







RESEARCH

Patients' experience while transitioning from the intensive care unit to a ward

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Abstract

Background: Intensive care unit (ICU) patients can experience emotional distress and post-traumatic stress disorder when they leave the ICU, also referred to as post-intensive care syndrome. A deeper understanding of what patients go through and what they need while they are transitioning from the ICU to the general ward may provide input on how to strengthen patient-centred care and, ultimately, contribute to a positive experience.

Aim: To describe the patients' experience while transitioning from the ICU to a general ward.

Design: A descriptive qualitative study.

Method: Data were gathered through in-depth interviews and analysed using a qualitative content analysis. The qualitative study was reported in accordance with the Consolidated Criteria for Reporting Qualitative Research guidelines.

Findings: Forty-eight interviews were conducted. Impact on emotional well-being emerged as a main theme, comprising four categories with six subcategories.

Conclusion: Transition from the ICU can be a shock for the patient, leading to the emergence of a need for information, and an impact on emotional well-being that has to be planned for carefully and addressed prior to, during, and following transition from the ICU to the general ward.

Relevance to clinical practice: It is essential that nurses understand patients' experiences during transfer, identifying needs and concerns to be able to develop and implement new practices such as ICU Liaison Nurse or Nurse Outreach for the follow-up of these patients, the inclusion of a consultant mental health nurse, and the application of patient empowerment during ICU discharge.

Pilar Delgado-Hito and Pedro Castro Rebollo contributed equally to this study.

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KEYWORDS

content analysis, ICU discharge, ICU transfer, ICU transition, post-intensive care syndrome, post-traumatic stress disorders, qualitative research, relocation stress

1 | BACKGROUND

Being admitted to an intensive care unit (ICU) can be a traumatic experience. A multitude of studies have shown that patients who leave the ICU present sleep disturbance,^{1,2} fear,³ traumatic memories,⁴ anxiety,⁵⁻⁷ depression,^{6,7} and post-traumatic stress disorder (PTSD).^{8,9} Around 50% to 70% of ICU survivors suffer from long-term physical, cognitive, and psychological impairments.¹⁰ Some of these symptoms have been grouped into “post-intensive care syndrome” (PICS)¹¹⁻¹³ and can also affect the patient's family (PICS-F).^{14,15} The incidence of psychological disorders in adult patients 3-month post-ICU is high, and these may persist during the first year following ICU discharge and are strongly associated with a reduction in the quality of life.¹⁶⁻¹⁸

Although much effort is made to reduce PICS by intervening during the ICU stay and post hospital discharge,¹⁹⁻²¹ little attention has been paid to the transition process and the understanding of the experiences and expectations of ICU patients during the transition from ICU to a general ward.

The ICU is a highly specialized area in the hospital designed and intended for those patients with life-threatening conditions and/or vital organ dysfunction. It requires specialized continuous care in a technical area, with specialist health care professionals and life support devices.²² With an increasingly aging population and advances in medicine, the demand for critical care beds is high and there is an acute awareness that they are a finite resource.²³ This means that patients, as soon as ICU care is not indicated, have to be transferred from a resource-rich environment to one with fewer resources, which is a genuinely challenging care transition.²⁴⁻²⁶

According to the well-documented Transitions Theory,²⁷⁻²⁹ a transition is a process of passing from one phase of life, condition, or status to another during which changes in health status, the relationship of roles, expectations, and abilities undergo a period of vulnerability. Patient anxiety associated with this transfer from the ICU is known as transfer anxiety or relocation stress.³⁰ This situation is also defined by the North American Nursing Diagnosis Association (NANDA) as when “a person experiences physiological and/or psychological disturbances as a result of transfer from one environment to another.”³¹ In line with NANDA, the defining characteristics of relocation stress include anxiety and depression, as well as a range of other physical and psychological symptoms such as feelings of insecurity, lack of trust, dependency, increased need for reassurance, concerns about being transferred, and an unfavourable comparison of pre-and post-transfer staff.³¹

To prevent PICS, the multidisciplinary team should pay attention to modifiable risk factors³² such as patients' ICU experience.³³ This is

What is known about this topic

- Intensive care unit (ICU) survivors suffer from long-term physical, cognitive, and psychological impairments.
- Studies have shown that patients who leave the ICU present anxiety, depression and post-traumatic stress disorder. These symptoms have been grouped into “post-intensive care syndrome”.
- Patient anxiety associated with the transfer from the ICU is also known as “transfer anxiety” or “relocation stress.”

What this paper adds

- Negative patient experience of transition from the intensive care unit (ICU) can be a modifiable risk factor.
- Person-centred care in the ICU also has to consider the transition process as including a need for information, emotional well-being, and expectations, which have to be addressed.
- Nurses need to improve their understanding of patients' experiences during the transition from the ICU to a general ward to assist them in therapeutic interventions.

a point where nursing intervention could be essential. Active listening means understanding beyond the message that the patient wants to convey to us: taking into account even non-verbal language and making the patients feel that nurses are really listening.^{34,35} Also, patients can express their needs, concerns, and expectations. A deeper understanding of what patients go through and what they need while they are transitioning from the ICU to the general ward may provide input on how to strengthen patient-centred care and, ultimately, contribute to a positive experience.

2 | AIM

The aim of this study was to describe the experiences lived by patients who have transferred from the ICU to the ward.

3 | METHODS

This was a qualitative descriptive study.^{36,37} A qualitative content analysis was performed.³⁸ The qualitative study was reported in

accordance with the Consolidated Criteria for Reporting Qualitative Research guidelines.³⁹

3.1 | Settings and participants

The study took place in the medical, trauma, and cardiac ICU of three University hospitals in Barcelona, which cover a total of 151 beds: level 3 ICU. The ICUs admit approximately 2000 patients per year with an average patient length of stay (LOS) of 10.6 days and a nurse/patient ratio of 1:2.

The respective ICU managers were contacted to request permission to recruit potential participants and to obtain help in identifying possible participants. Three of the researchers (CC, RMP, AND) were responsible for patient recruitment; and one researcher in each ICU. Purposive sampling was used. Based on various characteristics that have shown greater clinical relevance and have frequently been cited in studies that contemplate the lived experience of the critical patient, 32 features were defined. The final sample size was guided by the principle of theoretical saturation of data until no new data were found.⁴⁰

Inclusion criteria were as follows: age over 18 years; more than 48 hours of ICU stay; able to speak one of the two official languages; able to conduct a personal interview; and able to provide signed informed consent.

3.2 | Data collection

Data were collected between November 2016 and January 2018. Individual, in-depth face-to-face interviews⁴¹⁻⁴³ of 30 to 60 minutes each were performed. Interviews were carried out by three trained researchers. All interviews were conducted in the general ward in the first week following transfer from the ICU. Each interview was conducted with the main question: "Could you tell me how you experienced the transition from the ICU to the general ward?" The interviews were audiotaped and transcribed verbatim, including verbal and non-verbal language that revealed significant emotions and expressions of diverse feelings,⁴⁴ for subsequent anonymous analysis and processing. In addition to the in-depth interview, a field diary was used with notes collected throughout the interview process and included both descriptive and interpretive data based on patients' comments.⁴⁵ Moreover, sociodemographic data and ICU patient-related features were collected to describe participants' characteristics.

3.3 | Data analysis

Data were analysed using qualitative content analysis method by determining meaning units, condensed meaning units, codes, subcategories, categories, and theme.³⁸ The encoding process was conducted using the NVivo software (NVivo qualitative data analysis software; QSR International Pty Ltd. Version 11, 2015) in accordance with the qualitatively descriptive study design.

TABLE 1 Participant demographics

Characteristics	No (%)
Gender	
Male	34 (70.8)
Female	14 (29.2)
Age (years)	
Median	58
Min	22
Max	89
Level education	
University	19 (39.58)
Secondary school	8 (16.7)
Primary school	10 (20.8)
Less	11 (22.9)
Marital status	
Single	14 (29.2)
Married	27 (56.3)
Widowed	5 (10.4)
Divorced/separated	2 (4.2)

The interviews were read through several times to obtain a sense of the whole. The text was divided into meaning units that were condensed. The condensed meaning units were abstracted and labelled with a code. The codes were compared on the basis of differences and similarities and ordered into subcategories. Similar subcategories together formed categories. The tentative categories were discussed by two researchers (CC and PD-H) and revised. Finally, the content of the categories was formulated in a theme.³⁸ The derived theme and related codes, subcategories, and categories are presented in Table 1.

4 | ETHICAL AND RESEARCH APPROVALS

Ethical approval was obtained from each of the Clinical Research Ethics Committees at the three participating hospitals (HCB/2016/0484, PR209/16/070716, PR(ATR)197/2016). The study conformed to the principles of the Helsinki Declaration.⁴⁶ All participating patients received verbal and written information on the study and provided informed consent to participate. They were guaranteed anonymity in the findings report and research analysis.

5 | FINDINGS

Forty-eight interviews were conducted. Participants' demographics are summarized in Table 1, and the ICU patient-related features are described in Table 2.

A main theme, four categories with six subcategories emerged from the data (Table 3).

TABLE 2 ICU patient-related features

Characteristics	No (%)
Diagnosis ICU admission	
Acute myocardial infarction	10 (20.8)
Sepsis	7 (14.6)
Failure respiratory	7 (14.6)
Pneumonia	4 (8.3)
ICU events	
Yes	31 (64.6)
No	17 (35.4)
Patient comorbidities	
Yes	41 (85.4)
No	7 (14.6)
Illness severity by APACHE II score	
Median	15.2
Min	6
Max	45
ICU LOS (days)	
Median	10.6
Min	2
Max	44
No visited by family	13 (27.1)
Family presence	33 (68.89)
Friend presence	2 (4.2)

Note: Comorbidities: hypertension, diabetes, dyslipidaemia, chronic obstructive pulmonary disease, haematologic disease, oncological disease, at least one of these. Family presence: patients visited by his/her family during stay and discharge from ICU at least once. ICU events: non-invasive mechanical ventilation, invasive mechanical ventilation, self-extubation, reintubation, prone position, high-flow oxygen therapy, renal replacement therapy, extracorporeal membrane oxygenation vascular device, intra-aortic balloon counterpulsation, cardiopulmonary resuscitation, bronchoscopy, haemodialysis, non-invasive ventilation; at least one of these. Abbreviations: APACHE II, acute physiology and chronic health evaluation; ICU, intensive care unit; LOS, length of stay.

5.1 | Impact on emotional well-being

5.1.1 | Need to be informed

Participants reflected their experiences by describing a general lack of information about their health status and the ICU discharge process. Participants demanded it be accurate, consensual, appropriate, and correct:

A little more information but more than information that they had agreed among themselves to give me the information because one of them tells you one thing then probably the next day someone comes and tells you something else...the next day the guard comes and

tells you something very similar but it ends up not being the same (participant 17).

In most cases you don't know where you are...you are simply there because you are and you don't know why...in many cases, you don't even have the awareness to know (participant 25).

Some participants even claimed that no one had informed them of the expenses incurred by their stay in the ICU.

I would have liked to have some information about my health...in addition to the financial information to be able to manage the payment of the expenses incurred in time (participant 6).

In addition, participants considered it important that the family be provided with information about the situation of ICU discharge.

And I would have liked to have been told when my family was present (participant 15).

5.1.2 | Experience of mixed feelings

When participants were informed of their transfer from the ICU to the general ward, they manifested happiness. Later, however, they demonstrated feelings such as fear, nervousness, anger, distress, and disappointment.

And I'm still afraid that something will happen again (participant 8).

The thing is that everything makes you feel very afraid after being there (ICU) as so many things have happened to me and I thought I would have to go through more or go through some things again and I am still afraid that I will have to go through some things again (participant 10).

I was a little bit scared a feeling of not knowing what was going to happen (participant 34).

Humiliation was one of the feelings expressed by some participants in a specific situation.

The only problem has been the humiliation of when you poop and have to be washed (participant 4).

It makes you very uncomfortable when you have to ask them to clean your behind when they come in to clean you in bed (participant 30).

TABLE 3 Subcategories, categories, and theme from content analysis

Theme	Impact on emotional well-being				
	Experience of mixed feelings		Factors involved in the transition		
	Need to be informed Lack of information	Worrying about caring for myself	Expectations during transitioning Hope for the future	Facilitators	Barriers
Categories	Negative emotions	Autonomy	Receive personalized care	Being with the family	Nightmares
Subcategories	Fear	Loss of control	Flexible visiting hours	Recovering from the illness	Inability to stop thinking
Codes	Anxiety	Burden on family	Feeling protected	Sensation of feeling better	Not remembering
	Insecurity	Being alone	Continuity of care	Knowing the time of day	Denial of current health situation
	Distress				
	Depression		Be treated as a patient	Previous experience	Lack of experience
	Nervousness		Go back to doing things they did previously	Humane treatment	Lack of psychological and emotional support
	Anger		Be able to go home	Receiving considerable help in breathing	Low nurse/patient ratio
	Distress		Accompanied	Maintaining blood pressure	Lack of continuity of care
	Humiliation		Leave the closed environment	Pain control	Lack of beds
	Disappointment		To be independent	Appropriate transfer	Perceived unsafe
	Frustration			Entertainment and good atmosphere	Wasted time on the ward
	Nostalgia				Inequality in treatment from professionals: knowledge/experiences
	Loneliness				
	Sadness				
	Indifference				
	Resignation				
	Being overwhelmed				
	Suffocated				

Other participants described their sense of being a burden.

It lasted many days...I felt like I was being a burden (participant 20).

Participant survivors often stated that after receiving the information on the transfer from the ICU, it caused them to feel nostalgia, loneliness, sadness, indifference, and resignation.

And they say prepare yourself because when you go to the general ward...and it's not that I don't want to...it's that I can't my legs won't hold me up and since they told me that it makes me afraid (participant 31).

Nobody told me what I was doing here, what it would be like, what treatment I would have to follow or how long I would be staying...they gave no explanations of any kind (participant 5).

The participants thought about recovering their autonomy, recovering from the illness. They worried about the family, having to return home and being alone, and not knowing where they would go after the transfer.

I was worried about the family being able to organize themselves and I didn't know what information to give them (participant 9).

Look what happened to me and of course me going back to my village I can't go and what will I do at home alone...I need a lot of help (participant 31).

5.1.3 | Factors involved in the transition

Participants described some factors involved in the transition from ICU as facilitators. In contrast, others were experienced as barriers.

Patient, professional factors, and institutional factors, which helped the transition from the ICU, were also apparent in the findings.

The aspects that patients identified as facilitators were: being with the family, feeling better, knowing the time of day, together with previous experience.

It seemed good to me that the family was there because the family can give you a little bit of warmth... although they are dedicated and willing there is something that cannot be conveyed to you and that's the warmth of your family (participant 23).

I was glad when I left because I knew a little bit about what was coming after having been there various times before (participant 2).

The professional aspects described as helpful were as follows: dealing with patients in an appropriate, humane way; treatment and care; dedication to their jobs, and the ward nurses' visits in the ICU.

A nurse came introduced herself and told me that she had a report about me and that I was going to be admitted as they already had a room (participant 46).

Conversely, participants identified aspects as a hindrance to transfer from the ICU: feelings of distress, fear, depression, nightmares, not remembering certain moments they experienced, frustration, denial of current health situation, lack of experience, and lack of autonomy, as well as physiological responses such as suffocation, fever, or pain.

It is a different fear could be related to the same illness...when I closed my eyes I saw things that I was trapped in a place that I couldn't get out and I felt like I was suffocating (participant 20).

A participant shared their experiences of inability to stop thinking:

A very strange feeling that was like my head didn't know how to be on 'stand-by' with constant thoughts...I felt like a scratched record that made it feel like my rest wasn't long it was very short (participant 30).

Concerning professional aspects that acted as obstacles, a young woman identified a lack of information and a lack of psychological and emotional support.

There are things that are necessary...for instance in my case, for young people psychological and emotional support and information about what's happening (participant 5).

Some participants revealed institutional aspects that acted as barriers: a closed environment with much noise; light, limited space and strict schedules; organization of patient care in the ICU not done according to patient needs.

I saw it was not organized according to the patients or patient priority but rather the patient had to adapt to the organization of the ICU...there were days when it was real hell...when I got there the first thing I did was sit down...four more days there and I don't know what would have happened (participant 18).

It was very boring there with that closed door at least here I see the people and it entertains me a bit (participant 21).

More than one participant recognized the principal cause for transfer delay was the lack of beds in the destination ward not being taken into account.

The main reason for transfer delay was not my health status but the lack of beds on the ward where they were taking me (participant 9).

As institutional barriers on the general ward, participants especially highlighted the low nurse/patient ratio, a sensation of a lack of continuity of care, and wasted time.

They can't pay attention to you here because there is one nurse for a lot of patients (participant 10).

One participant reported feeling unsafe leaving the ICU to go to the ward:

I would have stayed there (ICU)...I didn't want to go because I felt very safe there...when they start to unplug things you think something is going to happen to me...I don't want to leave here (participant 10).

Concerning the transfer conditions, participants referred to the time it took and when it happened.

The transition from the ICU from when they told me they were going to discharge me was a long process because various days went by from when they told me until it happened (participant 9).

Perhaps it shouldn't be at meal times because everyone is moving to-and-fro and in the end it's uncomfortable because you don't know whether you're going to eat here or there and it makes you nervous...me anyway (participant 27).

5.1.4 | Expectations during transitioning

In the ICU discharge process, participants want to receive personalized care.

A young man said that not all patients are in the same state of health.

There should be different degrees that the same protocol shouldn't be used for patients that need to be closely monitored and for patients who are more or less ok...I could use the bathroom...they put too much importance on changing the sheets it's probably more important to deal with what the patient needs for their well-being (participant 30).

The participants also requested flexible visiting hours to feel more accompanied during discharge from the ICU.

I would have liked the visiting hours to be more flexible...the timetable is very restricted and just when you are in this

situation is when it makes you comfortable to have visitors and someone to talk to so that you are distracted and the distraction helps you to avoid feeling pain (participant 30).

On the general ward, participants hope to have care continuity and planning; they wanted to be treated as patients:

What I would have liked more would be to have had a link a little more continuity with the ICU and to feel a bit more covered in this respect...from both the medical and nursing teams to have a little more contact after spending a bit more than a month there (participant 2).

A common topic expressed by the participants was to go back to doing the things they did previously, be able to go home, to be accompanied at home, to be able to leave the closed environment, to be transferred with the family, and, especially, to be independent and recover their autonomy.

...go to a place where they make me rehabilitation to be independent as before, well, if it is not like before, at least I can walk (participant 20).

I hoped to get autonomy back because when you are in the ICU you feel that not only is your movement limited but also your capacity to lead a bit of a normal life (participant 30).

6 | DISCUSSION

Based on experts' experience of qualitative research, sample size is varied.^{40,47} This study had a large diverse sample, recruited through a range of locations with reference to features that were intrinsic to the study, and used in-depth interviews, which enhance the richness and generalizability of the results.

The aim of this study was to get a deeper understanding of the experiences of ICU patients during the transition from the ICU to the general ward. The findings suggest an impact on emotional well-being is experienced when a patient is transferred from ICU to a general ward.

Need for information, expressed as a lack of information about the transition, was an important issue in our findings and is consistent with the results found by Cullinane and Plowright.⁴⁸ According to Meleis et al²⁸ preparation and knowledge is facilitating and empowering for people in transition, whereas lack of preparation is an inhibitor. However, not enough quality information is provided to patients and their relatives during transition from the ICU. This could be because we have always thought that, after waking up from sedation, patients will manage by themselves with the information we provide. Information is vital throughout the transitional processes and nurses have an important pedagogical role in facilitating patient transition from the ICU in this regard. In fact, information provided during the ICU transitional process has been shown to diminish anxiety and contribute to patient

empowerment,⁴⁹ as well as improving perceptions regarding abandonment or lack of continuity of care.^{50,51} We believe that effective transition information can also help in the process of psychological recovery.

Feelings of fear, occasionally terror, loneliness, and sadness are reported in this study. These have also previously been mentioned by numerous authors.^{50,52,53} Patients expressed fear and anxiety about what would happen next and what ICU discharge meant.⁵⁴ Before ICU discharge, a sense of lack of control due to concern over loss of autonomy and independence is associated with anxiety, depression, and PTSD, and should therefore be assessed.⁸ Feelings of unimportance have been also revealed in this study, in line with the findings of other authors,^{54,55} related to perceptions of being ignored by staff who were too busy to listen to their concerns, both in the ICU and in the general ward.

Facilitators versus barriers to the transition from the ICU have also been previously reported.^{24,25,51} Closeness to staff and the prospect of getting immediate help made patients feel calm and secure, whereas the gap between the highly technological ICU and the general ward affects patients. Patients stated that visits by the ward staff to the patient in the ICU before transition helped to increase the sense of safety.

Barriers related to professionals included lack of information, while the most common barrier related to the institution was the lack of beds in the general ward. Other authors have reported similar findings and even direct transfer home, when feasible, has been proposed to improve this matter.⁵⁶ Some patients also stated, as an institutional barrier, that the care provided was not always patient-centred and adjusted to their needs. The imbalance between patient needs and available organizational resources leads to situations that do not necessarily serve the patients' best interests or consider their individual expectations and needs.⁴⁹ Timing of transfers has been also reported as a barrier to improving transitions. Transfers during the night shift or shift changes can contribute to increasing patient anxiety, as well as transfers programmed at short notice or delayed transfers, as reported by other authors.⁵⁷

Regarding patients' expectations during ICU discharge, little has been published. In the present work, continuity of care and personalization were important expectations. In line with other studies,⁵⁸ some patients attributed what they perceived as a lack of basic care to one of two things, nurses on the general ward being too busy to pay them much attention, or poor communication between staff from the ICU and the general ward. Recovering independence and autonomy were also significant hopes. This was especially important in trauma patients, who are often younger, have less pre-existing morbidity, and are usually more reluctant than medical and surgical patients to compare their functional status before and after ICU discharge.⁹ Analysis and knowledge of patients' expectations are essential in improving care. Underpinning any intervention strategy regarding patient choices and enhancing patient empowerment to recover autonomy is health care professionals' capacity to view patients as experts in recognizing and managing their own needs. All the issues mentioned can influence patient recovery and addressing them before discharge can improve patient outcomes. Some authors have suggested, and demonstrated, that PTSD may be preventable in critical care survivors,

and that early interventions may be more effective than interventions initiated after ICU discharge.^{16,59,60}

ICU nurses are an important factor in the transition of critically ill patients. One study focusing on ICU nurses concluded that nurses need improved understanding of critically ill patients' transition experiences from the ICU to assist them in therapeutic interventions for these patients.⁶¹ The nurses' role in this stage is essential in that they are in a unique position to cope with the patients' feelings during ICU discharge, identifying and reducing fears and adjusting patients' expectations through information and education, and offering anticipatory guidance. It is crucial to incorporate patients' experience and expectations into this process to improve care as modifiable risk factors and beneficial interventions are increasingly being identified that reduce the negative effect impact on emotional well-being after ICU discharge.

7 | STRENGTHS AND LIMITATIONS

To improve the trustworthiness of the study findings, Lincoln and Guba⁶² credibility, transferability, dependability, and confirmability criteria were applied. The methodological strength of this study is that to increase representativeness, credibility, and transferability of results, patients were included with different features based on the bibliography and defined at the beginning of the study. To ensure authenticity, results were recognized as real when a relationship was established between the data obtained by the researchers and the participant's reality.

This study also has some limitations. The physical and/or psychic state of patients discharged from the trauma ICU made it difficult to cope with in-depth, face-to-face interviews. Therefore, few patients from this site were included. Purposive sampling led to a variation in gender, age, and comorbidities. However, recruitment of participants with particular characteristics, such as those <65 years, women, or patients without comorbidities, was difficult due to their low incidence in the different ICUs, and increased the duration of recruitment and the study.

8 | IMPLICATIONS AND RELEVANCE TO CLINICAL PRACTICE

It is important that ICU nurses take into account the experiences of patients during the transfer from the ICU to the general ward so that they can help patients to have a positive ICU transfer experience and reduce the negative effects. Implementing new practices in the ICU, including nursing empowerment interventions, the role of advanced practice nurse that follows patients after ICU discharge, and a mental health nurse such as a consultant nurse would be important in patient care during the transfer from the ICU to the general ward.

9 | CONCLUSIONS

Patients have multiple feelings, concerns, and expectations when they are discharged from the ICU to the general ward. All of these

can potentially have an impact on their emotional well-being and recovery and need to be addressed. Giving information on the process to patients and relatives seems to be a principal issue. Patients want to understand and know more about the differences they will find regarding their care after being transferred to the general ward.

Encouraging patients to express their experience during the transfer from the ICU to the general ward can help to identify possible warning signs and increase their sense of control over their lives.

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CRedit STATEMENT

Cecilia Cuzco: Conceptualization; methodology; formal analysis; data curation; writing – original draft; writing – review & editing; visualization. **Raquel Marín Perez:** Conceptualization; investigation; resources; data curation. **Anna Núñez Delgado:** Conceptualization; investigation; resources; data curation. **Marta Romero-García:** Conceptualization; methodology; writing – review & editing. **María Antonia Martínez-Momblan:** Conceptualization; methodology; writing – review & editing. **Gemma Martínez Estalella:** Investigation; resources. **Inmaculada Carmona Delgado:** Conceptualization; methodology; writing – review & editing. **Pilar Delgado-Hito:** Conceptualization; methodology; formal analysis; data curation; writing – original draft; writing – review & editing; visualization; validation; supervision; project administration. **José María Nicolás:** Investigation; resources. **Pedro Castro:** Conceptualization; methodology; formal analysis; data curation; writing – original draft; writing – review & editing; visualization; validation; supervision; project administration.

DATA AVAILABILITY STATEMENT

The full data set from this study can be obtained by sending requests to Pilar Delgado Hito.

ETHICS STATEMENT

Ethical approval was obtained from each of the Clinical Research Ethics Committees at the three participating hospitals (HCB/2016/0484, PR209/16/070716, PR(ATR)197/2016). The study conformed to the principles of the Helsinki Declaration. All participating patients received verbal and written information on the study and provided informed consent to participate. They were guaranteed anonymity in the findings report and research analysis.

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