Title: Protocol For Sleep for Critically Ill Patients

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NCT: 5.882.443

Statistical Analysis

Sample Calculation: The primary outcome to be studied will be the implementation of a multi-intervention protocol to improve sleep quality, measured by the overall average score on the RCSQ (Richards-Campbell Sleep Questionnaire). According to Li et al.'s article (2011), the standard deviation (SD) for the control group was ±19.1, while for the intervention group, it was ±26.2. Based on these data, the sample calculation was performed, indicating that 50 patients will be required in each group to detect a 15-point difference in the average RCSQ score with 80% power and a 5% alpha level.

Data Analysis: The distributions of quantitative data will be evaluated using the Shapiro-Wilk and Kolmogorov-Smirnov tests with Lilliefors correction. Data with normal distributions will be presented as means and standard deviations and will be compared between the intervention and control groups using the independent samples t-test. Data with non-normal distributions will be presented as medians and interquartile ranges and compared using the Mann-Whitney test. Qualitative variables will be presented as absolute and relative frequencies (%) and compared between groups using the Pearson chi-square test and Fisher's exact test, as appropriate. Multivariate analysis models will be tested and applied to adjust for potential confounding covariates in the evaluated outcome. All tests will be two-tailed, and p-values ≤ 0.05 will be considered significant.

Statistical Software Used: The statistical software SPSS, version 23.0, will be used to conduct the analyses (SPSS Inc., Chicago, IL, USA).