



SNORE (Sleep Deprivation Among Night Shift Health Staff on Rotation Evaluation) Study Protocol

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ABSTRACT

Background: SNORE (Sleep deprivation among Night shift health staff On Rotation-Evaluation) study is conceptualized to study the effects of sleep deprivation on healthcare professionals working night shifts on rotation.

Materials and Methods: A comparative cross-sectional study is devised including health-care professionals working night shifts on rotation at a tertiary level health-care facility, using a semi-structured questionnaire which can test sleep deprivation, cognitive ability, and quality of life. The process is to approach 309 probable study participants based on stratified random sampling, after exclusion of health-care professionals with other factors which may interfere with sleep deprivation testing.

Discussion: The study protocol was set in such a way as to randomly include participants from all cadres of healthcare providers as per population proportion. By measuring the effects on cognitive effect and quality of life necessary steps can be taken to provide better quality of life and to decrease cognitive impairment, especially among health care professionals working night shifts.

Key words: SNORE, Sleep deprivation, Cognition disorders, Quality of Life, Healthcare providers, Work satisfaction, Shift work sleep disorders, Jet lag syndrome

BACKGROUND

SNORE (Sleep deprivation among Night shift health staff On Rotation Evaluation) study is conceptualized to study the effects of sleep deprivation on healthcare professionals working night shifts on rotation. Sleep deprivation has been suggested to have a deleterious effect on health workers who are involved in multitude of life-saving tasks, which often require more attention and concentration.¹ Centre for Disease Control and Prevention and the national health portal (Government of India) have now recognized sleep deprivation as a public health epidemic.²

The aim of the project is to study the effect of sleep deprivation on health-care providers working on night shifts in rotation with the following specific objectives:

Primary objectives of this study were to determine the effect of sleep deprivation on the cognitive functioning of health care providers working on night shifts in rotation and to determine the effect of sleep deprivation on the quality of life of health care providers working on night shifts in rotation

Secondary objectives were to determine difference, if any, in the cognitive function during day and night shifts; to determine the prevalence of sleep deprivation and daytime sleepiness among health care providers working on night shifts in rotation; to determine the relation between hours of sleep and Epworth sleepiness scale scores; and to evaluate the relation, if any, between the existing shift-work pattern and work satisfaction among healthcare providers working on night shifts in rotation

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METHODS

A comparative cross-sectional study was devised to be conducted at a Tertiary level healthcare facility in Chengalpattu District of the Indian state of Tamil Nadu over a period of 18 months. The study has now reached completion phase and is under report generation and publication phase.

Study population consists of health care providers (Doctors and Paramedical staff) working night shifts on rotation at a tertiary level health care facility who have completed 18 years of age and were willing to give consent at the time of study.

Inclusion Criteria: For a potential participant to be included in the study he/she had to have at least 7 hours of continuous night work with an active work pattern between 11 pm and 6 am irrespective of the shift scheduling, i.e. shift could commence any time before 11 pm and end any time after 6 am.³ This included doctors working on rotational night shifts, including consultants and resident doctors; nurses with rotational night shifts, working in wards, Intensive Care Units, Operation theaters, Casualty and Dialysis unit; and paramedical staff including Pharmacy staff and Technicians (Laboratory, Anesthesia, Blood bank, Imaging studies) working on rotational night shifts.

Exclusion criteria: Healthcare professionals with age above 60 years were included taking into consideration their increased susceptibility to sleeplessness due to various other causes like chronic diseases and age-related discomforts. Further, they are also less likely to be on rotational night shifts. The general decrease in sleeping hours with age, quality of life and cognitive ability were also considered.

In strict adherence to the objective of assessing sleep deprivation due to rotational night shifts, healthcare professionals with other potential factors which could cause sleep deprivation or would interfere with the sleep deprivation testing are excluded from the study sample.⁴ A few were - consumption of medicines that would interfere with the sleep, e.g. antihistamines, antitussives, etc. in the preceding 4 weeks; consumption of psychiatric medications at any time prior to the commencement of the study; personal or family history of sleep disorders like obstructive sleep apnoea, familial insomnia or psychiatric disorders; personal history of chronic disorders like migraine, bronchial asthma, diabetes mellitus, hypertension and thyroid dysfunction; pregnant or breast-feeding women up to 6 months post-delivery; and people with history of major life events in the past 6 months that could interfere with sleep like hospitalization or bereavement of a close family member, weddings, preparation for exams or seminars, etc.

Sample size calculation:

Assuming a 95% confidence interval, 8% allowable error, and a design effect of 2, the sample size for the

present study was calculated using the formula: $(4pq)/L^2$.

The minimum sample size required to identify the prevalence of cognitive impairment worked out to **281** taking a 66% anticipated prevalence of decreased cognitive function and the calculated minimum sample size required to identify the prevalence of sleep deprivation was **267** taking a 69% expected prevalence of poor sleep among health care providers working on night shifts from a previous study done under similar settings by Kaliyaperumal et.al.⁵

To account for both the variables 281, being the larger figure, is chosen as the minimum required target sample size for the SNORE study. To account for a non-response rate of about 10%, a total of 309 healthcare providers are approached for participation in the study.

Sampling method: Stratified Random sampling method was used for the selection of the study population (Figure 1). Health care professionals are divided into two strata: doctors and paramedical staff (Figure 2). The paramedical staffs are further divided into 3 strata: nurses, technicians & pharmacy staff.

Population proportional to size is taken for choosing sample from each stratum (Table 1) and each individual participant is finally chosen by simple random sampling. The staffs are placed in order according to their HR number and each individual participant is chosen using random number generation in SPSS.

Study tool: A 4-part, pre-validated, semi-structured interview schedule is used for the data collection. Prior to data collection, the schedule is validated for its content among 4 resident doctors to ensure that the contents are comprehended, and internal consistency is maintained with a Cronbach's alpha of 0.79. A pilot study (N=30) was conducted, prior to the commencement of the detailed study. The interview schedule is designed to include four sections, namely:

Section 1 - Socio-demographic details: This section included five areas: personal details, possible reasons (other than rotational night shifts) which may interfere with sleep testing or quality of life, details about rotational shift work schedule, sleeping patterns and work satisfaction.

Section 2 - Epworth Sleepiness Scale:⁶⁻⁹ The Epworth Sleepiness Scale directs the respondents to rate, on a 4-point scale (0-3), their likelihood of dozing off or falling asleep while involved in eight different activities; the minimum possible score from the scale being '0' and the maximum being '24'. A greater EPSS score implies a higher 'average sleep propensity' in daily life (ASP) or increased 'daytime sleepiness' for an individual (Table 2). If one or more item-scores are missing, that EPSS is unacceptable because it is not feasible to interpolate missing item-scores. It has the limitations of being a subjective measure (affected by bias and inaccuracy).

For the purpose of the present study, sleep deprivation based on EPSS scores are interpreted based on the values recommended by the 'Thoracic and sleep group' for the possibility of having a sleep abnormality. A score of 0-7 suggests that it is unlikely the patient is abnormally sleepy during the day and any higher score is indicative of the increasing possibility of abnormal daytime sleepiness resulting from inadequate sleep.

Section 3 - Short Form-12 Quality of Life Questionnaire (Version 1):¹⁰⁻¹³ The SF-12 is a self-reported outcome measure assessing the quality of life of an individual and is a shortened version of its predecessor, the SF-36. SF-12 was designed to reduce the burden of response on the individual as it uses only 12 questions to measure the functional health and well-being from the patient's point of view, under the same eight domains as SF-36 which are 1) Limitations in physical activities because of health problems, 2) Limitations in social activities because of physical or emotional problems, 3) Limitations in regular role activities because of physical health problems, 4) Bodily pain, 5) General mental health (psychological distress and well-being), 6) Limitations in regular role activities because of emotional problems, 7) Vitality (energy and fatigue), and 8) General health perceptions

The 12 items of SF-12 explain more than 90% of the variance of the physical and mental component scales. Two scores- physical (physical component summary-12 [PCS-12]) and mental (mental component summary-12 [MCS-12]) components summary-are computed from the individual responses. The scoring of SF-12 QOL for the SNORE study has been recommended by Ware, John & Kosinski, M. & Keller, S. The SF-12 scores run from 0 to 100, where higher scores indicate better QOL. A score more than 60 is regarded as high, 40-60 as normal, and <40 as impaired (low) QOL.

Section 4 - Montreal Cognitive Assessment Test (MoCA):¹⁴ The Montreal Cognitive Assessment (MoCA) is a brief, 30-question test which measures executive functions and multiple cognitive domains which are important components not measured by the MMSE (Mini Mental Status Examination). MoCA scores range from a minimum of 0 to a maximum of 30. The total scores are divided among alternating trail making (1 point), visuo-constructional skills (4 points), naming (3 points), attention (6 points), language (3 points), abstraction (2 points), delayed recall (5 points) and orientation (6 points). Time to administer the MoCA is approximately 10 minutes and a score of 26 or above is considered normal.

For the SNORE study, MoCA tests are administered to each participant twice throughout the study period; once during night shift and once during day shift. It will be ensured that the participants have at least 2-night work free days before the day of administration of the day shift MoCA test to account for any re-

sidual effects, if any, of the previous night shift. Various combinations of the MoCA full test versions- 8.1, 8.2 and 8.3 are used for day and night shifts, to do away with the biases that may arise due to development of familiarity with the study tool.

Study outcomes: The study will assess following factors in healthcare providers working on night shifts in rotation in a tertiary care hospital: (1) Sleep Deprivation, (2) Cognitive Function, (3) Quality of Life, (4) Daytime sleepiness and (5) Work satisfaction

Data management & Statistical analysis:

Data is collected using a semi-structured, standardized questionnaire and recorded using Microsoft excel spreadsheet. Statistical data analysis is done using the Statistical Package for Social Sciences (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp).

Qualitative variables are described in proportions and quantitative variables are described in mean and standard deviation / median and inter-quartile range. Normality of the quantitative data is assessed using Kolmogorov-Smirnov test for normality and all required statistical tests are applied according to the characteristics of the data and the relation with the outcome expected (Table 3). Significance of p value for the study was taken as $p < 0.05$.

Operational Definitions:

Hours of work per night: Duration, in hours, of night work in which a participant involved in, per 24 hours. It is calculated as the number of hours between their clock-in time and clock-out time, including any in shift breaks if present.

No. of working nights per month: Total number of nights a participant has to work in a month including all rotations. (E.g., If a participant has 2 rotations of 2 nights each in a month, the value was taken as 4.)

No. of non-working nights between 2 consecutive night shifts: Total number of off-duty days and number of day shift days present in between 2 consecutive night shift rotations.

No. of years of night shift: Total number of years the participant has been involved in rotational night shift work, both in the present institution and previous institutions (if any).

Hours of sleep: Duration of sleep, in hours, attained by a participant in a day (24 hours). This is calculated by counting the number of hours in between the time they go to bed and the time they wake up.

Sleep deprivation: For the SNORE study, 2 different criteria are applied for classifying a person as conceivably deprived of adequate sleep.

The National Sleep Foundation recommends **7-9 hours** of sleep for adults aged 18-64.¹⁵ For the

SNORE study, participants with self-reported hours of sleep less than 7 are classified as conceivably sleep deprived.

Defining sleep deprivation as “**obtaining inadequate sleep to support adequate daytime alertness**” participants of the SNORE study are classified as conceivably sleep-deprived using the Epworth Sleepiness Scale.^{5,16,17}

Cognitive impairment: According to the Centers for disease control and prevention (CDC), “*Cognitive impairment is when a person has trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life.*” For the purpose of the SNORE study, MoCA test scoring is used to classify a participant as probably having impairment in cognitive function.¹⁸

Quality of life: The World Health Organization defines Quality of Life as, “*an individual's perception of their position in life.*”¹⁹ For the purpose of the SNORE study, SF-12 QOL scores are used to identify the QOL of the study participants.

DISCUSSION

Being aware that occupational health is thoroughly linked to public health and health systems development, World Health Organization (WHO) has implemented a Global Plan of Action on Workers' health 2008-2017 as recommended by the World Health Assembly (WHA) in the year 2007 with the below mentioned objectives: (1)conceiving and employing policy instruments on workers' health; (2)guarding and upholding health at the workplace; (3)refining the performance of and access to occupational health services; (4)offering and communicating evidence for action and practice; and (5)integrating workers' health into other policies.²⁰

This demands for a need to reassess the existing working conditions in the healthcare industry and scrutinize its toll on the health and quality of life of healthcare professionals in a need to sustain or evolve the existing work pattern.

Maintaining sleep quality is vital, especially in individuals likely to develop shift-work sleep disorder, for the institution of positive physical/mental health.²¹ Nonetheless, lifestyle and environmental dynamics are gradually causing drawbacks in sleeping leading to glitches in daytime performance universally, which are more than often linked to significant changes in daily activities.

There is a necessity to evaluate the burden of sleep deprivation among health care providers for the identification of its deleterious effects. By measuring the effects on cognitive effect and quality of life necessary steps can be taken to provide better quality of life and to decrease cognitive impairment, especially among health care professionals working night shifts.

RESULTS OF PILOT STUDY:²⁴

A cross-sectional study was done including health-care professionals working night shifts on rotation at a tertiary level health-care facility, using a semi-structured questionnaire to test the status of their sleep deprivation, cognitive ability, and quality of life as a pilot study. Data were analyzed using IBM-SPSS, and required statistical tests were applied (Pearson Chi-square, Fisher exact, Spearman correlation, and Wilcoxon signed-rank test). About 95.12% of participants reported < 6 hours of sleep post night shifts, of which 51.2% were found to show signs of sleep deprivation. Of this 51.2%, 28.57% were also found to have lowered cognitive function scores, and statistically significant lower cognitive scores were observed during night shifts than during day shifts. The median value of the Montreal cognitive assessment (MOCA) score during the night shift was 27 (inter-quartile range [IQR] = 4) and the median value of MOCA score during the day shift was 29 (IQR = 1). A poor QOL was observed in 17.07% of the study participants, and it was found to have a significant positive correlation with hours of sleep obtained. The results from the pilot study points towards a significantly high burden of sleep deprivation among health-care professionals working rotational shifts (51.2%). This warrants a need for further evaluation on larger populations and adoption of comprehensive measures including preventive and promotive aspects like sleep counselling and yoga/meditation for management.

Figure 1: Process of sampling

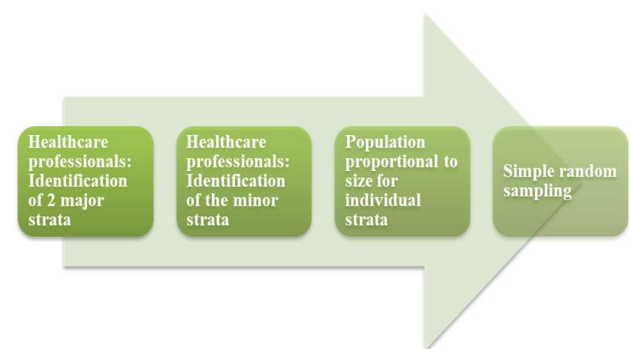


Figure 2: Stratification of healthcare professionals based on designation

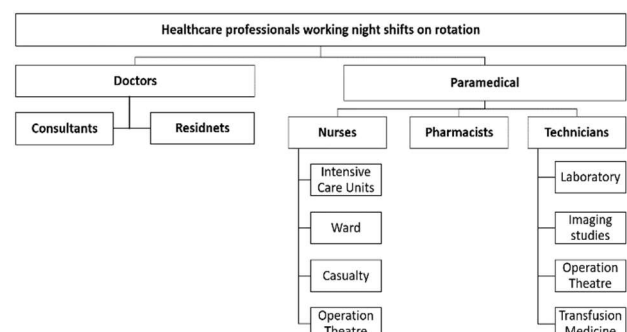


Table 1: Sample from each stratum according to population proportion

	Total Population	Sample proportion	Proportion to be approached
Doctors	323	114	126
Nurses	396	140	154
Technicians	62	22	24
Pharmacists	13	5	5
Total	794	281	309

Table 2: Grading of Daytime Sleepiness based on EPSS Scoring

Score	Grade of sleepiness
0-5	LNDS (Lower Normal Daytime Sleepiness)
6-10	HNDS (Higher Normal Daytime Sleepiness)
11-12	MiEDS (Mild Excessive Daytime Sleepiness)
13-15	MoEDS (Moderate Excessive Daytime Sleepiness)
16-24	SEDS (Severe Excessive Daytime Sleepiness)

STRENGTHS

The SNORE study protocol is set in such a way as to

randomly include participants from all cadres of healthcare providers as per population proportion. Even though the objective measure of daytime sleepiness is by multiple sleep latency test (MSLT), existing evidence shows that significant correlations have been established between EPSS and MSLT sleepiness outcomes, thus making EPSS a reliable measure for assessment of daytime sleepiness.^{22,23} Various combinations of the MoCA full test versions- 8.1, 8.2 and 8.3 are used per participant for day and night shifts to avoid biases that may arise due to familiarity with the study tool.

LIMITATIONS

Status of sleep deprivation by self-reported hours of sleep or EPSS scores are subjective and may give rise to biases due to social desirability or selective recall. The SNORE study lacks an objective assessment of status of sleep in the form of an actigraph or actimetry sensor and also confirmatory assessment of poor sleep quality by measurement of melatonin levels.

Table 3: Specific data handling plan during analysis

Objective	Data analysis
To determine the effect of sleep deprivation on the cognitive functioning of health care providers working on night shifts	<ul style="list-style-type: none"> • Pearson chi-square for association of cognitive function with socio-demographic factors and shift work pattern • Logistic regression for association of sleep deprivation and cognitive function • Median test for difference in cognitive function according to level of sleep deprivation
To determine the effect of sleep deprivation on the quality of life of health care providers working on night shifts	<ul style="list-style-type: none"> • Pearson chi-square and logistic regression for association of QOL with sociodemographic factors and shift work pattern • Independent samples T test for mean difference in QOL scores between sleep deprived and non-sleep deprived groups.
To determine difference, if any, in the cognitive function during day and night shifts To determine the prevalence of sleep deprivation and daytime sleepiness among health care providers working on night shifts	<ul style="list-style-type: none"> • Wilcoxon signed ranks test for analyzing difference in cognitive function during night and day shifts • Pearson chi-square for association of sleep deprivation with socio-demographic factors and shift work pattern • Paired samples T-test for difference in hours of sleep during night and day shift periods • Kruskal-Wallis H test for variance in status of sleep deprivation among professional groups
To determine the relation between hours of sleep and EPSS scores	<ul style="list-style-type: none"> • Independent samples T test for mean difference in hours of sleep • Logistic regression for association of sleep deprivation and EPSS scores
To evaluate the relation, if any, between the existing shiftwork pattern and work satisfaction	<ul style="list-style-type: none"> • Pearson chi-square and logistic regression for association of status of work satisfaction with socio-demographic factors and shift work pattern

DECLARATIONS

Ethics approval and consent to participate: The study has been reviewed and approved by the Institutional Human Ethics Committee, Chettinad Academy of Research and Education.

Competing interests: The authors declare that they have no competing interests

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Authors' contributions: All authors were involved in the conceptualization and write-up of the protocol. All authors have read and approved the final manuscript.

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