patients on mechanical ventilators and taking medications for sleep were excluded.

2.3 Procedure for Data Collection

A letter explaining the purpose of the study was given to the subjects. Signed informed consent was taken from the subjects. Random assignment to either of the two groups was done based on randomization table. Demographic related data was collected by interview technique using questionnaire. Group A received the intervention (earplugs and eye masks) during night from 9 pm to 6 am on the first day and did not receive intervention on second day. Group B did not receive any intervention during night on the first day and received intervention (earplugs and eye masks) on the second day from 9 pm to 6 am. The earplugs and eye masks were selected by reviewing criteria of noise and light reduction as mentioned by the manufacturers, previous research, cost and availability. After comparison of foam earplugs of various companies, PU (Polyurethane) foam earplugs were selected as it has highest noise reduction rating (SNR-37Db) and for single use. Eye masks with silky soft black taffeta inside, outside with cushioned filler and two elasticized straps with nose bridge were selected. Routine environment remained the same on both the days for both the groups. The quality of sleep was assessed in coming morning by using modified Richard Campbell Sleep Questionnaire (RCSQ).

Measures

1) A structured tool including the demographic, clinical data and selected variables was prepared to collect data from subjects using interview technique.
2) A 0 mm to 100 mm visual analogue scale (VAS) developed to assess sleep quality based on Richard Campbell Sleep Questionnaire (RCSQ). Reliability evaluated as 0.82.

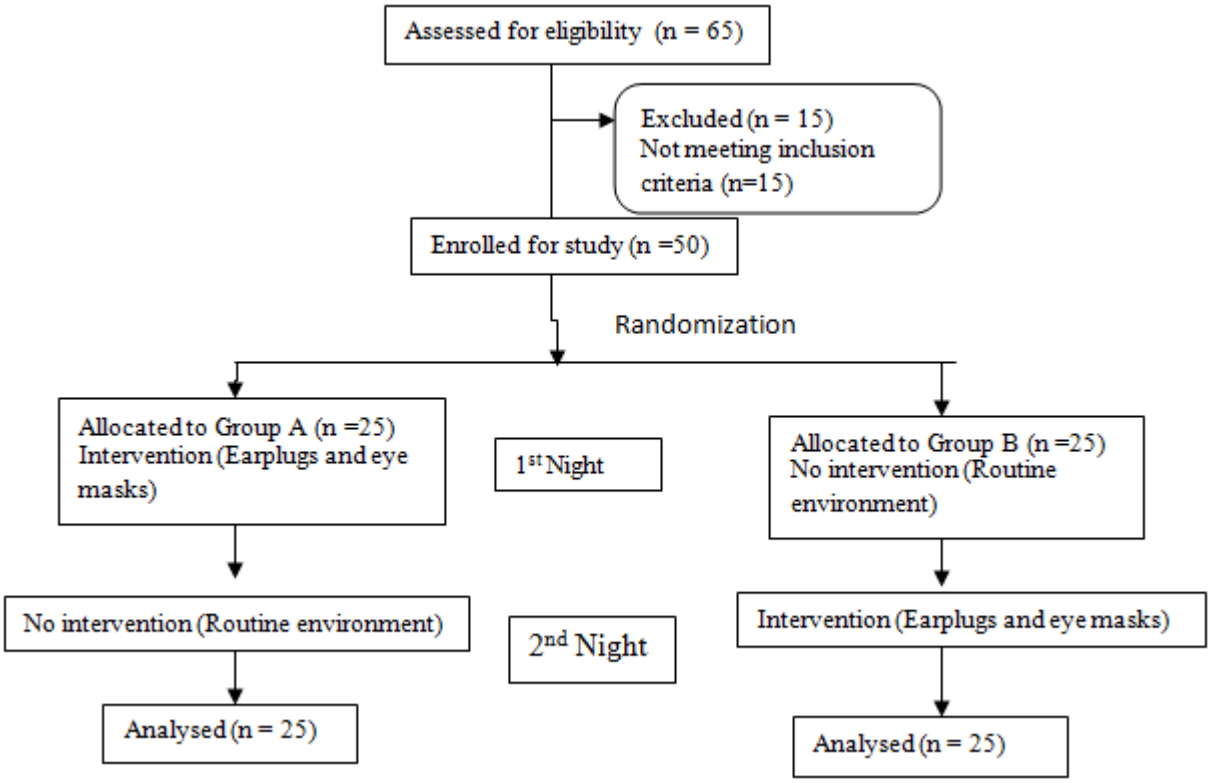

Figure 1: Consort diagram

3. Results

Demographic Characteristics

Mean age of the subjects was 40 years. 84% were male, 68% were married and 47% subjects were educated above 12th standard. 68% were employed out of which 74% were doing day shift duties.78% of the subjects expressed that they did not use any routine assistance to achieve sleep. 94% of the subjects expressed noise, 42% light and 8% pain as sleep disturbing factors in ICU environment. 60% were pre and post operative surgical patients.

Effectiveness of sleep promoting devices (earplugs and eye masks) on sleep quality:

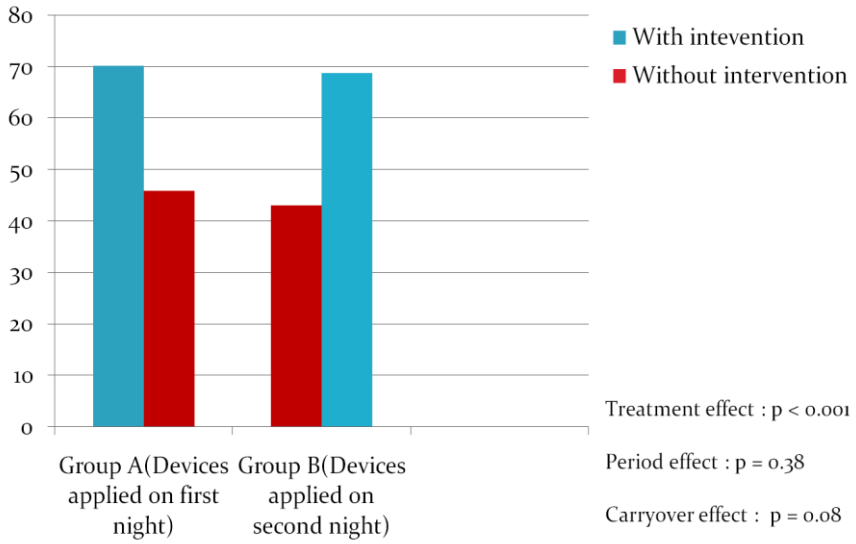

Figure 2: Sleep score (Mean ± SD) with and without intervention in two groups

As shown in figure 2, during first night, the mean sleep score was found to be 70.26 ± 5.89 in group A with intervention (using earplugs and eye masks) and during second night, the mean sleep score in the same group without intervention was found to be 45.86 ± 4.86.

During first night the mean sleep score in group B was found to be 43.06 ± 7.31 without intervention and during second night, the mean sleep score of 68.74 ± 6.54 with intervention (using earplugs and eye masks) among ICU patients. The treatment effect; $p < 0.01$, signifies that, the earplugs and eye masks have highly significant effect in improving quality of sleep among ICU patients. The period effect of $p = 0.389$ and carryover effect, $p = 0.085$ showed that there is no significant effect of the wash out period between the two nights on the quality of sleep of the total subjects. Thus a significance effect on quality of sleep was seen in intervention group as compared to non intervention group at 0.05 levels.

Noise and light were major sleep disturbing factors among ICU patients. Sleep score of subjects who expressed noise and light (70.5 and 69) as sleep disturbing factors were lower than subjects who expressed pain and other factors (61.5 and 73.75) with p value of 0.04.

4. Discussion

Subjective mean sleep score in Group A was found to be 70.26 ± 5.89 with intervention and 45.86 ± 4.86 without intervention. In Group B subjective mean sleep score was found to be 43.06 ± 7.31 without intervention and 68.74 ± 6.54 with intervention among ICU subjects. There was significant improvement ($p < 0.01$) in quality of sleep after intervention as compared to routine environment (no intervention).

The above findings were similar to the study conducted by **Wallace, Robins, Alvord, Walker (1999)** [11] evaluated the effect of earplugs on sleep. This study used a repeated measures cross over design with an average age of 25 +/- 3 years. After one night of adaptation, participants were divided into two groups: the first group wore earplugs and the second group did not. For participants using earplugs, REM latency (time to enter REM sleep) decreased significantly and the use of earplugs significantly increased the percentage of REM sleep.

The results of this study also revealed that noise and light were major sleep disturbing factors among ICU subjects, earplugs and eye masks were found to be significantly ($p = 0.04$) correlated with noise and light.

This study results are supported by **Lane T, East LA (2008)** [9] conducted a study to describe the sleep experience of patients in surgical wards and ICU. According to the study results environmental factors were found to be strongly correlated with sleep disruption with a Pearson's coefficient of + 0.795. This study found that environmental noise, light and tension were the major factors that disrupt the sleep of surgical patients.

This findings also supported by **Koen S Simons, Mark van den, Boogaard, Cornelis PC de (2012)** [10] conducted a study on ICU patients and concluded that for non-ventilated critical care patients noise the combination of earplugs and eye masks were effective to improve sleep. Koen and mark analyzed 18 ICU patients who were offered the choice of wearing earplugs and eye masks from 10 pm to 6 am. In these patients self-perceived quality of sleep improved from 6.6 (5.9 to 8.2) to 7.5 (7.0 to 8.0) ($P = 0.041$) when the earplugs and eye masks were worn.

Additional findings

Besides these results, more than 70% of the subjects in ICUs commented that earplugs and eye masks were comfortable to use and improved their sleep quality as compared to previous nights.

Study limitations

Study involved only ICU subjects, conducted in single setting with small sample size. Objective sleep assessment was not done.

Implications

- Nursing education

Alternative sleep promoting strategies can be incorporated in the curriculum of undergraduate nursing students**.**

- Nursing practice
  Earplugs and eye masks can be used as an adjuvant therapy to improve the quality of sleep among ICU patients. Nursing care and ward routine should be scheduled in such a way that it should not interfere with patients' sleep.

5. Future Recommendations

A multicentre study with a larger sample size can be undertaken. Studies can be done with earplugs and eye masks separately. Earplugs and eye masks can be applied for more than one night (From admission to discharge). Effectiveness of earplugs and eye masks may be assessed in other clinical areas of hospital. Objective measurement can be done like nocturnal melatonin and cortisol to evaluate the effectiveness of earplugs and eye masks on sleep quality.

6. Conclusion

Based on the findings of the present study it is concluded that the quality of sleep was improved after application of earplugs and eye masks among ICU patients. From the above results, it appears that simple interventions such as earplugs and eye masks may be a valuable addition to patients attempting to sleep in intensive care units. Earplugs and eye masks could be used as an acceptable sleep intervention and alternative to sleep medications for patients when appropriate.

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