Effects of the visit prior to hospital admission on anxiety, depression and satisfaction of patients in an intensive care unit: a randomized clinical trial with implications for nursing management

Running title: Patients visit to intensive care units

Abstract

Objectives: To assess the visit effects prior to hospital admission on anxiety, depression and satisfaction of patients in an intensive care unit (ICU).

Design: A randomized clinical trial [NCTXXXXXXX].

Setting: A sample of 38 patients was recruited from a hospital ICU and divided into experimental (n=19 patients receiving one visit prior to hospital ICU admission for surgery) and control (n=19 patients without receiving one visit prior to hospital ICU admission for surgery) groups.

Main outcome measurements: Hospital Anxiety and Depression Scale (HADS) and Impact of Event Scale-Revised (IES-R) were self-reported by patients before ICU admission, at 3-days and 90-days after ICU discharge. Critical Care Family Needs Inventory (CCFNI) and Family Satisfaction with Care in the Intensive Care Unit (FS-ICU) were used to measure the users' satisfaction before ICU admission and 3-days after ICU discharge.

Results: There were statistically significant differences between experimental and control groups for FS-ICU, but not for HADS, IES-R and CCFNI. Indeed, control group patients were more satisfied with regard to emotional support, ease of getting information, control

feeling, concerns and questions expression ability, and overall score for decision-making satisfaction.

Conclusions: The visit prior to hospital admission did not seem to modify anxiety or depression, but may impair satisfaction of ICU patients.

Keywords: Anxiety; Depression; Early Intervention (Education); Intensive Care Units; Patient Satisfaction.

Implications for Clinical Practice

- ICU patients visit prior to hospital admission did not influence anxiety/depression

- This visit impaired the satisfaction of patients in an ICU

- ICU patients visit prior to hospital admission is not recommended

1. Introduction

Nowadays, the intensive care units (ICUs) use is growing in hospital healthcare systems, generating an important cost and economic burden (Halpern and Pastores, 2010). In addition, ICUs may be services that produce a high level of stress in patients, who suffer physically and psychologically in long-term (Barr et al., 2013). This fact may be due to multiple factors, such as the performance of invasive procedures, separation from the family, lack of privacy, immobility, pain, need for mechanical ventilation, constant noise, confusion, sleep interruptions and the lack of familiarity with the medical or nursing staff (Alasad et al., 2015; Davydow et al., 2008; Wade D., Hardy R., Howell D., 2013).

Indeed, patients from ICUs may be informed by medical doctors and nurses about the required health care. Thus, nurses play a key role in order to inform patients who stay in an ICU service about critical health care necessities and status (Sánchez-Vallejo et al., 2016).

Up to one third of the ICU survivors may experience symptoms of anxiety which may be persistent during the first year of recovery (Hatch et al., 2018; Nikayin et al., 2016). Indeed, psychiatric symptoms such as stress reactions, anxiety at hospital discharge, and stressful nightmares and extreme fear during admission may be risk factors for anxiety levels of patients from an ICU (Nikayin et al., 2016). Depressive symptoms seem to occur in approximately 30% of general critical illness survivors with persistent severity over 12-month longitudinal follow-up (Rabiee et al., 2016). Several tools were developed in order to evaluate anxiety and depression in patients by personnel without formal training in psychiatry, such as nurses (Schandl et al., 2011). Indeed, the Hospital Anxiety and Depression Scale (HADS) (Herrero et al., 2003; Zigmond et al., 1983) and the Impact of Event Scale-Revised (IES-R) (Báguena et al., 2001; Sterling, 2008) may be useful tools for the evaluation of anxiety and depression as well as the subjective discomfort secondary to stressful and/or traumatic experiences from patients in an ICU, respectively.

A high grade of stress and anxiety may be suffered by patients with a prevalence from 12% to 47%) (Pochard, 2010) and families with a prevalence about 69.1% (Pochard et al., 2001) or 70% (Schmidt and Azoulay, 2012) from an ICU, suffering from psychological and physical problems in long-term (Cutler et al., 2013). As patients as their relatives from an ICU may suffer from symptoms of post - intensive care syndrome (PICS) and post - intensive care syndrome - family (PICS-F), respectively, which may include depression, anxiety and/or posttraumatic stress disorder (PTSD) generating a reduced quality of life (Petrinec and Martin, 2018). According to this, the Critical Care Family Needs Inventory (CCFNI) (Gómez Martínez et al., 2011; Molter, 1979) and the Family Satisfaction with Care in the Intensive

Care Unit (FS-ICU) (Heyland et al., 2001) may be adequate tools to measure the users' assessment and satisfaction during their ICU stay, respectively. Despite there is a low level of scientific evidence related to the information or education intervention effects to adult ICU patients, the improvement of the communication between healthcare professionals could reduce physical and psychological conditions including anxiety, depression and PTSD, as well as improve patient's satisfaction (Lai et al., 2016; Lewis et al., 2018).

According to these physical and psychological conditions, such as depression, stress and/or anxiety, which seem to occur commonly in patients who stay in an ICU (Alasad et al., 2015; Davydow et al., 2008; Wade D., Hardy R., Howell D., 2013), the effects of the patient´s visit to the ICU prior to hospital admission have not yet been studied. We hypothesized that this fact could improve the levels of anxiety, depression and satisfaction showed by patients who stay in an ICU. Thus, the aim of this study was to assess the effects of the visit prior to hospital admission on anxiety, depression and satisfaction of patients in an ICU.

2. Methods

2.1. Study design

This research was a randomized clinical trial of parallel groups in order to determine the effects of the visit prior to hospital admission on anxiety, depression and satisfaction of patients in an ICU, following the Consolidated Standards of Reporting Trials (CONSORT) criteria (Moher et al., 2012). This study was previously approved by the Ethic Committee of the XXXXXXX University Hospital XXXXXXX) and registered at Clinicaltrials.gov [NCTXXXXXXX].

2.2. Recruitment and sample

Thirty-eight patients were received for hospital admission and recruited from programmed surgeries in the XXXXXXX University Hospital (XXXXXXX). The inclusion criteria were patients undergoing a cardiac scheduled surgery who voluntary accepted to participate in this study, older than 18 years, and XXXXXXX language. Thus, the exclusion criteria were patients with cognitive impairment or altered level of consciousness who present limitations to verbalize pain, incapacitating pathology to understand or express themselves, not sign the informed consent and re-entry in the ICU due to worsening.

2.3. Randomization and intervention

An automatic method (Microsoft Office Excel) was used to assign patients to the control or intervention group. This assignment to each group was exclusively carried out by a member of the nursing staff who was not involved in the study (including treatment and follow-up of patients). A stratified randomization of patients was applied according to the week of admission to the ICU in order to prevent the coincidence of patients of the intervention and control groups in the same hospitalization room the day before the intervention or in the waiting room prior to the intervention. Finally, A total sample of 38 patients was recruited and divided into experimental (n = 19 patients receiving one visit prior to hospital ICU admission for surgery) and control (n = 19 patients without receiving one visit prior to hospital ICU admission for surgery) groups. The intervention was carried out in a single ICU. A trained nurse explained the protocol of the ICU service during admission and the expected course of schedule in this unit prior to admission.

2.4. Sociodemographic and clinical data

The following socio-demographic and clinical data were registered: sex (male or female), age (y), weight (kg), height (m), body mass index (BMI; kg/m^2), educational level (without studies, primary education, secondary education, high school, and university), days of stay of

the patient in ICU, religious beliefs (such as Christian, Atheist, Jehovahs Witness, Aconfessional or no religious, and Muslim), previous psychiatric illness (yes or no), previous experience in ICU as patient or relative (yes or no), days with mechanical ventilation, use of benzodiazepines in the ICU (days), re-intervention (days), use of renal replacement therapy (yes or no), use of blood transfusions (yes or no), re-intubation (yes or no), complications suffered by the patient such as mortality, episodes of delirium and aggressiveness according to medical record (yes or no), physical sequelae according to medical record (yes or no), and number of visits per day for the studied family (according to the nursing registry in the unit and divided into none, once a day and twice a day).

2.5. Outcome measurements

The HADS (Chivite et al., 2007; Tejero et al., 1986; Terol-Cantero et al., 2015; Zigmond and Snaith, 1983) and IES-R (Báguena et al., 2001; Horowitz et al., 1979; Sterling, 2008) tools were self-reported by patients before ICU admission, at 3 days and 90 days after ICU discharge. In addition, the CCFNI (Gómez Martínez et al., 2011; Molter, 1979) and FS-ICU (Heyland et al., 2001) were used to measure the patient' assessment and satisfaction at 3 days after ICU discharge. These instruments were completed before ICU admission and at 3 days after ICU discharge presentially, as well as at 90 days after ICU discharge presentially or by telephone.

2.6. HADS

This tool evaluated the level of depression and anxiety symptoms in hospitalized non-psychiatric patients (Chivite et al., 2007; Tejero et al., 1986; Terol-Cantero et al., 2015; Zigmond and Snaith, 1983). This is a self-administered questionnaire with 14 items divided into 7 items to assess the anxiety domain and 7 items to evaluate the depression domain (each item is scored by a Likert-type scale from 0 as minimum value to 3 as maximum value).

Physical symptoms are not included in order to avoid the confusion of the patient with the physical illness. This scale was Spanish-validated (Tejero et al., 1986). The internal consistency coefficients evaluated by the Cronbach α were 0.90 for the total score, 0.84 for the depression domain and 0.85 for the anxiety subscale (Herrero et al., 2003). In addition, an adequate reliability was reported by factorial analyses, showing values of 0.80 for anxiety domain and 0.85 for depression domain (Cabrera et al., 2015).

2.7.IES-R

This scale is used to assess the subjective response that accompanies stressful and/or traumatic experiences. It is a self-administered tool composed of 22 items evaluating the patient's experience during the last week (each item is scored by a Likert-type scale from 0 as minimum value to 3 as maximum value), which may be divided into 3 domains (avoidance, intrusion and hyperexcitation) (Báguena et al., 2001; Horowitz et al., 1979; Sterling, 2008). Good internal consistency coefficients (Cronbach α) were reported for the intrusion (0.87), avoidance (0.85) and hyperexcitation (0.79), with adequate test-retest coefficients (0.57, 0.51 and 0.59) for each domain, respectively (Sterling, 2008). The Spanish validation also showed Cronbach α coefficients of 0.86 for the total score, 0.78 for the intrusion domain and 0.82 for the avoidance domain. Nevertheless, the hyperexcitation domain showed discrepancies regarding gender characteristics of the hyperexcitation domain (0.19 for total sample, 0.10 for men, and 0.80 for women) (Báguena et al., 2001).

2.8.CCFNI

This scale is used to measure the needs perceived by the family members of the patient admitted to the ICU. It is a self-administered tool composed of 45 items and each item is scored by a Likert-type scale from 1 as minimum value to 4 as maximum value, which may be divided into 4 domains (medical care, communication, personal attention, and possible

perceived improvements). Internal consistency with Cronbach α coefficients of 0.65 for the total score, 0.72 for medical care, 0.60 for communication, 0.60 for personal attention, and 0.64 for possible perceived improvements were shown. The correlation of each item with the total score was higher than 0.30 showing an adequate homogeneity index (Gómez Martínez et al., 2011; Molter, 1979).

2.9. FS-ICU

This tool is used to measure the satisfaction of patients and relatives with the ICU. It is a self-administered scale composed of 35 items and each item is scored by a Likert-type scale from 1 as minimum value to 5 as maximum value, which may be divided into 2 domains (satisfaction with healthcare and satisfaction with decision making) (Heyland et al., 2001). Internal consistency with Cronbach α coefficients of 0.84 for the total score and from 0.74 to 0.97 for domains, as well as a correlation of 0.63 was shown as psychometric properties of this tool (Olano and Vivar, 2011).

2.10. Sample size calculation

The sample size of this study was calculated with the software GP Power 3.1.9.2. according to a prior study which evaluated an education program for the relatives and patients in an ICU using the CCFNI (Chien et al., 2006), obtaining a score of 145.58 ± 15.91 points for the experimental group and a score of 132.05 ± 13.55 points for the control group. In addition, an unilateral analysis, an α error of 0.05, a desired power of 70 % ($\beta = 30\%$) and a moderate to large effect size (d=0.75) were considered for the sample size calculation. According to these parameters, a total sample size of 18 individuals per independently group was considered. In the case of our study, we have collected a total of 19 individuals in each independent group, so we compared 19 patients in the control group with 19 patients in the experimental group.

2.11.   *Statistical analyses*

Data were analyzed with the statistical software "IBM SPSS Statistics" (version 22.0 for Windows; SPSS Inc., Chicago, Illinois). The statistically significant level was set at $p < 0.05$, with a confidence interval of 95%. Firstly, Shapiro-Wilk test was used to assess normality. Regarding the statistical analysis of quantitative data, Wilcoxon test for related samples and Student t test for paired samples were used to compare results during follow-up periods for non-parametric and parametric data, respectively. In addition, Mann-Whitney U Test and student t test for independent samples were used to compare data between both groups. Indeed, a repeated-measures general lineal model (GLM) analysis was used to compare intra-subject factors for the HADS and IER-S tools. Considering the statistical analysis of categorical data, Chi-square tests were applied to analyze differences between both groups (Ferrán Aranaz, 2001).

3. Results

3.1. *Socio-demographic and clinical characteristics*

Socio-demographic and clinical characteristics did not show any statistically significant difference ($p > 0.05$) between control and experimental groups of patients in the ICU (Table 1). There were not participants lost to follow-up.

---Insert Table 1 here---

3.2. *Outcome measurements*

There were statistically significant differences between experimental and control groups for the FS-ICU, but not for the HADS (Table 2), IES-R (Table 3) and CCFNI (Table 4). Indeed,

the control group patients were more satisfied with regard to emotional support, ease of getting information, control feeling, concerns and questions expression ability, and overall score for decision-making satisfaction (Tables 5 and 6).

---Insert Table 2, 3, 4, 5 and 6 here---

4. Discussion

To the authors´ knowledge, this is the first study assessing the effects of the visit prior to hospital admission on anxiety, depression and satisfaction of patients in an ICU environment. Despite multiple factors may influence depression, stress and/or anxiety from patients who stay in an ICU (Alasad et al., 2015; Davydow et al., 2008; Wade D., Hardy R., Howell D., 2013), the effects of the patient´s visit to the ICU prior to hospital admission did not influence anxiety or depression levels, but may impair the satisfaction of patients in an ICU. Further research studies are necessary in order to clarify the reason of the ICU patients' satisfaction impairment secondary to their prior ICU visit. In addition, a possible explanation may be the modification of patients' beliefs after the ICU visit (Ding et al., 2017; Khaleghparast et al., 2015). Therefore, the UCI visit of patients prior to hospital admission for scheduled surgery is not recommended for nursing management and practice, due to visit may impair the patients´ satisfaction with regard to emotional support, ease of getting information, control feeling, concerns and questions expression ability, and overall score for decision-making satisfaction.

The disturbance environment in an ICU may alter patients` sleep, emotions and anxiety according to the perceptions and beliefs of patients (Ding et al., 2017). Thus, the decreased emotional support, difficult of getting information, lack of control feeling, increase of

concerns and questions expression ability, as well as a worse decision-making satisfaction of patients who received a preadmission ICU visit could be secondary to the modification of these patients' beliefs.

Regarding similar research, a prior quasi-experimental study with two randomized groups carried out an informative intervention protocol (Chien et al., 2006). Three days after admission, the experimental group, who received an individualized education program based on the specific needs of each relative during ICU admission, was compared group control, who received the usual information protocol. Thus, the levels of anxiety through the Chinese version of the State-Trait Anxiety Inventory (C-STAI) and the satisfaction through the Chinese version of the CCFNI were self-reported by a total of 66 relatives. These results are in contrast to our findings, due to the intervention carried out in the study by Chien et al. (Chien et al., 2006) supposed a reduction of the levels of anxiety and depression, and a better satisfaction of relatives´ needs. Nevertheless, long-term results were not measured in comparison to our study, whose experimental group suffered from higher levels of anxiety and depression (without statistical significant differences) and showed less satisfaction with the received healthcare with respect to the control group.

4.1. *Implications for nursing management and practice*

Thus, an individualized education program based on the specific needs of each relative during ICU admission may reduce anxiety and depression as well as improve satisfaction (Chien et al., 2006); while the UCI visit of patients prior to hospital admission for scheduled surgery may not be recommended for nursing management due to this fact may impair the patients´ satisfaction.

For nursing management and practice, the ICU visit of the patients prior to hospital admission for scheduled surgery did not influence anxiety or depression. This visit impaired

the satisfaction of patients in an ICU considering emotional support, ease of getting information, control feeling, concerns and questions expression ability, and overall score for decision-making satisfaction. Nurses should promote an individualized education program based on the specific needs of each relative during ICU admission due to may reduce anxiety and depression as well as improve satisfaction (Chien et al., 2006). Nurses should not include the UCI visit of patients prior to hospital admission for scheduled surgery due to this fact may impair the patients´ satisfaction. Individualized relatives´ education programs, but not the patient´s visit prior to hospital admission, should be systematically included in multimodal approaches of nursing management and practice.

4.2.*Limitations*

Several limitations should be considered regarding the present study. First of all, the sample of patients comprised only patients who suffered from cardiopathies with a scheduled surgery. Thus, different types of patients suffering from various conditions should be studied in order to generalize our findings due to satisfaction may vary depending on different pathologies suffered from ICU patients (Jensen et al., 2017). In addition, our study did not include any patient who died during the research course and this fact could increase anxiety and depression levels (Quenot et al., 2017). Finally, symptoms of anxiety, depression, and posttraumatic stress according to cut-off scores or psychological diagnoses could show a low prevalence. These issues may mean that the overall prevalence of these symptoms in our sample could have influenced the differences between both groups. Further future studies should consider cut-off scores and diagnoses in order to get a more homogenous sample.

5. Conclusions

The visit prior to hospital admission did not seem to modify anxiety or depression, but may impair the satisfaction of patients in an ICU. The patients´ visit prior to hospital admission for surgery is not recommended in nursing management and practice regarding ICU environments, due to this fact impairs the patients´ satisfaction.

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Table 1. Socio-demographic and clinical characteristics between control and experimental groups of patients in an ICU.

	CONTROL (n=19)	EXPERIMENTAL (n=19)	CONTROL VS EXPERIMENTAL
	Mean ± SD / Median (IL−SL, 95% CI)	Mean ± SD / Median (IL−SL, 95% CI)	p-value
Age (years)	67.78 ± 10.45 / 4.70 (63.08–72.49)	71.10 ± 7.68 / 3.45 (67.64–74.56)	0.272 ***
Weight (Kg)	75.13 ± 14.44 / 6.49 (68.63–81.62)	73.74 ± 13.81 / 6.21 (67.53–79.95)	0.763 ***
Height (m)	1.63 ± 0.12 / 0.05 (1.58–1.69)	1.61 ±0.07 / 0.03 (1.58–1.65)	0.530 ***
BMI (Kg/m²)	27.87 ±3.87 / 1.74 (26.13–29.61)	27.94 ± 3.67 / 1.65 (26.29–29.59)	0.951 ***
ICU stay (days)	8 ± 12.95 / 5.82 (2.17–13.82)	4.00 ± 3.34 / 1.50 (2.49–5.50)	0.200 ***
Mechanical ventilation (days)	3.47 ± 6.91 / 3.10 (0.36–6.58)	1.63 ± 1.49 / 0.67 (0.95–2.30)	0.263 ***
Benzodiazepines intake (days)	6.42 ± 13.54 / 6.08 (0.33–12.50)	1.68 ± 1.52 / 0.68 (0.99–2.37)	0.138 ***
	Frequency (%)	Frequency (%)	p-value
Sex Men Women	11 (57.9%) 8 (42.1%)	9 (47.4%) 10 (52.6%)	0.516 **
Education Without studies Primary education Secondary education High school University	6 (31.6%) 2 (10.5%) 5 (26.3%) 1 (5.3%) 5 (26.3%)	7 (36.8%) 3 (15.8%) 4 (21.1%) 4 (21.1%) 1 (5.3%)	0.303 **
Religious beliefs Christian Atheist Jehovah's Witness Aconfessional Muslim	15 (78.9%) 2 (10.5%) 0 (0%) 2 (10.5%) 0 (0%)	13 (68.4%) 0 (0%) 1 (5.3%) 4 (21.1%) 1 (5.3%)	0.307 **
Previous psychiatric illness Yes No	1 (5.3%) 18 (94.7%)	3 (15.8%) 16 (84.2%)	0.290 **
Prior UCI experience as patient Yes No	6 (31.6%) 13 (68.4%)	4 (21.1%) 15 (78.9%)	0.461 **
Prior UCI experience as relative Yes No	10 (52.6%) 9 (47.4%)	8 (42.1%) 11 (57.9%)	0.516 **
Re-intervention Yes No	3 (15.8%) 16 (84.2%)	3 (15.8%) 16 (84.2%)	1.000 **
Renal replacement therapy use Yes No	0 (0%) 19 (100%)	0 (0%) 19 (100%)	N/A

Use of blood transfusions			
Yes	12 (63.2%)	12 (63.2%)	1.000
No	7 (36.8%)	7 (36.8%)	**
Re-intubation			
Yes	3 (15.8%)	1 (5.3%)	0.290
No	16 (84.2%)	18 (94.7%)	**
Patient´s death			
Yes	0 (0%)	0 (0%)	N/A
No	19 (100%)	19 (100%)	
Delirium episode			
Yes	5 (26.3%)	4 (21.1%)	0.703
No	14 (73.7%)	15 (78.9%)	**
Physical sequelae at discharge			
Yes	9 (47.4%)	11 (57.9%)	0.516
No	10 (52.6%)	8 (42.1%)	**
Visit number per day			
None	0 (0%)	0 (0%)	
Once a day	0 (0%)	0 (0%)	N/A
Twice a day	19 (100%)	19 (100%)	

Abbreviations: SD, standard deviation; BMI, body mass index: 95% CI, 95% confidence interval; IL, inferior limit; SL, superior limit; N/A, not applicable; ICU, intensive care unit. A p value < 0.05 was considered as statistically significant with a 95% CI. *Wilcoxon-Mann-Whitney ** Chi squared test ***Independent student t test.

Table 2. HADS total and domains scores between control and experimental groups of patients in an ICU.

		CONTROL Mean ± SD (IL-SL, 95% CI)	EXPERIMENTAL Mean ± SD (IL-SL, 95% CI)	CONTROL VS EXPERIMENTAL p-value
ANXIETY	**Before ICU admission**	7.26 ± 4.17 5.38 - 9.14	8.63 ± 4.85 6.44 - 10.81	0.178
	3 days after ICU discharge	7.10 ± 6.16 4.33 - 9.87	6.89 ± 5.11 4.59 - 9.19	0.454
	90 days after ICU discharge	5.36 ± 6.18 2.58 - 8.14	6.89 ± 5.32 4.50 - 9.28	0.210
DEPRESSION	**Before ICU admission**	5.00 ± 3.74 3.31 - 6.68	5.68 ± 3.40 4.15 - 7.21	0.279
	3 days after ICU discharge	5.15 ± 5.10 2.86 - 7.45	6.78 ± 5.07 4.50 – 9.07	0.164
	90 days after ICU discharge	2.68 ± 6.00 0.01 - 5.38	3.89 ± 5.85 1.26 - 6.52	0.266
TOTAL SCORE	**Before ICU admission**	12.26 ± 7.50 8.88 - 15.63	14.32 ± 6.79 11.25 - 17.37	0.191
	3 days after ICU discharge	12.26 ± 10.34 7.61 - 16.91	13.68 ± 9.11 9.58 - 17.78	0.327
	90 days after ICU discharge	8.05 ± 10.43 3.35 - 12.74	10.79 ± 9.77 6.39 - 15.18	0.266

Abbreviations: SD, standard deviation; 95% CI, 95% confidence interval; IL, inferior limit; SL, superior limit; ICU, intensive care unit; HADS, Hospital Anxiety and Depression Scale. A p value < 0.05 was considered as statistically significant with a 95% CI. Higher HADS score indicated higher values of anxiety, depression and total major depression.

Table 3. IES-R scores between control and experimental groups of patients in an ICU.

	CONTROL Mean ± SD (IL-SL, 95% CI)	EXPERIMENTAL Mean ± SD (IL-SL, 95% CI)	CONTROL VS EXPERIMENTAL p-value
Before ICU admission	5.73 ± 6.00 3.03 – 8.43	5.78 ± 5.90 3.13 – 8.44	0.489
3 days after ICU discharge	17.15 ± 21.26 7.59 – 26.72	15.10 ±18.87 6.61 – 23.59	0.377
90 days after ICU discharge	12.47 ± 14.97 5.74 – 19.20	17.78 ± 14.17 11.41 – 24.16	0.134

Abbreviations: SD, standard deviation; 95% CI, 95% confidence interval; IL, inferior limit; SL, superior limit; ICU, intensive care unit; IES-R, Impact of Event Scale-Revised. A p value < 0.05 was considered as statistically significant with a 95% CI. Higher IES-R score indicated higher values of stress.

Table 4. CCFNI total and domains scores between control and experimental groups of patients in an ICU.

	CONTROL Mean ± SD (IL-SL, 95% CI)	EXPERIMENTAL Mean ± SD (IL-SL, 95% CI)	CONTROL VS EXPERIMENTAL p-value
MEDICAL CARE	1.63 ± 1.53 0.94 – 2.32	1.84 ± 2.14 0.87 – 2.80	0.364
COMUNICATION	1.94 ± 1.98 1.05 – 2.84	1.78 ±2.43 0.69 – 2.88	0.414
PERSONNAL ATTENTION	2.68 ± 1.79 1.87 – 3.49	3.42 ± 2.24 2.41 – 4.43	0.135
PERCEIVED IMPROVEMENTS	2.47 ± 0.96 2.04 – 2.90	2.21 ± 0.91 1.79 – 2.62	0.197
TOTAL SCORE	8.73 ± 3.94 6.96 – 10.50	9.26 ± 6.49 6.34 – 12.18	0.382

Abbreviations: SD, standard deviation; 95% CI, 95% confidence interval; IL, inferior limit; SL, superior limit; ICU, intensive care unit; CCFNI, Critical Care Family Needs Inventory. A p value < 0.05 was considered as statistically significant with a 95% CI. Higher CCFNI score indicated higher satisfaction with the received attention.

Table 5. FS-ICU total, domains and items scores between control and experimental groups of patients in an ICU.

	CONTROL Mean ± SD (IL-SL, 95% CI)	EXPERIMENTAL Mean ± SD (IL-SL, 95% CI)	CONTROL VS EXPERIMENTAL p-value
ITEM 1-1 **Concern and care of the ICU staff**	1.63 ± 0.76 1.28 – 1.97	1.52 ± 0.90 1.11 – 1.93	0.350
ITEM 1-2 **Symptom management: pain**	1.78 ± 1.03 1.32 – 2.25	1.52 ± 0.84 1.14 – 1.90	0.197
ITEM 1-3 **Symptom management: dyspnea**	2.63 ± 1.89 1.78 – 3.48	2.52 ± 1.71 1.75 – 3.29	0.429
ITEM 1-4 **Symptom management: agitation**	2.47 ± 1.80 1.66 – 3.28	2.68 ± 1.73 1.90 – 3.46	0.358
ITEM 1-5 **Consideration of your needs**	1.57 ± 1.01 1.12 – 2.03	2.68 ± 1.73 1.90 – 3.46	0.236
ITEM 1-6 **Emotional Support**	1.89 ± 1.14 1.37 – 2.41	1.84 ± 1.21 1.29 – 2.38	0.020
ITEM 1-7 **Care coordination**	1.84 ± 1.34 1.23 – 2.44	2.78 ± 1.43 2.14 – 3.43	0.449
ITEM 1-8 **Concern and care of the ICU staff**	1.78 ± 1.03 1.32 – 2.25	2.05 ± 1.31 1.46 – 2.64	0.248
ITEM 1-9 **Skills and competence of ICU nurses**	1.52 ± 0.96 1.09 – 1.95	1.52 ± 0.84 1.14 – 1.90	0.500
ITEM 1-10 **Frequency in communication with nurses**	2.21 ± 1.31 1.61 – 2.80	1.84 ±1.16 1.31 – 2.36	0.183
ITEM 1-11 **Skill and competence of ICU doctors**	1.57 ± 1.26 1.01 – 2.14	1.31 ± 0.67 1.01 – 1.61	0.213
ITEM 1-12 **ICU environment**	1.73 ± 0.87 1.34 – 2.12	1.78 ± 1.08 1.30 – 2.27	0.434
ITEM 1-13 **Waiting room environment**	0.26 ± 1.14 -0.25 – 0.77	0.26 ± 1.14 -0.25 – 0.77	0.500
ITEM 1-14 **Satisfaction with the care provided by the patients´ relatives**	0.42 ± 1.01 -0.03 – 0.87	0.57 ± 1.42 -0.06 – 1.22	0.348
1st PART TOTAL SCORE **Satisfaction with healthcare**	23.36 ± 11.39 18.24 – 28.49	24.05 ± 10.38 19.38 – 28.72	0.423
ITEM 2-1 **Frequency of communication with ICU doctors**	1.78 ± 0.97 1.35 – 2.22	1.94 ± 1.12 1.43 – 2.45	0.323
ITEM 2-2 **Ease of getting information**	1.84 ± 0.83 1.46 – 2.21	1.42 ± 0.60 1.14 – 1.69	0.041
ITEM 2-3 **Understanding of the information**	2.05 ± 1.22 1.50 – 2.60	1.52 ± 0.84 1.14 – 1.90	0.065

ITEM 2-4 **Honest information**	2.05 ± 1.12 1.54 – 2.59	1.57 ± 1.01 1.12 – 2.03	0.091
ITEM 2-5 **Accurateness of information**	2.42 ± 1.42 1.77 – 3.06	1.89 ± 1.19 1.35 – 2.43	0.112
ITEM 2-6 **Consistency of information**	2.36 ± 1.46 1.71 -3.02	1.78 ± 1.13 1.27 – 2.29	0.090
ITEM 2-7 **Feeling of exclusion in the decision-making**	3.94 ± 1.02 3.48 – 4.40	3.31 ± 1.49 2.64 – 3.98	0.068
ITEM 2-8 **Feeling of support in the decision-making**	3.94 ± 0.91 3.53 – 4.35	3.52 ± 1.12 3.02 – 4.03	0.106
ITEM 2-9 **Feeling of control on the care of your relative**	3.89 ± 0.87 3.50 – 4.28	3.15 ± 1.57 2.45 – 3.86	0.041
ITEM 2-10 **Adequate time to raise your concerns and answer your questions**	2.15 ± 0.50 1.93 – 2.38	1.68 ± 0.47 1.46 – 1.89	0.002
ITEM 2-11 **In case of patient´s death: prolongation of life**	0.00 ± 0.00 0.00 – 0.00	0.00 ± 0.00 0.00 – 0.00	1.000
ITEM 2-12 **In case of patient´s death: last hours of life**	0.00 ± 0.00 0.00 – 0.00	0.00 ± 0.00 0.00 – 0.00	1.000
ITEM 2-13 **In case of patient´s death: staff support**	0.00 ± 0.00 0.00 – 0.00	0.00 ± 0.00 0.00 – 0.00	1.000
2nd PART TOTAL SCORE **Family satisfaction with decision-making**	26.47 ± 4.99 24.22 – 28.71	21.84 ± 3.87 20.09 – 23.58	0.001
GENERAL TOTAL SCORE	49.84 ± 15.62 42.81 – 56.86	45.89 ± 11.29 40.81 – 50.97	0.189

Abbreviations: SD, standard deviation; 95% CI, 95% confidence interval; IL, inferior limit; SL, superior limit; ICU, intensive care unit; FS-ICU, Family Satisfaction with Care in the Intensive Care Unit. A p value < 0.05 was considered as statistically significant with a 95% CI. Higher FS-ICU score indicated higher satisfaction with the received attention.

Table 6. FS-ICU dichotomous items responses between control and experimental groups of patients in an ICU.

	CONTROL Frequency (%)	EXPERIMENTAL Frequency (%)	CONTROL VS EXPERIMENTAL p-value
Lack of time in medical information			
Yes	0 (0%)	0 (0%)	1.000
No	19 (100%)	19 (100%)	
Need to improve the information room			
Yes	0 (0%)	0 (0%)	1.000
No	19 (100%)	19 (100%)	
Excessive noise in the ICU			
Yes	0 (0%)	1 (5.3%)	0.311
No	19 (100%)	18 (94.7%)	
Appreciation for the received healthcare			
Yes	5 (26.3%)	9 (47.4%)	0.179
No	14 (73.7%)	10 (52.6%)	
Lack of entertainment for patients			
Yes	1 (5.3%)	1 (5.3%)	1.000
No	18 (94.7%)	18 (94.7%)	
Dirty rooms			
Yes	0 (0%)	3 (15.8%)	0.071
No	19 (100%)	16 (84.2%)	
Lack of staff			
Yes	1 (5.3%)	3 (15.8%)	0.290
No	18 (94.7%)	16 (84.2%)	
Increase in visiting time			
Yes	0 (0%)	1 (5.3%)	0.311
No	19 (100%)	18 (94.7%)	
Toilet areas for family members			
Yes	0 (0%)	0 (0%)	1.000
No	19 (100%)	19 (100%)	
Rooms and lockers for family members			
Yes	0 (0%)	1 (5.3%)	0.311
No	19 (100%)	18 (94.7%)	
Poor regulation of environmental temperature			
Yes	0 (0%)	2 (10.5%)	0.146
No	19 (100%)	17 (89.5%)	
Lack of religious support			
Yes	0 (0%)	1 (5.3%)	0.311
No	19 (100%)	18 (94.7%)	

Abbreviations: ICU, intensive care unit; FS-ICU, Family Satisfaction with Care in the Intensive Care Unit. A p value < 0.05 was considered as statistically significant with a 95% confidence interval.