

**THE EFFECT OF REPOSITIONING FREQUENCY DETERMINED ACCORDING
TO BODY MASS INDEX ON PRESSURE ULCER DEVELOPMENT TIME:
RANDOMIZED CONTROLLED TRIAL**

ClinicalTrials.gov ID: [NCT05504980](https://clinicaltrials.gov/ct2/show/NCT05504980)

Document Date: June 30, 2023

Setting/Participants

This study was conducted in the intensive care and palliative care units of a university hospital between 01.07.2022 - 29.01.2023. The sampling volume that should be included in the sample of the study was calculated using power analysis; considering the margin of error ($\alpha= 0.05$), effect size ($f= 0.347$) and power 80% ($1-\beta= 0.80$) values and research design, the sample calculation was made for the Chi-Square test and a total of 66 people were determined. Considering the losses, the number of patients included in the sample was planned to be 86 patients (43 intervention group, 43 control group), 30% above the calculated value, and the study was completed with 71 patients. According to body mass index, weight status was stratified into four groups as underweight ($\leq 18.49 \text{ kg/m}^2$), normal weight (18.5 kg/m^2 - 24.9 kg/m^2), overweight (25kg/m^2 - 29.9kg/m^2) and obese ($\geq 30\text{kg/m}^2$).

Body Mass Index	Intervention Group	Control Group
Underweight	1	1
Normal Weight	8	12
Overweight	17	14
Obese	11	7
Total	37	34
General Total		71

Statistical Analysis

Statistical analysis of the research data was performed in the "Statistical Package for the Social Sciences (SPSS) 25.0" statistical package program (PASW Inc., Chicago. IL.USA) under the supervision of a statistical expert. In descriptive statistics; number and percentage distributions were shown and mean (mean) \pm standard deviation (SD) values were given. Demographic quantitative data were compared between the groups by Mann Whitney U test. The distribution of qualitative characteristics of the patients in the groups was analyzed using Pearson Chi-square test or Fisher's exact probability test. "Kaplan Meier - Survival Time" analyses were performed for the duration of pressure ulcer development. General Linear model analysis was performed for effect size. For repeated measures, changes in groups were

analyzed using the nonparametric Brunner Langer (F1 LD F1 model) method. Since only one patient in the intervention group developed pressure ulcers, intra-group statistical analysis could not be performed. The results were evaluated at 95% confidence interval and $p<0.05$ significance level.

Results

Socio-demographic characteristics, data on health status, pressure injury development risk assessment scale score, averages of some laboratory findings, and interface pressure values measured from pressure points of patients in the intervention and control groups in intensive care clinics are homogeneously distributed. Pressure injuries developed in 2.70% of the patients in the intervention group and 14.70% of the patients in the control group, the difference between them wasn't statistically significant ($p=0.098$). The effect size is 0.216 and has a low/medium effect size. Injury development time was 16 days in the intervention group and 6.00 ± 2.0 days in the control group (earliest 3rd day, latest 8th day), the difference between them was not statistically significant ($p=0.137$). Pressure injury developed in one underweight, one normal weight, and three obese patient in the control group and one obese patient in the intervention group, the difference between them was statistically significant ($p=0.006$).

In the control group, one patient with underweight, one patient with normal weight and three patients with overweight developed pressure injuries and the difference between them was statistically significant ($p=0.003$). Since only one of the obese patients in the intervention group developed pressure injuries, the development of pressure injuries according to body mass index could not be evaluated. The risk of pressure injury development is higher in underweight and obese patients, and less in overweight patients.

Pressure injuries developed in the gluteal area and sacrum in the patient in the intervention group, and in the sacrum in 8.8% of the patients in the control group, there was no statistically significant difference between them ($p=0.143$).

Conclusion

It was concluded that the frequency of position changes should be done with a personalized program for each patient, not at routine two-hour intervals, and the risk of pressure injury development is higher in low-weight and obese patients, while it is less in overweight patients.