Name of the Research: The Effect of Using Illustrated Communication Material on Anxiety and Comfort in Communication with Patients Receiving Mechanical Ventilation Support: A Randomized Controlled Clinical Study

Date of the Document: 11.01.2017

Objective: In communication with patients receiving mechanical ventilation support, to determine the effect of the use of illustrated communication material on the anxiety and comfort levels of these patients. **Study design:** This study was planned as a randomized controlled clinical trial with two arms: Patients who had undergone cardiac surgery were randomly assigned to intervention (illustrated communication material were used) and control (routine methods in the communication were used) groups when they were connected to the mechanical ventilator. **Setting and Participant:** The study was conducted in the Cardiovascular Surgery Clinic of a Training and Research Hospital in Ankara, Turkey between 15 July 2016 and 15 June 2017. The sample of the research consisted of patients undergoing cardiac surgery. This patient population was preferred because the initiation and termination of mechanical ventilation therapy in patients undergoing cardiac surgery were carried out within a specific time frame and within certain standards, except for exceptional cases. The sample size of the study was calculated with the Sample Size Calculators package program of DSS Research (https://www.dssresearch.com). Since this research is the first research on the subject, a reference value for the impact value could not be reached. Therefore, a total of 20 patients, ten from the control group, and ten from the intervention group were piloted. Considering that the mean comfort score is 87.1 ± 13.7 in the control group and 110.8 ± 9.2 in the intervention group, it was calculated that there should be at least eight patients in each group with 95% confidence interval, 99% power, 0.05 Type I error, 0.01 Type II error for the difference between groups. However, considering the other parameters to be measured in the research and the sample size criterion required to perform parametric testing, a total of 60 patients, 30 in each group, formed the sample size. As there was no change in the data collection method, patients who were in pre-application were included in the study. The inclusion criteria of the patients were as follows: having undergone cardiac surgery; having mechanical ventilation therapy; being 18 and over; having a minimum of -2

and a maximum of +2 from the Richmond Agitation Sedation Scale (RASS); to agree to participate in the research. Criteria of exclusion of patients from the study were: not speaking Turkish; having vision and hearing loss; having a cognitive or psychological problem preventing them from communicating; having previous intubation experience; undergoing revision surgery because of bleeding in the early stages of the postoperative period or development of a complication such as needing additional sedation. **Randomization:** Weekly randomization was performed since the use of different communication techniques at the same time may confuse during the intensive care period of the research. “Which method to be used in which week” was determined by block randomization with groups of 2 in the "R" Studio program. **Blindness:** In the study, blindness could not be achieved because patients were followed up in a common area in intensive care after the operation, communication with the patient was established more than once in line with the needs of the patient and the material was visible

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Data analysis: Statistical Package of Social Sciences (SPSS, Inc., Chicago, IL, USA) 15.0 package program was used to evaluate the data. Descriptive statistics for variables that were calculated by counting were presented as number and percentage (%) and for variables that were calculated by measurement were presented as mean ± standard deviation (± SS) or median and minimum-maximum (min-max) values. The normality of the measurement values was evaluated with the Single Sample Kolmogorov Smirnov test. Accordingly, in the investigation of the difference between the two groups, "Independent Sample T-Test" was used for the data that fit the normal distribution, and the "Mann Whitney U Test" was used for those that did not fit to normal distribution. In the evaluation of repeated measurements, "Dependent Sample T-Test" was used for measurements that fit the normal distribution, and the "Wilcoxon Signed Rank Test" was used for those who did not fit to the normal distribution. The "Chi-square Test" was used to show the difference between the variables determined by counting. In the presence of fewer than five values observed in one of the cells, the “Fisher Exact Chi-square Test” was taken as the basis. $p < 0.05$ value was accepted as an indicator of statistical significance.

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T.C.
SAĞLIK BAKANLIĞI
TÜRKİYE KAMU HASTANELERİ KURUMU
Ankara İli Kamu Hastaneleri Birliği 2 Nolu Genel Sekreterliği
Keçiören Eğitim ve Araştırma Hastanesi Baştabipliği
Klinik Araştırma Etik Kurulu

Sayı : 2012-KAEK-15/1268 11.01.2017
Konu: Keçiören Eğitim ve Araştırma Hastanesi
Etik Kurul Kararı

KEÇİÖREN EĞİTİM VE ARAŞTIRMA HASTANESİ KLİNİK ARAŞTIRMA ETİK KURULU

"Mekanik Ventilatör Desteği Alan Hastalarla İletişimde, Resimli İletişim Materyali Kullanımının, Anksiyete ve Konfor Üzerine Etkisi" adlı klinik araştırma başvuru dosyası ve ilgili belgeler araştırmanın gerekçe, amaç, yaklaşım ve yöntemleri dikkate alınarak incelenmiş, çalışmanın başvuru dosyasında belirtilen merkezlerde gerçekleştirilmesinde etik ve bilimsel sakınca bulunmadığına ve kurulumuz kararının başvuru sahibi tarafından sağlık bakanlığına arzına gerek olmadığına toplantıya katılan Etik Kurul üye tam sayısının salt çoğunluğu ile karar verilmiştir.

Op.Dr. Ömer Faruk TANER
Keçiören Eğitim ve Araştırma Hastanesi
Klinik Araştırmalar Etik Kurul Başkanı

Keçiören Eğitim ve Araştırma Hastanesi
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