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Mixed-method research protocol: Development and evaluation of a nursing intervention in patients discharged from the intensive care unit

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Abstract

Aim: (a) To understand patients' lived experience at intensive care unit (ICU) discharge and (b) to evaluate the impact of a nursing empowerment intervention (NEI) on patients' anxiety and depression levels at ICU discharge.

Design: A mixed-methods approach will be applied.

Methods: In the qualitative phase, the hermeneutic phenomenological method will be used. Participants will be patients from three university hospitals who will be selected by purposive sampling. Data will be gathered through in-depth interviews and analysed using content analysis. The qualitative data obtained will be employed to develop the nursing intervention. Subsequently, a multicenter, parallel-group, experimental pre-test/post-test design with a control group will be used to measure the effectiveness of the nursing empowerment intervention in the quantitative phase by means of the Hospital Anxiety and Depression Scale (HADS). Simple random probabilistic sampling will include 172 patients in this phase.

KEYWORDS
ICU discharge, mixed-method design, nursing intervention, post-intensive care syndrome

Pedro Castro Rebollo and Pilar Delgado-Hito are senior authors and contributed equally to this work.

1 | INTRODUCTION

Surviving a severe acute illness entailing intensive care unit (ICU) admission may be associated with considerable morbidity. Health problems remaining after critical illness are known as post-intensive care syndrome (PICS) (Needham et al., 2012). The most obvious components are probably those related to reduced respiratory function in long-term ventilated patients and neuromuscular disorders and physical dysfunction due to prolonged admission (polyneuropathy, myopathy, atrophy) (Harvey & Davidson, 2016). However, psycho-cognitive health problems occur in 30%–80% of cases (Desai et al., 2011; Needham et al., 2012) and have a direct impact on the quality of life (QoL) of patients and caregivers (Desai et al., 2011; Myhren et al., 2010) even several years after ICU discharge (Harvey & Davidson, 2016; Parker et al., 2015). Post-ICU patients often have mental health problems, including post-traumatic stress disorder (PTSD) (Cox et al., 2017; Davydow, 2015; Milton et al., 2017; Svenningsen et al., 2017), which includes pain, fatigue, weight loss and sleep disorders (Cox et al., 2017), anxiety and depression (Myhren et al., 2011; Rattray et al., 2010; Sevin et al., 2018), and worsened QoL (Da Costa et al., 2019; Ferrand et al., 2019; Mckinley et al., 2016; Thomas & Mehrholz, 2018).

The high incidence of post-ICU mental health problems has various causes. ICU patients experience many stress factors, including the motive for admission, invasive and painful procedures, lack of sleep, unnatural noise and light, inability to communicate, feelings of impotence and loss of control and, above all, the threat of imminent death (Cox et al., 2017; Garrouste-Orgeas et al., 2012; Ullman et al., 2015). ICU discharge may also be stressful, as patients are transferred from an environment rich in resources to one with fewer resources, which is a genuinely challenging care transition (De Grood et al., 2018; Stelfox et al., 2015). According to the well-documented Transitions Theory (Meleis, 2010), a transition is a process of passing from one phase of life, condition or status to another during which changes in the health status, the relationship of roles, expectations and abilities involve a period of vulnerability. It causes instability and may induce feelings of displacement and lack of control (Häggström & Bäckström, 2014), anxiety (Bench et al., 2011) and depression (McKinney & Melby, 2002). This phenomenon is also known as "transfer anxiety" and "relocation stress" (Carpenito-Moyet, 2006; McKinney & Melby, 2002; Won & Son, 2020). Therefore, ICU discharge may be a modifiable risk factor associated with PICS that could benefit from interventions, especially by nurses.

2 | BACKGROUND

Most interventions and efforts aimed at reducing PICS are focused on the ICU stay or post-ICU follow-up. Interventions proposed to prevent the psychological, cognitive and physical consequences of ICU admission (Colbenson et al., 2019; Devlin et al., 2018) include the Clinical Practice Guidelines for the Management of Pain, Agitation and Delirium in Adult Patients in the Intensive Care Unit (ICU PAD guidelines) of the American College of Critical Care Medicine and

the Society of Critical Care Medicine, updated in 2018 (Devlin et al., 2018). They emphasize preventing and treating delirium, daily interruption of sedatives and early mobilization (Kress & Hall, 2014). Studies have shown differing results for interventions to decrease PICS. The Early Psychologic Intervention (Peris et al., 2011) has been shown to cut the prevalence of anxiety, depression and PTSD by half. Another programme that included a complex, preventive psychological intervention (Lee et al., 2020) found self-reported PTSD symptom severity did not fall at six months. Some reports have shown a favourable impact of the ICU diary in patients and families (Garrouste-Orgeas et al., 2012; Knowles & Tarrier, 2009). However, a systematic review (Ullman et al., 2015) of randomized controlled trials (RCTs) that used ICU diaries to address PICS concluded that there was insufficient evidence of their effectiveness in improving psychological recovery after critical illness. A systematic review (Lewis et al., 2018) that assessed the effectiveness of information or educational interventions in improving outcomes in ICU patients and their carers found no evidence of an effect on PTSD. Some interventions are based on peer support: the Thrive Collaborative identified six general models: community-based, psychologist-led outpatient, ICU follow-up clinic, online, intra-ICU and peer mentor (McPeake et al., 2019). Other postdischarge follow-up programmes include the ICU structured nurse-led follow-up (Jónasdóttir et al., 2018), which did not improve post-ICU psychological recovery. A systematic review (Schofield-Robinson et al., 2018) of follow-up services found it was unclear whether they reduced depression, cognitive or physical function, or increased work and educational attendance. The ABCDE bundle on the prevention of PICS (Lee et al., 2020) reduced deep sedation and immobilization. A Spanish trial found that a visit before hospital admission did not influence anxiety or depression (González-Martín et al., 2019).

Despite these initiatives, discharge from the ICU has been little studied. Assessing patient experience during ICU discharge may be useful in understanding patient concerns and needs during this transition. By listening to patients, nurses could improve their care and help lessen these negative effects at this transition point.

The aims of this study are:

1. To understand patients' lived experience at ICU discharge.
2. To evaluate the impact of a nursing empowerment intervention (NEI) on patients' anxiety and depression levels at ICU discharge.

3 | METHODS

The study protocol was drafted according to the SPIRIT (Chan et al., 2013) checklist.

3.1 | Design

We will use a mixed-methods design with two sequential phases (Zhang & Creswell, 2013): phase I, with a qualitative

phenomenological approach, and phase II, with a quantitative experimental method (Figure 1). Mixed-methods research combines the strengths of qualitative and quantitative methodologies to increase understanding (Johnson et al., 2007) and provide more complete answers to the research question (O'Cathain et al., 2010, 2014).

3.2 | Phase I. Qualitative research study design

3.2.1 | Methods

A hermeneutic phenomenological approach based on Ricoeur's theory (Ricoeur, 1976).

3.2.2 | Setting and participants

We will include patients from three tertiary hospital ICUs with 151 level 3 ICU beds and a nurse/patient ratio of 1:2 that admit around 2,000 patients annually, mainly with medical, cardiology and trauma diagnoses.

Bearing in mind that qualitative sampling is not intended for statistical representation, but rather for typological representation, corresponding to the objectives of the study, purposive sampling will be used to recruit participants. Based on various characteristics that have shown greater clinical relevance and have been cited in studies as influencing the lived experience of critical patients (Romero García et al., 2013), 32 profiles will be created (Figure 2): (a) age (<65 years, >65 years), (b) sex (male, female), (c) family (yes, no), (d) comorbidities (yes, no) and (e) events (cardiopulmonary resuscitation, bronchoscopy, haemodialysis, non-invasive ventilation, invasive mechanical ventilation, self-extubation, reintubation, prone position) (yes, no). Although we will try to include at least two participants per profile, the sample size will be always guided by the theoretical saturation of data principle until no new data are found (Mason, 2010).

Box 1 lists the inclusion and exclusion criteria.

CAM-ICU, Confusion Assessment Method for the Intensive Care Unit.

3.2.3 | Qualitative data collection

Data will be collected by individual in-depth interviews (Curry et al., 2009; Denzin & Lincoln, 2005) that will take place two to five days after ICU discharge to the general ward. In their narratives, patients will be encouraged to think about the effect of their ICU discharge on their health, feelings, concerns, needs and expectations. Three researchers (CC, RM and AN) will carry out the interviews in each participating ICU and will make transcripts of the interviews. Interviews will be recorded and transcribed, including verbal and non-verbal language that reveals significant emotions and expressions of diverse feelings (McLellan et al., 2003). In addition to the in-depth interview, a field diary will be used with notes collected throughout the interview that will include descriptive and interpretive data based on patients' comments (Delgado-Hito, 2012).

In addition, sociodemographic (age, sex, educational level, occupation, family situation and civil status) and clinical variables (APACHE II score, motive for admission to the ICU, days of ICU stay) will be collected.

3.2.4 | Qualitative data analysis

Qualitative data will be analysed using descriptive analysis and interpretive analysis (Aujoulat et al., 2007):

Descriptive analysis: The descriptive analysis will start with data encoding using NVivo 11.0 software (QSR International Pty Ltd., 2012). Once the analysis of the first interviews is completed, two independent reviewers will verify the definition and content of the common categories and subcategories; subsequently, the definition
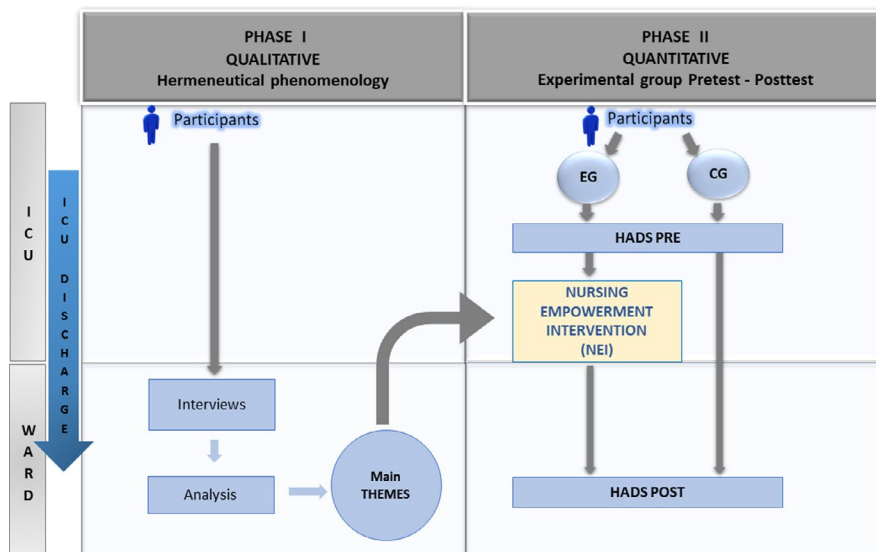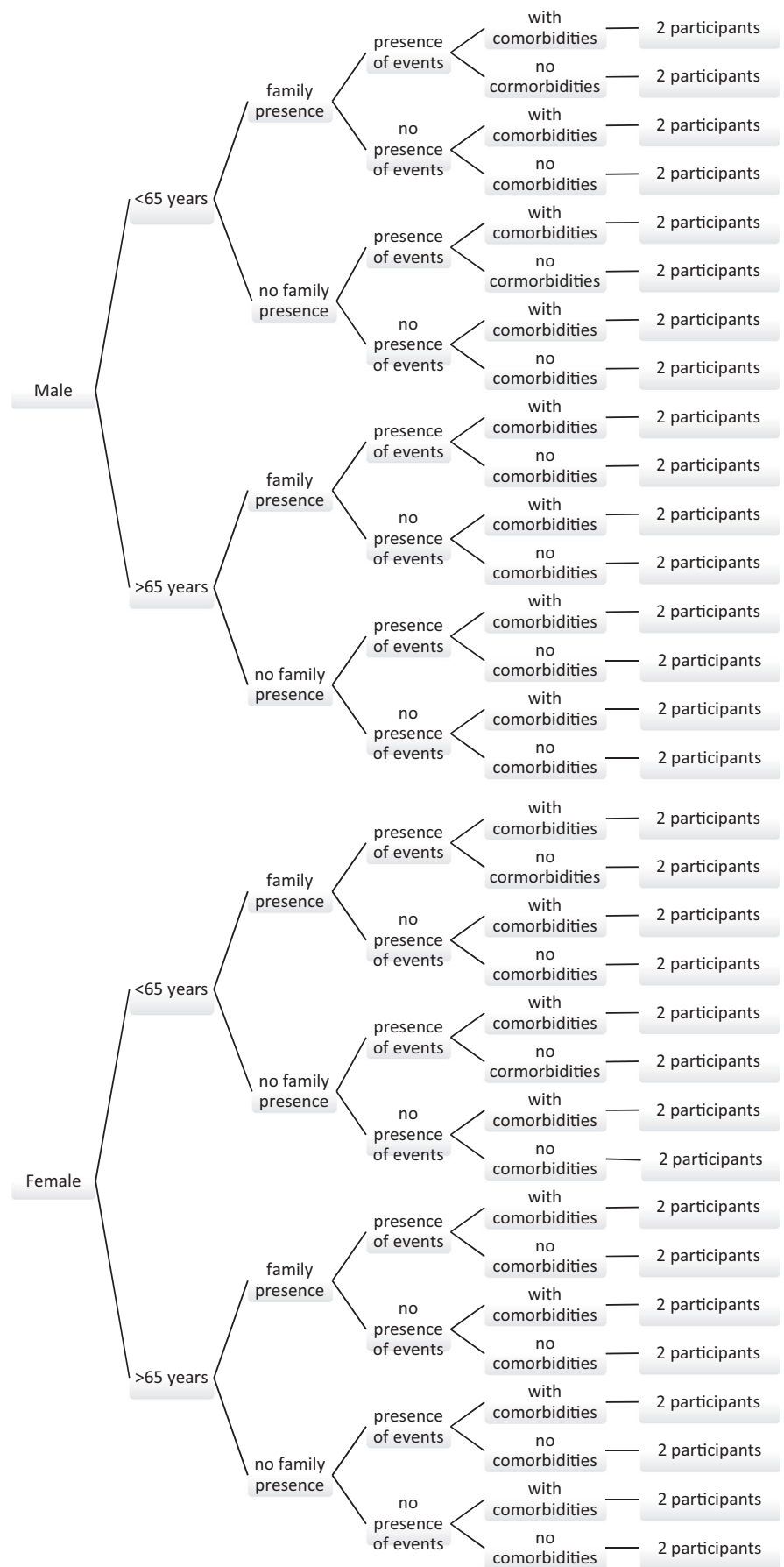

FIGURE 1 Mixed method study design. The structure of the study design is presented, with a qualitative approach in the phase I and a quantitative approach in phase II

FIGURE 2 Participants profiles

of some of the categories already described will be refined. Each definition will be supported by a quote from one of the interview transcripts. Every time a new topic comes up in an interview, it will be checked against previous transcripts. This will allow the general categorization to evolve until the end of the analysis.

Interpretative analysis: The categories obtained in the descriptive analysis will be interpreted to develop conceptual categories, that is categories that go beyond the mere description of the phenomenon being studied to begin to assign an interpretive meaning to the thematic descriptions that will emerge from the transcripts of the interviews. At this point, Ricoeur's Theory of Interpretation will be used for deeper analysis of the interviews (Ricoeur, 1976).

The interpretation will be in three phases: initial reading, structural analysis and integral comprehension (Lindseth & Norberg, 2004). First, preliminary comprehension of the text after an initial reading will consist of an initial interpretation of the total text and will lead to a first interpretation. The text will be read various times to understand its overall meaning. Secondly, structural analysis will discard or validate the first initial reading. Then, the text will be divided into units of meaning that will be condensed to form sub-themes and subjects, which will be compared with the preliminary comprehension for validation. Subsequently, the whole text will be read, and the initial comprehension and the subjects will be assessed with respect to the literature on the significance of the lived experience. The final step will be comprehensive understanding, which will assess the initial and the interpretive readings (Lindseth & Norberg, 2004). The process

will be dynamic, and the final interpretation will be the result of circular repetitions of the three methodological phases (Ricoeur, 1976). The analysis based on Ricoeur's Theory of Interpretation will allow a comprehensive, structured understanding and formulation of the main themes reflected in the interviews.

Two researchers (CC and PD) will perform individual analysis of the interviews, followed by a joint final analysis. Two co-investigators (MR and MAM) will verify the interpretation of the interviews.

3.3 | Phase II. Quantitative research study design

3.3.1 | Methods

In a mixed-methods study, quantitative data collection is built on the findings from the initial, qualitative approach (Zhang & Creswell, 2013). In phase II, a multicenter, parallel-group, experimental pre-test/post-test design will be used. The study timeline, schedule of enrolment, intervention and assessment are presented in Figure 3

3.3.2 | Setting and participants

We will include patients from three tertiary hospital ICUs in Barcelona, with 151 level 3 ICU beds and a nurse/patient ratio of

	Study Period				
	Enrollment	Allocation	Postallocation		Closeout
Time Point	ICU admission	48 hours of ICU admission	ICU stay	ICU discharge	2 to 5 days of general ward
Enrolment:					
Eligibility screen			X		
Informed consent			X		
Patient information			X		
Allocation		X			
Interventions:					
Experimental group: Nursing Empowerment Intervention				X	
Control group: Usual nursing information				X	
Assessments:					
A Demographic Questionnaire			X		
APACHE II score	X				
Glasgow Score			X		
CAM-ICU			X		
SCALE HADS			X		X

APACHE II: Acute Physiology and Chronic Health Evaluation
CAM-ICU: Confusion Assessment Method for the Intensive Care Unit
HADS: Hospital Anxiety and Depression Scale

FIGURE 3 Study timeline, schedule of enrollment, intervention and assessment

BOX 1 Inclusion and exclusion criteria in the study (phase I and phase II).

Inclusion criteria
Age ≥18 years
>48 hr in the critical care unit
Spanish- or Catalan-speaking
Ability to communicate orally
Able to provide informed consent
Glasgow Coma Scale Score = 15
Without delirium (CAM-ICU negative)
> 48 hr in the general ward after ICU discharge

Exclusion criteria
Pre-existing chronic cognitive impairment, such as dementia
Pre-existing psychotic illness, such as schizophrenia
End-of-life care

1:2 that admit around 2,000 patients annually, mainly with medical, cardiology and trauma diagnoses. Box 1 lists the inclusion and exclusion criteria. To reduce the potential confounding effects of medications or procedures, only patients who meet the inclusion criteria will be included, thus ensuring a relatively homogeneous sample of the three participating ICUs. To reduce potential confounding effects of the clinical condition in the ICU, the patient will be evaluated using the Glasgow and Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) scales to assess whether the patient is able to be assessed using the HADS scale. The Glasgow Coma Score (Teasdale & Jennett, 1974) is an objective and easily reproducible scale designed to evaluate the level of consciousness. The CAM-ICU scale has high sensitivity (93%–100%) and specificity (89%–100%) for the diagnosis of delirium in the ICU and a Spanish version has been adapted and validated (Tobar et al., 2010).

Simple random probabilistic sampling will be used. Patients will be included using the list of ICU admissions and randomly assigned to experimental (EG) and control groups (CG). The 1:1 randomization will be stratified by the investigating nurses (CC, RM and AN) in each ICU. The sample size calculation will be made according to a statistical power of 80% and 95% confidence intervals in a unilateral analysis. The percentage of patients with high anxiety at ICU discharge will be estimated at 50% (between 30%–75% according to previous reports) (Hatch et al., 2018; Nikayin et al., 2016). Assuming a rate of losses of 15% per group, 86 patients per group will be required to detect a difference of >20% as significant (expected to be 0.5 for the CG and 0.28 for the EG).

3.3.3 | Nursing empowerment intervention

The intervention will be made during planning for ICU discharge. Based on the literature review on patient empowerment during the transition from the ICU to the general ward, the findings in our study of individual interviews with patients, the collaboration of patients

who survived the ICU and experts in the development of patient information guides were taken into account in developing an informative guide for patients at ICU discharge, which will support the implementation of the NEI in the quantitative phase. The informative guide will be divided into sections that will provide information on ICU admission and education on basic patient needs. Information will be added according to the areas of knowledge required to ensure empowerment: biophysiological, functional, cognitive, social, experimental, ethical and economic (Leino-Kilpi et al., 1998). It will also contain information on the main procedures carried out and the care that will be needed on the general ward, the general ward characteristics and the differences with the ICU.

The aim of the NEI is to prepare patients for discharge from the ICU and assist them during the early ward stay and reduce anxiety and depression levels during the transition from the ICU to the general ward. The introduction of empowerment in patients has proven to be beneficial clinically and in care (Jørgensen et al., 2018; Lambrinou et al., 2019). Reports show that empowered patients actively contribute to their health recovery and participate in decision-making (Castro et al., 2016) since they feel they are in control of their lives, especially taking into account the manifest loss of autonomy and lack of control during this transition. The information and education provided the basis for empowerment, increases confidence, promotes recovery, reduces treatment complications and allows healthy behaviours to be learned. In intensive care, empowerment has been found to generate dominance over the anxiety felt (Wåhlin, 2017) and contribute to satisfaction (Fitzpatrick et al., 2011; Hauck et al., 2011).

The NEI will be administered by the investigating nurses (CC, RM and AN) in the participating ICUs, starting the day the decision to transfer the patient to the general ward is made. The NEI will include a written booklet as a guideline and will be verbally explained to the patient. The research nurse will ensure that the patient has acquired the knowledge and information necessary for the moment of transition from the ICU to the ward by asking feedback questions. They will also offer the possibility of requesting more information or clarification of doubts at any other time.

3.3.4 | Quantitative variables and data collection

Variables

1. Independent variable: NEI carried out during discharge from the ICU.
2. Dependent variable: Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) before and after discharge from the ICU.
3. Sociodemographic variables will include sex, age in years, level of education (basic, primary, secondary, higher), profession, family situation (living alone, with family or friends) and civil status (single, married or cohabiting, widow/er, divorced).
4. Clinical variables: severity level at ICU admission (assessed using the APACHE II score), reason for ICU admission and days of ICU stay.

The investigating nurses will collect the data during the ICU stay, where the objectives of the study will be explained, and informed consent obtained.

Instruments

1. *Glasgow Coma Score* (Teasdale & Jennett, 1974): The Glasgow scale is designed to assess the level of consciousness and includes the assessment of the ocular, verbal and motor responses. It is simple, objective and easily reproducible.

2. *The Confusion Assessment Method for the Intensive Care Unit* (CAM-ICU) (Ely et al., 2001; Inouye,) adapted and translated to Spanish by Tobar et al., (2010), which is recommended and validated for the detection of delirium. The four criteria that characterize delirium are evaluated using four questions for each area (change in mental status, inattention, altered consciousness and disorganized thinking).

3. The HADS (Zigmond & Snaith, 1983): Adapted and validated in Spanish by Tejero et al., (1986), it comprises two 7-item subscales for anxiety and depression. The intensity/frequency of symptoms is evaluated on a four-point Likert scale. For each subscale, the score ranges between 0–21:0–7 normal; 8–10 doubtful/possible clinical problem; and >10 likely clinical problem. It measures the status during the last seven days. Designed for patients with organic disease, the physical aspects of anxiety or depression were eliminated, leaving only the emotional factors. As well as the quantitative assessment that may be stratified into not anxious or not depressed when the scores are below 8, possible / doubtful when the scores are between 8-10, and anxious and depressed when the scores are ≥11. The authors suggest that an upper limit of 10/11 may be used when the rate of false positives is low and a limit of 8/9 to prevent false positive. We used a value of 10 as a cut-off point to measure anxiety and depression.

4. *Acute Physiology and Chronic Health Evaluation* (APACHE) II (Knaus et al., 1985): The original version used 34 items to measure the severity of critical illness. This was reduced to 14 in the 1985 revised version. Disease severity is measured using twelve common physiological measures, the pre-existing health status and age. The score ranges between 0–71 points.

The HADS will be administered in the EG and CG groups before administration of the NEI. Two to five days later, in the general ward, the HADS will be administered again to assess the impact of the intervention on patients' anxiety and depression during ICU discharge.

Once the measuring instruments have been collected, the same sociodemographic and clinical variables as in phase I will be collected.

3.3.5 | Quantitative data analysis

The statistical analysis will be made using SPSS v23. Values will be expressed as means (standard deviation) for continuous variables with a normal distribution, or medians and interquartile range, and frequencies and percentages will be used for categorical variables.

Linear correlations will be assessed using Pearson's correlation coefficient.

Between-group differences will be analysed through parametric and non-parametric tests (Kruskal–Wallis for groups exceeding 2, ANOVA in homogenous samples and Student's *t* test for dichotomous variables, with frequencies, mean and *SD*). Statistical significance will be established as $p < .05$.

The results will be reported using the Consolidated Standards of Reporting Trials (CONSORT) criteria.

3.3.6 | Data triangulation

Triangulation is a methodological approach that will contribute to the validity of the research results by linking qualitative and quantitative data. Data will be collected and analysed separately for each phase of the study, obtaining two sets of findings. Subsequently, the data will be triangulated. Preliminary findings from the interviews will be checked against quantitative data. The Triangulation Protocol for Health Research Studies will be used to aid data integration (Farmer et al., 2006).

3.4 | Rigour of the study

Mixed-methods research has methodological challenges, particularly with respect to rigour (Wisdom et al., 2012). Quantitative studies usually rely on quality criteria, including internal validity, generalizability and reliability (Campbell, 1957; Campbell & Stanley, 2015; Messick, 1995; Onwuegbuzie, ; Onwuegbuzie & Daniel, 2002; Onwuegbuzie & Daniel,). However, qualitative studies use roughly comparable quality criteria (Lincoln & Guba, 2000), saturation criteria, meaning in context and credibility (Leininger, 1990) and ethical reflection (Gastaldo & McKeever, 2000). All will be taken into account. Finally, investigator triangulation will reinforce the data analysis (Denzin, 1978, 1989; Farmer et al., 2006).

3.5 | Ethical approval and informed consent

Ethical approval was obtained from the Clinical Research Ethics Committees of the study hospitals (HCB/2016/0484, PR209/16/070716, PR(ATR)197/2016). All participants will be required to sign an informed consent form containing the study details and guaranteeing anonymity and confidentiality, which will be carried out according to the Declaration of Helsinki (The World Medical Association, 2013). The study complies with the recommendations of the Belmont Report. Participation in the study will be totally voluntary. If any participant decides not to participate or not continue the study, they may withdraw consent at any time without altering their relationship with the bedside nurse or causing any harm to their care. The treatment, communication and transfer of personal data of all participating subjects will comply with the provisions of Spanish Law

(3/2018) on the protection of personal data and development regulations. The data collected in the study will be identified by a code and only the study researchers/collaborators will be able to relate said data to the participant. This material will be destroyed 5 years after the end of the study. None of the three researchers who will conduct the interviews and administer the intervention in each ICU will be involved in the usual ICU care of patients.

Date and version identifier of Protocol Study: "Issue date: 20 Jul 2017. Protocol version number 3" Revision chronology: 04 April 2016 Original. 28 June 2016: Amendment No 2: At the request of the Ethics Committee, information was added to better clarify the Patient Information Sheet. 20 Jul 2017. Amendment No 3: At the request of the university, the title of the study was modified.

The study results will be sent to a peer-reviewed nursing journal and presented to the local intensive care community and other stakeholders.

4 | DISCUSSION

Nurses need to improve their understanding of patients' experiences during ICU discharge to assist them in therapeutic interventions. Listening to patients' lived experiences will help determine what their real needs, concerns, feelings and expectations during transfer from the ICU are.

The implementation of a nursing intervention, through a specific "Patient Information Guide for Intensive Care Unit patients," aims to inform in a consensual, structured manner and to meet the information needs expressed by ICU patients during the ICU stay. Likewise, it will help to provide information during the transfer from the ICU to the general ward and clarify any doubts patients may have. The intervention is intended to be easy to apply in ICU and general ward patients.

The application of the HADS scale will help detect patients with possible anxiety and depression disorders related to PTSD and PICS and is easily applicable to patients in the ICU and general wards. It will be administered by the investigating nurse or by the patient themselves, as the scale was designed for self-administration.

The results will permit better understanding of the anxiety and depression due to transfer from the ICU and will facilitate comparison with international studies their results that have implemented nursing interventions during this transition to help and treat patients and improve care.

The results will also contribute to increased translational knowledge to lines of research such as the empowerment of the ICU patient and the humanization of the ICU and the need to incorporate other professionals such as mental health nurses and psychologists into the multidisciplinary ICU team. Finally, the study may advance mixed-methods research in nursing science.

CONFLICT OF INTEREST
The authors declare they have no competing interests.

AUTHOR CONTRIBUTIONS
CC is the principal investigator of the project, whose design and development are directed by PDH and PCR. RMP and AND recruited participants. PDH, MRG and MAMM contributed specifically to the qualitative analysis plan. GME contributed specifically to the design of the budget impact analysis and also oversaw the study logistics. DER involved in drafting the intervention, which was analysed and supplemented by all other authors. PCR contributed specifically to the statistical analysis plan. All authors have revised and approved the submitted manuscript.

TRIAL REGISTRATION
NCT04527627. Registered: 08/22/2020. "retrospectively registered" https://clinicaltrials.gov/ct2/show/NCT0452762

DATA AVAILABILITY STATEMENT
All data related to the present mixed-method research protocol can be obtained by sending requests to the corresponding author.

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