Manuscript (All Manuscript Text Pages in MS Word format,
including References and Figure Legends)

Impact of a nurse-driven patient empowerment intervention on the reduction in patients' anxiety and depression during intensive care unit discharge: a randomized clinical trial

Authors

Cecilia Cuzco, RN, PhDc[1,2,3]

Pedro Castro, MD, PhD[1,2,4]

Raquel Marín Pérez, RN, MSc[5,6]

Samuel Ruiz García, RN, MSc[5,6]

Ana I. Núñez Delgado, RN, MSc[7]

Marta Romero García, RN, PhD[3,6]

M. Antonia Martínez Momblan, RN, PhD[3,6]

Llucia Benito Aracil, RN, PhD[3,6]

Inmaculada Carmona Delgado, RN, MSc[1]

Montse Canalias Reverter, RN, MSc[8]

José M. Nicolás, MD, PhD[1,2,4]

Gemma Martínez Estalella, RN, MSc[6,8]

Pilar Delgado-Hito, RN, PhD[3,6]

[1] Medical lntensive Care Unit, Hospital Clinic of Barcelona, Spain.

[2] Department of Biomedical Research Institute August Pi Sunyer (IDIBAPS), Hospital Clínic of Barcelona, Spain.

[3] Department of Fundamental Care and Medical-Surgical Nursing, Nursing School of Faculty of Medicine and Health Sciences University of Barcelona, Barcelona, Spain.

[4] Faculty of Medicine and Health Sciences University of Barcelona, Barcelona, Spain.

[5] Department of Cardiologic. Hospital Bellvitge. L'Hospitalet de Llobregat, Barcelona, Spain.

[6] Department of Nursing Research Group (GRIN), Bellvitge Biomedical Research Institute (IDIBELL), L'Hospitalet de Llobregat, Barcelona, Spain.

[7] Department of lntensive Care Unit, Hospital Valle d'Hebron, Barcelona, Spain.

[8] Department of Nursing Head, Hospital Clínic of Barcelona, Spain.

This work was performed at:

1. Hospital Clínic of Barcelona, Barcelona, Spain.
2. Hospital Bellvitge. L'Hospitalet de Llobregat, Barcelona, Spain.
3. Hospital Valle d'Hebron, Barcelona, Spain.

Funding: This study was partially funded through a grant from the Nursing and Society Foundation (PR-248/2017) and was sponsored by the Hospital Clinic Barcelona.

Corresponding author:

Pedro Castro

Medical lntensive Care Unit, Hospital Clinic of Barcelona

C/Villarroel, 170, 08036

Barcelona, Spain.

+34932275400- 2044 pcastro@clinic.cat

Keywords: Anxiety, depression, patient empowerment, intensive care unit discharge, nursing intervention.

Copyright Form Disclosure: Drs. Cuzco, García, Aracil, Delgado, and Delgado-Hito received support for article research from the Nurse and Society Foundation as a part of the Nurse Research Projects Grants (PR-248/17). The remaining authors have disclosed that they do not have any potential conflicts of interest

Abstract

Objective: To assess the impact of a nurse-driven patient empowerment intervention on anxiety and depression of patients during intensive care unit discharge.

Design: A prospective, multi-center, randomized clinical trial.

Setting: Three Intensive Care Units (ICU) (1 medical, 1 medical and surgical and 1 coronary) of three tertiary hospitals.

Patients: Adults admitted to the ICU aged > 18 years for ≥ 48 hours with preserved consciousness, the ability to communicate and without delirium, who were randomized to receive the nurse-driven empowerment intervention (NEI) (intervention group (IG) or standard of care (control group CG)) before ICU discharge.

Intervention: The NEI consisted of an individualized intervention with written information booklets, combined with verbal information, mainly about the ICU process and transition to the ward, aimed at empowering patients in the transition process from the ICU to the general ward.

Measurements and Results: Patients completed the Hospital Anxiety and Depression Scale before and after (up to one week) ICU discharge. IG (n=91) and CG (n=87) patients had similar baseline characteristics. The NEI was associated with a significant reduction in anxiety and depression ($p<0.001$) and the presence of depression ($p=0.006$). Patients with comorbidities and those without family or friends had greater reductions in anxiety and depression after the NEI. After the intervention, women and persons with higher education levels had lower negative outcomes.

Conclusions: We found that a NEI before ICU discharge can decrease anxiety and depression in critically ill survivors. The long-term effect of this intervention should be assessed in future trials.

Trial registration: NCT04527627https://clinicaltrials.gov/ct2/show/NCT04527627

Key Points

Question: Does a nurse-driven empowerment intervention (NEI) decrease anxiety and depression levels in critically ill patients during discharge from the ICU?

Findings: In a randomized clinical trial, a NEI based on structured information to the patient was associated with a significant reduction in anxiety and depression ($p<0.001$) and the presence of depression ($p=0.006$) after ICU discharge.

Meaning: A NEI during ICU discharge can decrease anxiety and depression in critically ill survivors.

Introduction

Studies have shown that 30-50% of patients after intensive care unit (ICU) discharge have anxiety (1,2) and depression (3–5), which may be associated with long-term complications (6–10), such as difficulties returning to work (11), increased suicide risk (12), worse quality of life (13) and increased mortality (14), in what is known as post-ICU syndrome (15).

Various factors have been identified as a cause of anxiety and depression in these patients, some associated with the patient (especially female gender, younger age, lower educational level, unemployment, previous psychiatric symptoms and personality) and others related to ICU admission (reason for admission, traumatic memories during ICU stay, delirium, sedation, deterioration of physical function, and duration of mechanical ventilation, among others) (5). Evidence suggests that ICU discharge to the general ward provokes negative emotions, such as feelings of loss of control and autonomy that are associated with increased anxiety and depression (16,17).

Therefore, in 2009 the United Kingdom National Institute for Health and Care Excellence (NICE) made recommendations for ICU survivors, including the need to evaluate patients at risk of physical or mental morbidity before ICU discharge and offer them information about what could be expected during the ICU discharge process (18). One strategy to reduce anxiety and depression associated with ICU discharge is the nurse-driven patient empowerment intervention based on information and education provided to guide decision-making (19). This intervention, especially when nurse led, has proved useful in other health areas (20,21). However, the evidence for these interventions in the context of the critical patient and their transfer to the ward is limited. Data from previous studies have found uncertain effects (22), with small sample sizes (23,24), and very concrete population as coronary patients (25). These

limited data warrant further investigation of the key elements of ICU discharge empowerment that lead to a better patient experience.

Therefore, the aim of this study was to assess the impact of a nurse-driven patient empowerment intervention (NEI) on anxiety and depression in patients discharged from the ICU to the general ward.

Methods

Study design

This was a multicenter, parallel-group randomized clinical trial registered in ClinicalTrials.gov (NCT04527627) and approved by site-specific Institutional Review Boards. The results are reported using the Consolidate Standards of Reporting Trials (CONSORT) criteria (26).

Setting

The trial was conducted in three ICUs of three tertiary hospitals in Barcelona, Spain: one mainly medical, one general (medical and surgical) and one coronary unit. The three units have 49 ICU beds in total and admit around 2000 patients annually. All three have a registered nurse/patient ratio of 1:2.

Participants

We included patients admitted to the ICU aged > 18 years, with an ICU stay of ≥ 48 hours, who survived ICU discharge between September 2019 to April 2021. At inclusion (pre-discharge) exclusion criteria were delirium (assessed by the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) (27), an inadequate level of consciousness (Glasgow Coma Score < 15) (28), inability to express, read and write in Catalan or Spanish and provide consent to participate, mental disability and difficulty communicating, and patients admitted for COVID-19.

Reasons for exclusion were relevant patients diagnosed with mental illness before admission to the ICU because these patients either have already higher incidence of anxiety and depression, patients with difficulty in communication (speaking or writing) because it is associated to greater stress and anxiety for the patient and COVID-19 patients because they exhibited higher levels of anxiety associated to the pandemic situation.

Randomization

Simple random probabilistic sampling was carried out. Patients were recruited using the ICU admission list and randomly assigned to the intervention group (IG) or the control group (CG) in a 1:1 ratio.

Sample size

Based on data from previous studies (1–3), and estimating a percentage of patients with anxiety and depression at ICU discharge of 50%, we estimated that a sample size of 172 patients (86 in each group) was necessary to detect differences of >20% (CG 0.5 and IG 0.28), with a statistical power of 80% and a confidence level of 95% in a unilateral analysis, assuming a loss of 15%.

Data collection

The variables collected included sociodemographic data (gender, age, educational level, living with family and marital status), comorbidities (considered as a unique variable and defined as the presence of any other disease or condition in addition to the primary disorder, including chronic cardiovascular, respiratory, kidney or neurological diseases, diabetes or cancer, among others), clinical variables related to ICU admission (reason for admission, days of stay, level of severity at admission evaluated using the Acute Physiology and Chronic Health Evaluation (APACHE) II (29), events in the ICU (need for non-invasive mechanical ventilation, high-flow oxygen therapy, invasive mechanical

ventilation, self-extubation, reintubation, prone position, renal replacement therapy, intra-aortic balloon pump counter pulsation, extracorporeal oxygenation membrane, cardiopulmonary resuscitation, bronchoscopy, hemodiafiltration), level of consciousness (measured using the CGS), delirium (measured using the CAM-ICU), and the level of anxiety and depression at inclusion and after discharge measured by the validated Spanish version of the Hospital Anxiety and Depression Score (HADS) (30), a scale widely used in critical care (2,3). The HADS includes two subscales: anxiety and depression, with 7 items each, which assess the intensity of each item with a Likert-type scale from 0 to 4. The score ranges from 0-21 on each subscale, with scores of 0-7 being normal, and a score ≥ 8 on any of the subscales as symptoms of anxiety or depression.

Intervention

The NEI consisted of an individualized intervention aimed at empowering patients in the transition process from the ICU to the general ward. Briefly, it consisted of providing information to the patients about the ICU process (the reason for ICU admission, general information and description of the ICU and the care team, techniques and main procedures performed in the ICU day-to-day, devices present in the patient room, dynamics and recommendations for family visits) and the transition to the general ward process (characteristics and workflow in the destiny ward, personnel present there and differences between the two units). The information was structured by a guide in pamphlet format (“Information guide for patients admitted to the intensive care unit"), combined with verbal information.

The elements of the intervention were based on three main sources. First, on patients’ needs detected in previous qualitative research published elsewhere (31), mainly need to be informed about factors involved in the transition and expectations during transitioning from ICU. Second, it also considered the dimensions of empowerment

(32): biophysiological, cognitive, functional, experiential, ethical, social and financial. Finally, it was also based on the Guide for family members of the International Network "HUCI Project: Humanizing Intensive Care", a conceptual framework designed with the aim of developing specific actions that contemplates humanization as a transversal dimension of quality (33). The guide was reviewed by experts in developing information guidelines for patients and family members (doctors and nurses) and by ICU survivors. Finally, it was adapted to each participating ICU.

The intervention also included information about the current health status and patient education according to individual health needs, encouraging patient participation and promoting their autonomy during the transition from the ICU. Finally, specific concerns and needs expressed by each patient were individually answered, and they were informed that they could ask to the team after the planned encounter if they had any other questions or concerns. The NEI was initially expected to be performed in one 30-60 minutes session, being its duration adjusted according to the patient's preferences. It could be repeated if the patient asked for it, and the patient kept the informative guide in pamphlet format.

The NEI was applied by three research nurses (RN) (CC, RMP, AND) with more than 20 years of experience in critical patient care. Each of the 3 nurses was responsible for each participating ICU in the study. The RN nurse first contacted patients when a decision to discharge was made, which was defined as the starting point of the transition. Then, the objectives and development of the study were explained, and informed consent was obtained. At that moment, in the ICU, screening for anxiety and depression using the Hospital Anxiety and Depression Scale (HADS) was performed in both IG and CG for the first time. After that, the NEI was administered in IG at ICU. The RN agreed with the patient to perform the NEI at the most appropriate time for the

patient. RN had access to the patient's medical history, was aware of the reason for admission, including diagnosis, procedures and treatment, medications, discharge planning and any other essential issues, and individualized the NEI according to the health condition of each patient. ICU nurses were informed of the NEI implementation, and they could participate whenever they wanted, both during the NEI procedure (together with the RN) or afterwards.

Once the patient was in the general ward, the early effects of the NEI on anxiety and depression were assessed again using the HADS up to one week later, point when we considered the transition had finished. Outcome data were collected from participating patients in the two groups (IG and CG). All patients were discharged to the regular ward.

Primary Outcome

Reduction in anxiety and depression in patients discharged from the ICU to the general ward measured by Hospital Anxiety and Depression Scale.

Secondary Outcome

Association between sociodemographic and clinical variables and changes in anxiety and depression.

Statistical analysis

Qualitative or categorical variables were described using absolute frequencies and percentages and quantitative variables as means and standard deviation (SD). Between-group baseline sociodemographic and clinical characteristics were compared using the chi-square test for categorical variables and the t-test for independent samples for continuous variables. The t-test for repeated samples was used for continuous variables and McNemar’s test for categorical variables in the pre- vs. post-intervention between-group comparison of the level of anxiety and depression. Between-group differences

were compared using a t-test for independent samples. The relationship between sociodemographic and clinical variables and changes in anxiety and depression was studied using Pearson's correlation coefficients between continuous variables and changes in anxiety and depression were first calculated. Subsequently, to determine the independent factors associated with the changes, multiple linear regression models were constructed, based on covariance analysis (ANCOVA), considering the pre- and post-intervention differences as a response variable and the pre-intervention values as a variable to adjust (34). In the models, interactions between covariates with a significant effect on the response variable were included. A value of $p<0.05$ was considered statistically significant. We calculated the 95% confidence intervals (95% CI). The statistical analysis was performed using the R statistical program version 4.1.0. for Windows.

Ethical Considerations

The Ethics and Clinical Research Committees of the participating hospitals, Hospital Clinic Barcelona (HCB/2016/0484), Hospital Bellvitge (PR209/16/070716) and Hospital Vall d'Hebron (PR(ATR)197/2016) approved the project in each hospital. Written consent was obtained from all patients who agreed to participate. Participants' anonymity, confidentiality and voluntariness were guaranteed according to the Helsinki report. The scientific and social value of this research was guaranteed, and the prevalence of the interests of the participants over those of the research team through absolute respect for their person, following the recommendations of the Belmont Report.

Results

Baseline characteristics

Of the 1581 potential participants, 1403 were excluded due to death (n=219), COVID-19 (n=289) and no-meeting/meeting inclusion/exclusion criteria (n=895) (Figure 1). Therefore, 178 (84, 45 and 49 in each of the participating ICUs) patients were randomly assigned to the IG (n=91) and CG (n=87). Table 1 describes the baseline characteristics of participants, of whom 64.6% were male, with a mean age (SD) of 60.8 (14.8) years; 52.8% had primary or no education, 62.9% were married, and 77.3% had ≥ 1 comorbidity. At admission, the mean APACHE II was 15.5 (6.4) and 60.8% had an event during the ICU stay. The mean ICU stay was 11.9 (14.7) days. No significant between-group differences were found in the main variables at ICU admission, except for APACHE II, which was 14.5 in the CG vs. 16.6 in the IG (p=0.030) (Table 1).

Twelve patients were lost to the study during the follow-up (IG=7 and CG=5), of which 7 were due to death (IG=4 and CG=3), 3 patients were discharged to home before the second HADS assessment and 2 patients refused to continue in the study. No adverse effects associated with the intervention were recorded.

Primary outcomes

Baseline anxiety and depression and effect of the nursing intervention

Of the 178 patients, in the first evaluation (pre-ICU discharge) 49 patients (27.5%) presented anxiety and 35 (19.7%) depression. The results of the pre- vs. post-intervention comparison are shown in Supplementary material. Both groups showed a significant reduction in anxiety and depression between pre-discharge and post-discharge ($p<0.001$). However, the IG showed a significantly greater reduction in levels, with a mean of 1.46 points difference (95% CI 0.32-2.59) for anxiety and 1.98 (95% CI 0.86-3.09) for depression ($p<0.05$) (Figure 2). Similarly, the reduction in the percentage of patients who did not present anxiety or depression after discharge was greater in the IG (a reduction of 74.1 and 63.7%, respectively, vs. 50% and 38.4% in the CG.

Secondary outcomes

Association between sociodemographic and clinical variables and changes in anxiety and depression

The presence of comorbidities was associated with a greater reduction in anxiety (in the IG) and depression (in both groups) ($p<0.05$). Patients who lived alone (compared with those who lived with family or friends) also had a significantly greater reduction in anxiety in the IG ($p=0.047$). The remaining variables were not associated with significant differences in the reduction of anxiety or depression. The correlations between the degree of change in anxiety and depression on the HADS scale and the continuous variables (age, APACHE II and ICU stay) were not significant (Table 2).

In the ANCOVA model, comorbidities (beta estimate -2.889 and -1.870 for anxiety and depression, respectively, $p<0.01$), receiving the intervention (beta estimate -1.101 and -1.538 for anxiety and depression, respectively, $p<0.01$) and baseline level of anxiety (beta estimate -0.471, $p<0.001$) and depression (beta estimate -0.454, $p<0.001$) were independently significantly associated with a reduction in anxiety and depression (Supplementary material).

An interaction analysis was made to determine independent factors associated with changes in anxiety and depression pre- and post-intervention. There was a negative interaction between intervention group and female gender, indicating that the NEI significantly decreased depression in females ($p=0.045$). Likewise, an interaction between the educational level and the IG was found, with a higher level of education correlating with a significantly lower level of anxiety ($p=0.008$) (Supplementary material).

Discussion

This trial investigated the impact of a NEI on patients' anxiety and depression during ICU discharge. The results show a positive impact of the NEI on anxiety and depression compared with usual care. Patient loss of control and autonomy caused by dependence during the acute situation of ICU admission and by uncertainty during ICU discharge have been associated with anxiety and depression (16,17).

We found that at least 27.5% of patients presented symptoms of anxiety and 19.7% of depression. These data are in accordance with the results of other studies on the prevalence of anxiety and depression in ICU survivors (1,3,4), and are higher than the prevalence in the general population (35).

However, through information, the basis of empowerment (19), and of fostering feelings of motivation and providing the opportunity for patient participation in their care, patients can understand their current health status, what happened to them, the planning of continuity of care during the transition to the general ward and what is expected to happen. Thus, patients may feel they regain control of their lives and autonomy and consequently reduce anxiety and depression.

In our case, the NEI consisted of giving information using a leaflet as a support. This information took into account the needs expressed by the patients found in a first phase of a previously published study (31) and the literature, considering the dimensions of empowerment (32). Patient empowerment should follow the patient's preferences and learning abilities. Some patients preferred the NEI first thing in the morning, others after eating, and others before dinner. The choice of the topics of most interest is also important: some preferred to receive more information about the disease evolution, others wanted education on how to administer heparin or insulin or how to place oxygen masks; others needed motivation to recover and information about their rehabilitation and the resources available outside the hospital; and, for some foreign patients, their

biggest concern was how to pay for admission. New technologies can aid the development of innovative interventions, such as guides in digital format, videos or the creation of an interactive portal, always taking into account patient capabilities.

The results showed that anxiety and depression were also reduced in some patients in the CG. The transition from the ICU to the general ward may, for some patients, mean having overcome the acute reason for ICU admission, recovering limited mobility in the ICU, and being able to communicate and spend more time with the family, all factors that may justify this reduction. However, the reduction was much greater in the IG, both quantitatively, with a reduction in the HADS scale, and also in the reduction of the proportion of patients with pathological levels of anxiety or depression. This suggests that the NEI may, therefore, contribute to lower levels of post-ICU anxiety and depression.

We found no direct relationship between factors related to ICU admission, such as the reason for admission, the level of severity and the days of stay, and age with depression and anxiety levels (2,3,5,15). However, we did find, in contrast, that comorbidities and living alone were associated with a greater reduction in anxiety in the intervention group. Regarding comorbidities, previous studies have shown that people with chronic diseases are at higher risk of anxiety (36), as their diseases are difficult to diagnose and treat, contributing to low rates of remission, a poor prognosis and the risk of suicide (37). The greater decrease in anxiety and depression in these patients could be partially explained because these patients use to have previous experience of similar situations, which would act as a facilitating factor in the transition. However, comorbidities should be taken into account from the admission of these patients to the ICU for an early assessment and early care of post-ICU anxiety and depression. In regard to living alone, although it is known that the presence of family members in the ICU can have positive

effects on the emotional well-being of the patient and family (38,39) our results suggest a greater reduction in anxiety and depression in the IG among patients who live alone compared with those who live accompanied. A possible explanation, suggested by the interviews performed in the first phase of the present study (31), is that people living with family are concerned about them during the ICU transition; whereas those who live alone might be already "more prepared" to face the transfer due to their lifestyle. Further study of this aspect is required.

We found that women who received the NEI had a greater decrease in depression than men. There is evidence that gender is not a risk factor for post-ICU depression (2,3). However, a study which found a higher incidence of post-traumatic stress in women than in men who survived an ICU admission (40), also showed that women responded better to a follow-up intervention. We also observed that patients with higher educational levels had a better response to the NEI in reducing anxiety. A greater ability to understand the informational intervention due to their prior knowledge could help explain this finding.

Our results provide information in favor of interventions to increase patient empowerment during ICU discharge, and they should begin in the ICU, continue during the transition to the general ward and, subsequently, to hospital discharge (41).

Although the impact of implementing the NEI in the ICU nurses' workload was not specifically measured during the study, as it was performed entirely by the RN there was no evidence that it was increased. In other scenarios where the ICU nurses are the responsible of the NEI performance, impact on her workload should be considered. Considering the emotional and physical burden of ICU nurses, we suggest that the inclusion of advanced practice nurses and consulting mental health nurses in the ICU is key to this type of intervention. As we did not performed follow-up after discharge we

cannot assess if there was a lasting impact. Future research should look for long-term impact of these interventions too. The creation of a post-ICU follow-up team for the early detection and intervention of anxiety and depression would help to improve the quality of life of ICU survivors.

Limitations

The study has some limitations. Firstly, we assessed the impact of the NEI in a fairly short time frame (up to one week after ICU discharge). However, longer-term problems are also described (6,8). Even so, studies have shown that the data on the prevalence of anxiety, depression and PTSD at one week of ICU discharge correlate with those obtained at 3 months (9,10). This shows the need to assess these symptoms early, in order to intervene in a timely manner, although long-term post-discharge assessments are required to confirm the impact of the NEI. Second, all patients came from the metropolitan area of Barcelona, thus limiting the generalization of the results. Third, the complexity and communication problems presented by some patients at ICU discharge made it difficult to include patients, lengthening the recruitment period. Fourth, NEI was implemented by 3 different RN with experience in critical care. Although we cannot affirm that the implementation by other nurses would have obtained the same results, ability to communicate and inform are common capacities among ICU nurses and therefore similar results could be expected with other interveners. Fifth, results cannot be generalized to patients diagnosed with mental illness or with communication problems before ICU admission, as these populations were excluded of the study. These criteria were adopted to avoid inclusion bias, as those patients could present with higher incidence of anxiety and depression. Finally, the COVID-19 pandemic occurred during the study, limiting the inclusion of patients and extending its duration. COVID-19 patients were excluded because, at the beginning of the pandemic, we considered that in

the context of uncertainty, with an overwhelmed health system, and the required isolation measures, these patients were different to others and the intervention more difficult. This caused an extension of the inclusion period.

Conclusions

A NEI administered in critically-ill patients during ICU discharge was associated with reductions in anxiety and depression. Nurses can assess and optimize factors influencing the level of anxiety and depression in ICU survivors through interventions to help them achieve better health outcomes, overcome adverse situations related to ICU discharge and adapt to their current health situation.

Further studies are needed to demonstrate the long-term impact of a NEI in reducing levels of anxiety and depression among ICU survivors during ICU discharge.

Abbreviations

APACHE II: Acute Physiology and Chronic Health Evaluation II. **CAM-ICU:** Confusion Assessment Method for the Intensive Care Unit. **CONSORT:** Consolidated Standards of Reporting Trials. **GCS:** Glasgow Coma Score. **HADS:** Hospital Anxiety and Depression Scale. **ICU:** Intensive Critical Unit. **NEI:** Nursing Empowerment Intervention. **RCT**: Randomized Clinical Trial. **PTSD:** Post Traumatic Stress Disorder

Acknowledgements

Not applicable

Funding

This study was partially funded through a grant from the Nursing and Society Foundation (PR-248/2017) and was sponsored by the Hospital Clinic Barcelona.

Availability of data and materials

The datasets used and analyzed during the study are available from the corresponding author on reasonable request.

Authors' contributions

CC: Conceptualization, Methodology, Formal analysis, Data curation, Writing - original draft, Writing - review & editing, Visualization. **RMP** and **AND**: participated in data collection and are co-leaders of the study at each hospital. **SR**: participated in data collection. **MRG**: Conceptualization, Methodology, Writing - review & editing. **MAMM**: Conceptualization, Methodology, Writing – review & editing. **LLBA**: Formal analysis & Writing – review. **ICD**: Writing - review & editing the Information Guide for Patients. **GME**: Investigation, Resources and Networking. **MCR**: Investigation, Resources. **JMN**: Critical revision of the Guide and the manuscript for important intellectual content. **PDH**: Conceptualization, Methodology, Formal analysis, Data curation, Writing - original draft, Writing - review & editing, Visualization, Validation, Supervision, Project administration. **PC**: Conceptualization, Methodology, Formal analysis, Data curation, Writing - original draft, Writing - review & editing, Visualization, Validation, Supervision, Project administration. All authors read and approved the manuscript.

Consent for publication

Not applicable.

Competing interests

The authors declare they have no competing interests.

References

1. Hatch R, Young D, Barber V, Griffiths J, Harrison DA, Watkinson P. Anxiety, Depression and Post Traumatic Stress Disorder after critical illness: A UK-wide prospective cohort study. Crit Care. 2018;22(1):1–13.
2. Nikayin S, Rabiee A, Hashem MD, Huang M, Bienvenu OJ, Turnbull AE, et al. Anxiety symptoms in survivors of critical illness: a systematic review and meta-analysis. Gen Hosp Psychiatry. 2016;43:23–9.
3. Rabiee A, Nikayin S, Hashem MD, Huang M, DInglas VD, Bienvenu OJ, et al.

Depressive Symptoms after Critical Illness: A Systematic Review and Meta-Analysis. Crit Care Med. 2016;44(9):1744–53.

4. Proffitt T, Menzies V. Relationship of symptoms associated with ICU-survivorship: An integrative literature review. Intensive Crit Care Nurs [Internet]. 2019;53:60–7. Available from: https://doi.org/10.1016/j.iccn.2019.02.004

5. Davydow DS, Gifford JM, Desai S V., Bienvenu OJ, Needham DM. Depression in general intensive care unit survivors: A systematic review. Intensive Care Med. 2009;35(5):796–809.

6. Desai S V, Law TJ, Needham DM. Long-term complications of critical care. Crit Care Med. 2011;39(2):371–9.

7. Cutler LR, Hayter M, Ryan T. A critical review and synthesis of qualitative research on patient experiences of critical illness. Intensive Crit Care Nurs [Internet]. 2013;29(3):147–57. Available from: http://dx.doi.org/10.1016/j.iccn.2012.12.001

8. Bienvenu OJ, Friedman LA, Colantuoni E, Dinglas VD, Sepulveda KA, Mendez-Tellez P, et al. Psychiatric symptoms after acute respiratory distress syndrome: a 5-year longitudinal study. Intensive Care Med [Internet]. 2018 Jan 26 [cited 2021 Jun 19];44(1):38–47. Available from: http://link.springer.com/10.1007/s00134-017-5009-4

9. Milton A, Brück E, Schandl A, Bottai M, Sackey P. Early psychological screening of intensive care unit survivors: A prospective cohort study. Crit Care. 2017;21:273.

10. Wawer E, Viprey M, Floccard B, Saoud M, Subtil F, Wafa H, et al. Early detection of patients at risk of developing a post-traumatic stress disorder after an ICU stay. Crit Care Med. 2020;48(11):1572–9.

11. Myhren H, Ekeberg Ø, Stokland O. Health-related quality of life and return to work after critical illness in general intensive care unit patients: A 1-year follow-up study. Crit Care Med. 2010;38(7):1554–61.

12. World Health Organization. No Title [Internet]. 2020 [cited 2021 Jan 25]. Available from: https://www.who.int/news/item/14-05-2020-substantial-investment-needed-to-avert-mental-health-crisis

13. Petrinec AB, Martin BR. Post-intensive care syndrome symptoms and health-related quality of life in family decision-makers of critically ill patients. Palliat Support Care. 2018;16(6):719–24.

14. Won MH, Son YJ. Development and psychometric evaluation of the Relocation Stress Syndrome Scale-Short Form for patients transferred from adult intensive care units to general wards. Intensive Crit Care Nurs [Internet]. 2020;58:102800. Available from: https://doi.org/10.1016/j.iccn.2020.102800
15. Needham DM, Davidson J, Cohen H, Hopkins RO, Weinert C, Wunsch H, et al. Improving long-term outcomes after discharge from intensive care unit. Crit Care Med. 2012 Feb;40(2):502–9.
16. Cullinane JP, Plowright CI. Patients' and relatives' experiences of transfer from intensive care unit to wards. Vol. 18, Nursing in Critical Care. 2013. p. 289–96.
17. Tonelli MR, Misak CJ. Compromised autonomy and the seriously III patient. Chest. 2010;137(4):926–31.
18. NICE. National Institute for Health and Clinical Excellence. Rehabilitation after critical illness. NICE clinical guideline. [Internet]. London: The Stationery Office; 2009. Available from: www.nice.org.uk/guidance/cg83
19. Aujoulat I, D'Hoore W, Deccache A. Patient empowerment in theory and practice: Polysemy or cacophony? Patient Educ Couns. 2007;66(1):13–20.
20. Jørgensen CR, Thomsen TG, Ross L, Dietz SM, Therkildsen S, Groenvold M, et al. What Facilitates "Patient Empowerment" in Cancer Patients During Follow-Up: A Qualitative Systematic Review of the Literature. Qual Health Res. 2018;28(2):292–304.
21. Etemadifar S, Heidari M, Jivad N, Masoudi R. Effects of family-centered empowerment intervention on stress, anxiety, and depression among family caregivers of patients with epilepsy. Epilepsy Behav [Internet]. 2018;88:106–12. Available from: https://doi.org/10.1016/j.yebeh.2018.08.030
22. Lewis SR, Pritchard MW, Schofield-Robinson OJ, Evans DJ, Alderson P, Smith AF. Information or education interventions for adult intensive care unit (ICU) patients and their carers. Cochrane Database Syst Rev. 2018;2018(10).
23. Castillo MI, Mitchell M, Davis C, Powell M, Le Brocque R, Ullman A, et al. Feasibility and acceptability of conducting a partially randomised controlled trial examining interventions to improve psychological health after discharge from the intensive care unit. Aust Crit Care [Internet]. 2020;33(6):488–96. Available from: https://doi.org/10.1016/j.aucc.2020.01.002
24. Bench S, Day T, Heelas K, Hopkins P, White C, Griffiths P. Evaluating the feasibility and effectiveness of a critical care discharge information pack for

patients and their families: a pilot cluster randomised controlled trial. BMJ Open. 2015;5(11):e006852.

25. Kuchi ZG, Zakerimoghadam M, Esmaeili M, Geraiely B. The effect of an empowerment program on the perceived risk and physical health of patients with coronary artery disease. Holist Nurs Pract. 2020;34(3):163–70.

26. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. J Clin Epidemiol [Internet]. 2010 Aug [cited 2021 Jun 22];63(8):e1–37. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0895435610001034

27. Tobar E, Romero C, Galleguillos T, Fuentes P, Cornejo R, Lira M., et al. Método para la evaluación de la confusión en la unidad de cuidados intensivos para el diagnóstico de delirium: adaptación cultural y validación de la versión en idioma español (Method for the assessment of confusion in the intensive care unit to diagnose). Med Intensiva. 2010;34(1):4–13.

28. Teasdale G, Jennett B. Assessment of coma and impaired consciousness: a practical scale. Lancet. 1974;2(7872):81–4.

29. Knaus WA, Draper EA, Wagner DP, Zimmerman JE. APACHE II: a severity of disease classification system. Crit Care Med. 1985;13(10):818–29.

30. Tejero A, Guimera E, Farre J, Peri J. Uso clínico del HADS (Hospital Anxiety and Depresión Scale) en población psiquiátrica: Un estudio de su sensibilidad, fiabilidad y validez. Rev del Dep Psiquiatr la Fac Med Barcelona. 1986;13:233–238.

31. Cuzco C, Delgado-Hito P, Pérez Marín R, Núñez Delgado A, Romero-García M, Martínez Momblan MA, et al. Patients' experience while transitioning from the intensive care unit to a ward. Nurs Crit Care. 2021;(June):1–10.

32. Leino-Kilpi H, Luoto E, Katajisto J. Elements of empowerment and MS patients. J Neurosci Nurs. 1998;30(2):116–23.

33. de la Cueva-Ariza L. Guía de información de los familiares. Unidad de Cuidados Intensivos [Internet]. 2017. Available from: https://proyectohuci.com/wp-content/uploads/2017/06/guia_familiares_general_definitiva2.pdf

34. Clifton L, Clifton DA. The correlation between baseline score and post-intervention score, and its implications for statistical analysis. Trials [Internet]. 2019 Dec 11 [cited 2021 Jul 4];20(1):43. Available from:

https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-3108-3

35. Myhren H, Ekeberg Ø, Tøien K, Karlsson S, Stokland O. Posttraumatic stress, anxiety and depression symptoms in patients during the first year post intensive care unit discharge. Crit Care. 2010;14(1):2–13.

36. Villagrasa B, Olaya B, Lopez-Anton R, de la Cámara C, Lobo A, Santabárbara J. Prevalence of anxiety disorder among older adults in Spain: A meta-analysis. J Affect Disord [Internet]. 2019;246(November 2018):408–17. Available from: https://doi.org/10.1016/j.jad.2018.12.087

37. Remes O, Brayne C, van der Linde R, Lafortune L. A systematic review of reviews on the prevalence of anxiety disorders in adult populations. Brain Behav. 2016;6(7):e00497.

38. Simpson HB, Neria Y, Lewis-Fernandez R, Schneier. F. Anxiety disorders – theory, research and clinical perspectives. 1st ed. Cambridge: Cambridge University Press; 2010.

39. Kentish-Barnes N, Degos P, Viau C, Pochard F, Azoulay E. "It was a nightmare until I saw my wife": the importance of family presence for patients with COVID-19 hospitalized in the ICU. Intensive Care Med [Internet]. 2021 Jul 11;47(7):792–4. Available from: https://link.springer.com/10.1007/s00134-021-06411-4

40. Cypress BS, Frederickson K. Family Presence in the Intensive Care Unit and Emergency Department: A Metasynthesis. J Fam Theory Rev [Internet]. 2017 Jun;9(2):201–18. Available from: https://onlinelibrary.wiley.com/doi/10.1111/jftr.12193

41. Christensen M, Hewitt-Taylor J. Patient empowerment: does it still occur in the ICU? Intensive Crit Care Nurs [Internet]. 2007 Jun [cited 2014 Sep 25];23(3):156–61. Available from: http://www.sciencedirect.com/science/article/pii/S0964339706000383

Legend of Figures and Tables

Figure 1. Flow diagram of sample recruitment.

Figure 2. Levels of anxiety and depression in the intervention and control groups.

Table 1. Sociodemographic and clinical variables of the control and intervention groups.

Table 2. Changes in the levels of anxiety and depression (post-pre) according to sociodemographic and clinical variables and control and intervention groups.

Figure1. Flow diagram of sample recruitment.

Click here to access/download;Figure;Fig 1.tif

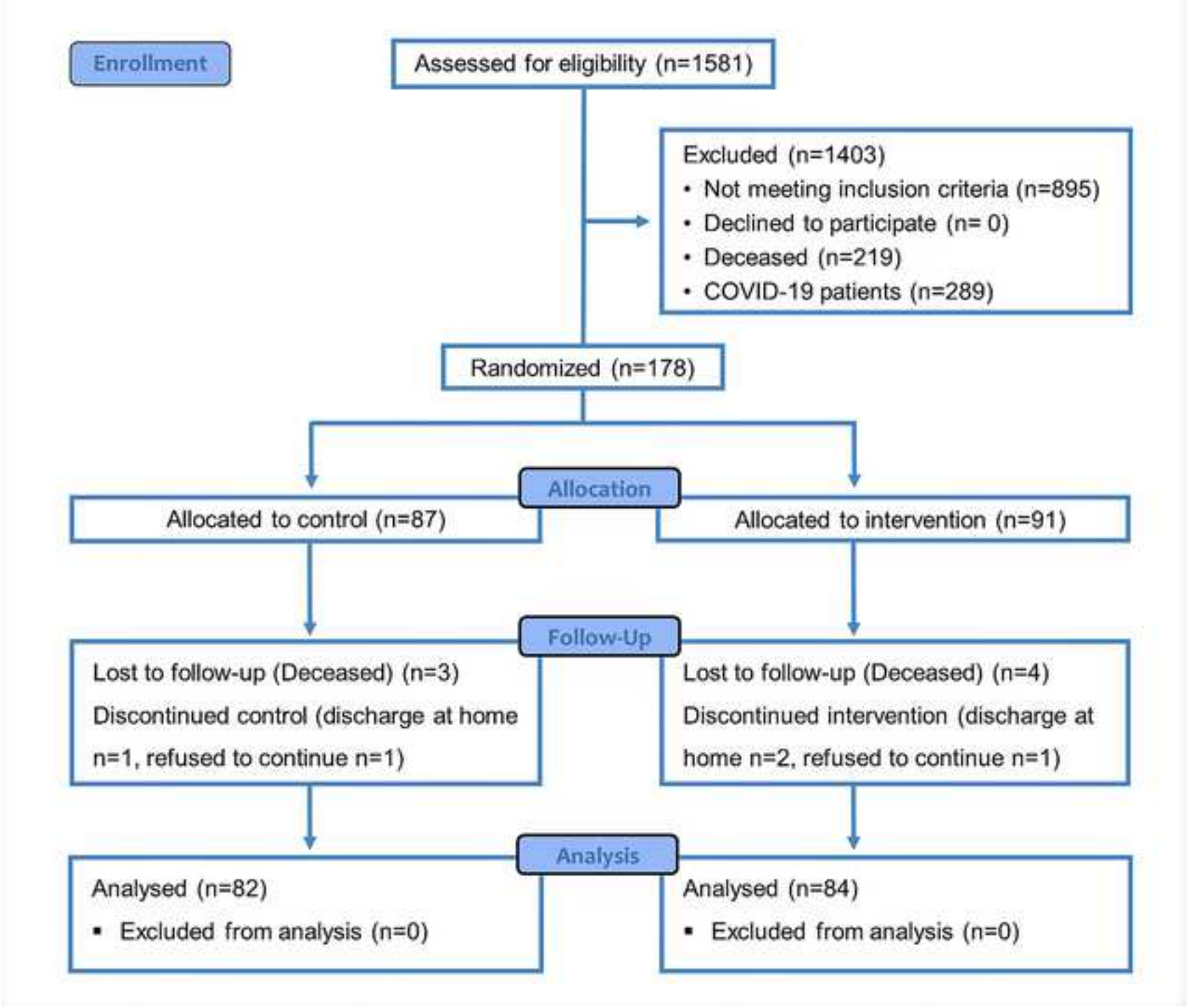

Figure 2

Click here to access/download;Figure;FIGURE 2.tif

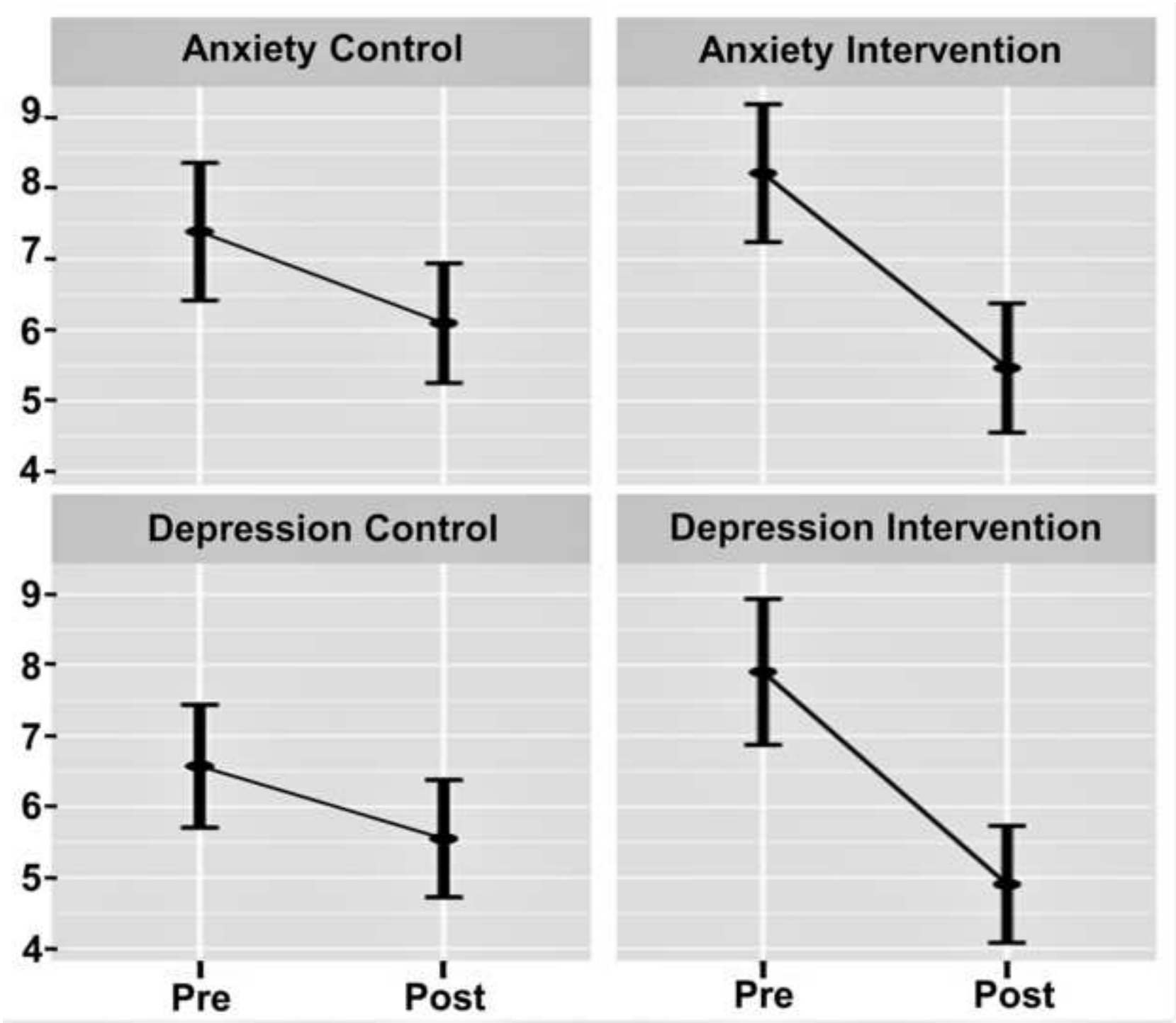

Table 1. Sociodemographic and clinical variables of the control and intervention groups.

Variables	**Total (n=178)**	**Control (n=87)**	**Intervention (n=91)**	**P-value†**
Gender, female	63 (35.4)	33 (37.9)	30 (33.0)	0.592
Age, years	60.8 ± 14.8	61.9 ± 14.8	59.7 ± 14.9	0.323
Educational level				0.315
No studies	12 (6.7)	9 (10.3)	3 (3.3)	
Primary	82 (46.1)	38 (43.7)	44 (48.4)	
Secondary	48 (27.0)	23 (26.4)	25 (27.5)	
Superior	36 (20.2)	17 (19.5)	19 (20.9)	
Family presence				0.305
Live alone	31 (17.4)	19 (21.8)	12 (13.2)	
Family	137 (77.0)	63 (72.4)	74 (81.3)	
Friends	10 (5.6)	5 (5.7)	5 (5.5)	
Marital status				0.187
Unmarried	32 (18.0)	17 (19.5)	15 (16.5)	
Married	112 (62.9)	53 (60.9)	59 (64.8)	
Couple	4 (2.2)	1 (1.1)	3 (3.3)	
Widow/er	17 (9.6)	12 (13.8)	5 (5.5)	
Divorced	13 (7.3)	4 (4.6)	9 (9.9)	
APACHE II	15.5 ± 6.4	14.5 ± 5.3	16.6 ± 7.2	0.03
ICU days of stay	11.9 ± 14.7	12.3 ± 18.5	11.5 ± 9.7	0.725
Event in ICU	107/176 (60.8)	48 (55.2)	59/89 (66.3)	0.175
Comorbidities	136/176 (77.3)	67/86 (77.9)	69/90 (76.7)	0.987

Values are expressed as mean ± standard deviation or n (%).

† Chi-square test for categorical variables and t-test for independent samples for continuous variables.

APACHE II: Acute Physiology and Chronic Health Evaluation. **ICU:** Intensive Care Unit.

Table 2. Changes in the levels of anxiety and depression (post-pre) according to sociodemographic and clinical variables in control and intervention groups

Variables	Control (n=82)		Intervention (n=84)	
	Anxiety (HADS)	Depression (HADS)	Anxiety (HADS)	Depression (HADS)
Gender				
Male	-1.3 ± 2.9	-1.3 ± 2.8	-2.5 ± 4.3	-2.6 ± 4.7
Female	-1.3 ± 3.3	-0.6 ± 2.5	-3.4 ± 4.1	-3.8 ± 3.7
P-value	0.937	0.280	0.361	0.243
Age, years†	0.020	-0.014	-0.119	-0.088
Educational level				
No Studies/Primary	-1.7 ± 3.6	-1.2 ± 2.7	-2.2 ± 4.5	-2.7 ± 4.7
Secondary/Higher	-0.8 ± 2.2	-0.8 ± 2.7	-3.4 ± 3.9	-3.4 ± 4.0
P-value	0.218	0.515	0.187	0.488
Family presence				
Live alone	-1.2 ± 3.5	-0.7 ± 3.7	-5.0 ± 4.2	-5.1 ± 5.3
Family/Friends	-1.3 ± 2.9	-1.1 ± 2.3	-2.4 ± 4.2	-2.7 ± 4.2
P-value	0.845	0.524	0.047	0.075
Marital status				
Single/Widowed/Divorced	-1.2 ± 3.1	-1.1 ± 3.2	-2.7 ± 3.6	-3.1 ± 4.7
Married/Couple	-1.4 ± 3.1	-1.0 ± 2.3	-2.8 ± 4.6	-3.0 ± 4.3
P-value	0.805	0.852	0.903	0.916
APACHE II†	-0.037	-0.115	0.110	0.176
ICU length of stay (days)†	0.072	0.025	0.011	-0.009
Event in ICU				
No	-1.5 ± 3.0	-1.2 ± 2.6	-1.8 ± 4.2	-2.8 ± 4.7
Yes	-1.1 ± 3.1	-0.8 ± 2.7	-3.2 ± 4.3	-3.1 ± 4.2
P-value	0.557	0.505	0.158	0.794
Comorbidities				
No	-0.4 ± 0.8	0.6 ± 1.2	-0.6 ± 2.8	-0.9 ± 3.3
Yes	-1.6 ± 3.4	-1.5 ± 2.8	-3.5 ± 4.4	-3.7 ± 4.5
P-value	0.139	0.003	0.007	0.011

The values are expressed as mean ± standard deviation in the case of categorical variables or correlation coefficient in the case of continuous variables (†). **APACHE II:** Acute Physiology and Chronic Health Evaluation. **HADS:** Hospital Anxiety and Depression. **ICU**: Intensive Care Unit.