward (LOCF) method is used to handle any missing data so that all respondents will be included in the final data analysis (Gupta, 2011). For bivariate analyses, chi square and logistic regression will be used for categorical DV; whereas t-test and linear regression will be used for continuous DV. The assumptions for each statistical method will be checked before its application. The level of significance are set at 0.05 and the confidence level at 95%. For multivariate analysis, Generalized estimating equations (GEE) will be used to adjust for the clustering effect in this study.

2.8 Quality control

A pre-test will be done conducted to verify the validity and reliability of the questionnaire. As the questionnaire in available in both English and Malay version, the forward (English to Malay) and backward (Malay to English) translation will be done by five volunteers who can understand both languages to ensure the similarity of the questions.

For content validity, the questionnaire will reviewed by a panel of subject experts with regards to the domain clarity, content relevance and representativeness.
For face validity, the formatting, wording, sequencing and understanding of all the questions will be considered based on feedback from respondents during the pre-test.

For the reliability, the questionnaire will be checked by the internal consistency test or Cronbach’s alpha test on a similar study population of different location.

### 2.9 Operational definitions

Sleep quality is defined as the assessment of an individual sleep quality based on PSQI scoring. A higher score indicates worsening of sleep quality and it can also be categorised into good sleep quality (PSQI≤5) or poor sleep quality (PSQI>5) (Buysse et al., 1989).

Sleep hygiene practice is defined as the assessment of individual’s level of sleep hygiene practice based on SHPS scoring. A higher score indicates poorer sleep hygiene practice and vice versa (Yang et al., 2010).

### 3.0 Intervention strategies

#### 3.1 Intervention development

A situational analysis is done to explore the magnitude sleep issues among the HCW and the necessity for intervention. Based on the literature review, the higher prevalence of poor sleep quality among HCW could be attributed to their poor sleep hygiene knowledge and practice in addition to other factors like socio-demography and employment factors. The need for an intervention to address the poor sleep quality among the HCW is indicated.

Consultation with a panel of subject experts from Universiti Putra Malaysia (UPM) and Ministry of Health (MOH) via a series of meeting are done to develop the intervention module. The expert panel comprises of one occupational health specialist, otorhinolaryngology specialist with special interest in sleep medicine, one public health physician and one medical officer in charge of quality unit in district health office. The first draft of the intervention module is prepared based on the initial meeting outcome with the expert panel. The revised draft is again presented to the expert panel for more inputs during subsequent meetings. HBM has been identified as a suitable model in which the six constructs have been incorporated in the final module.

#### 3.2 Intervention implementation

Engagement with the stakeholders prior to implementation is done to anticipate the challenges or barriers during the study period. As mentioned earlier, permission form cluster and individual have been obtained before baseline assessment of the participants. Respondents are informed of their rights to withdraw from study at any time without any implications on their medical benefits and other work entitlements.
The baseline data collection is anticipated to complete within two weeks (week 1 to week 2). The delivery of intervention to all clusters is also anticipated to complete within the subsequent eight weeks (week 3 to week 10). The intervention can be divided into initial phase and maintenance phase.

During the initial phase, participants are required to attend a one-day seminar once during the study period. The seminar includes health talks, group discussion and group presentation which starts from 8.00 in the morning until 4.00 in the afternoon. There are three topics for the health talk and each topic is allocated 45 minutes for presentation, 10 minutes for quiz and 5 minutes for question and answer (Q&A) session. A checklist has been prepared to ensure the similar program content to be given during all sessions. Each session only allows up to fifteen participants to enhance their learning experience. The different groups will receive different module accordingly as mentioned earlier.

During the maintenance phase, text messages are sent out to each participant for four consecutive weeks. These messages serves as a checklist to monitor their sleep quality in addition to encourage their compliance with the sleep hygiene practice.

The second evaluation starts twelve weeks after the intervention and to be completed within two weeks (week 23 to 24) by using the same questionnaire. In summary, the intervention would be completed within twenty four weeks. Monitoring will be done throughout the study period and participants are advised to report any adverse events experienced related to the study. For those who miss the follow-up visits, the researcher will make one additional on-site visit and sent up to 2 reminder messages to encourage them to complete the post-intervention evaluation.

3.3 Intervention evaluation

Evaluation is done for the study process and desired study outcomes. For process evaluation, the time management, quality of intervention module, satisfaction among respondents, competency of the helpers and the study data security will be taken into consideration for improvement in future study. As for the outcomes evaluation, comparison of the respondents’ behavioural change before and after intervention are explored by using various statistical methods. In addition, respondents with persistent poor sleep quality are offered for optional follow-up visits under medical specialist.

4.0 Discussion

WHO estimated 59.2 million HCW worldwide and has recognised them as the most valuable resource for health (WHO, 2006). The HCW’s job responsibility, which includes extended working hours whenever necessary, stay vigilant while on duty, constant learning of any evolving medical technologies, and to perform life saving measures under time constraint, had exerted enormous pressure on them (Senol, Soyuer, Guleser, Argun & Avsarogullari, 2014). There is a growing concern of poor sleep quality among HCW in view of its adverse effects on workers’ health, work productivity and workplace safety. Study had reported that HCW with poor sleep quality would experience mood disturbance, higher stress level, potential for
substance or alcohol abuse which in turn will negatively affect their personal and family life (Owens, 2007). Thus, this study intend to develop a study protocol to improve HCW’s sleep quality via sleep health education.

For the study design, CRT has several challenges during implementation phase (Taljaard & Grimshaw, 2014; Schlevis et al., 2015) which are discussed as below. The refusal of cluster to be in the control group is common as most would prefer the desired intervention rather than placebo. Thus, the cluster should be briefed on the randomisation and allocation concealment process prior to enrolment in order to avoid selection bias. Besides, application of blinding technique in any clinical trials is necessary to prevent assessment bias (Campbell, Piaggio, Elbourne & Altman, 2012). For community trial, the intervention is usually group based and the participants would know the type of intervention received through communication with others. Therefore, strict adherence to blinding technique in community trial, unlike clinical trial, may not be feasible. Besides, the internal change within the cluster, for example staff turnover may affect the final result reliability. Thus, the attrition rate needs to be considered in sample size estimation to ensure that adequate clusters and participants will be recruited. In addition, intention to treat analysis is the method of choice for data analysis in community trial than per protocol analysis to avoid bias due to exclusion of certain participants.

The intervention module is based on HBM, which is one of the popular social-psychological models to predict preventive health behaviour as well as to determine the sustainability of the behaviour change (Darnton, 2008). Study has shown that the HBM constructs, such as self-efficacy, perceived severity, cues to action and perceived barriers as the significant predictors by using a statistical model (Knowlden & Sharma, 2014). The same author elaborated that perceived severity, cues to action, self-efficacy were shown to have positive relationship with sleep behaviour whereas there is negative relationship between perceived barriers and sleep behaviour in his hypothesis testing. All six constructs of HBM are incorporated in the delivery of intervention during the initial phase and subsequent maintenance phase.

In terms of the module content, sleep health education alone was not effective to improve sleep quality significantly (Nishinoue et al., 2012; Carter et al., 2013). The combined sleep health education and behavioural approaches had demonstrated better results among participants, even for the non-clinical population (Ridge, Wells, Denny, Cunningham & Chalder, 2011; Kaku et al., 2012; Nishinoue et al., 2012; Carter et al., 2013; Gavrilă-Ardelean & Moldovan, 2014). Thus, the combined approach has been adopted in the study protocol to improve the intervention’s effectiveness.

Besides, intervention that required input from a trained occupational health personnel rather than a clinical specialists was reported to be more cost-effective and more feasible for large scale implementation (Kojima et al., 2010). This study has adopted the similar approach to engage with a medical officer with occupational health training to deliver the module instead of a clinical specialist. In addition, the group sessions held at worksite had also enhanced participation and compliance among participants during the study period (Orly, Rivka, Rivka & Dorit, 2012; Poulsen et al., 2015). Both the group based session (face to face interaction) and the individual based session (telecommunication) are included in the study protocol for better effect.
Intervention that required longer time commitment in the program was reported with lower completion rate due to poor acceptability among participants. (Imamura et al., 2014; Imamura et al., 2015). Although higher frequency of intervention increased the likelihood of better outcome among participant, it is not feasible to implement in the worksite setting (Kojima et al., 2010). Positive effect on sleep quality had been reported in study which required only single session of health education (Kaku et al., 2012). This intervention is designed to deliver the necessary training to the participants within one full day session at worksite followed by telecommunication in order to reduce the drop out rate.

5.0 Conclusion

In summary, sleep health education is important to improve the HCW’s sleep hygiene practice and sleep quality. CRT is an ideal study design to explore the effectiveness of such occupational health intervention. This intervention has adopted the combined approach during its implementation which includes the individual and group sessions, face to face and telecommunication interactions, health education and behavioural approach in order to enhance participants’ learning experience and to promote better compliance. This worksite intervention also facilitates the participants’ accessibility to the essential sleep health information for self-improvement. Besides, the intervention only requires medical officer with occupational health training to deliver the module has lowered the threshold for replication in future study. The sleep health education as the primary preventive measure to improve sleep quality among HCW has the potential to reduce both the direct and indirect cost in long term.

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Declaration

The authors declare that there is no conflicting interest.
Authors contribution

Author 1: Literature gathering, information analysis and preparation of manuscript
Author 2: Supervision of research, final review and editing of manuscript

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