Received: 1 November 2023 | Revised: 7 March 2024 | Accepted: 11 March 2024

DOI: 10.1111/nicc.13066

RESEARCH ARTICLE

BACCN Nursing in Critical Care WILEY

Adaptation and validation of the Physical Restraint-Theory of Planned Behaviour Questionnaire to the paediatric context

Alejandro Bosch Alcaraz PhD, RN, MSc[1,2] | Pedro Piqueras Rodríguez RN, MSC[3,4] | Jesús Corrionero Alegre RN, MSC[5] | José Miguel García Piñero PhD, RN, MSc[6] | Sylvia Belda Hofheinz PhD, MD[7] | Sonia Gil Domínguez RN[7] | Esperanza Zuriguel Pérez PhD, RN, MSc[8,9] | Patricia Luna Castaño PhD, RN, MSc[10,11] | M. Ángeles Saz Roy PhD, RN, MSc[1,2] | Marta Martínez Oliva RN[5] | Susana González Rivas RN[5] | Nerea Añaños Montoto RN[5] | María José Espildora González RN[6] | Elena Martín-Peñasco Osorio RN[6] | Eva Carracedo Muñoz RN[7] | Eduardo López Fernández MD[7] | Gema Lozano Almendral RN[3] | Alicia Gomez Merino RN[3] | David Morales Cervera RN[3] | Rocío Fernández Lorenzo RN, MSc[12] | María Mata Ferro RN, MSc[12] | Ainhoa Martín Gómez RN[12] | Marta Serradell Orea RN[12] | Cristina Esquinas López PhD, RN, MSc[1] | Gemma Via Clavero PhD, RN, MSc[13,14,15,16]

[1]Department of Public Health, Mental Health and Maternal and Child Health Nursing, Faculty of Nursing, University of Barcelona (UB), Barcelona, Spain

[2]Mental Health, Psychosocial and Complex Nursing Care Research Group-NURSEARCH, University of Barcelona, Barcelona, Spain

[3]Pediatric Intensive Care Unit, La Paz Hospital, Madrid, Spain

[4]Health Research Institute, La Paz Hospital – IdiPAZ, Madrid, Spain

[5]Pediatric Intensive Care Unit, Vall Hebron Hospital, Barcelona, Spain

[6]Pediatric Intensive Care Unit, Carlos Haya Hospital, Málaga, Spain

[7]Pediatric Intensive Care Unit 12 de Octubre Hospital, Madrid, Spain

[8]Department of Knowledge Management and Evaluation, Vall d'Hebron Hospital, Barcelona, Spain

[9]Multidisciplinary Nursing Research Group, Vall d'Hebron Research Institute (VHIR), Barcelona, Spain

[10]Alfonso X el Sabio University, Madrid, Spain

[11]Health Care and Services Research Unit (Investén-ISCIII), Madrid, Spain

[12]Pediatric Intensive Care Unit, Sant Joan de Déu Hospital, Barcelona, Spain

[13]Hospital Universitari de Bellvitge, Barcelona, Spain

[14]Faculty of Nursing, University of Barcelona (UB), Barcelona, Spain

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

[16]International Research Project for the Humanization of Health Care, Proyecto HU-CI, Madrid, Spain

Correspondence
Alejandro Bosch Alcaraz and M. Ángeles Saz Roy, Department of Public Health, Mental Health and Maternal and Child Health Nursing, School of Nursing, Faculty of Medicine and Health Sciences, University of Barcelona (UB), Barcelona, Spain
Email: alejandrobosch@ub.edu; masazroy@ub.edu

Abstract

Objective: To create and test psychometrically a paediatric version of the Physical Restraint-Theory of Planned Behaviour Questionnaire to assess paediatric critical care nurses' intention to use physical restraint.

Design: A psychometric study.

Setting: Five medical-surgical Paeditric Intensive care Units from five hospitals in Spain.

Methods: The study took place in three phases. In phase 1, the questionnaire was adapted. In phase 2, the content validity of each item was determined, and a pilot test was conducted. In phase 3, we administered the questionnaire and determined its psychometric properties.

Results: The assessment of the intention to use physical restraint was extended to all critical paediatric patients, two items were eliminated from the initial questionnaire, four new items were included, and the clinical scenarios of the intention subscale were expanded from three to six. Overall content validity index for the full instrument of 0.96 out of 1. The Paediatric Physical Restraint-Theory of Planned Behaviour Questionnaire is made up of four subscales (attitude, subjective norms (SN), perceived behavioural control (PBC), and intention) subdivided into 7 factors and 51 items. The internal consistency for the attitude subscale obtained a Cronbach's Alpha of 0.80 to 0.73, for the SN it was 0.72 to 0.89, for the PBC it was from 0.80 to 0.73 and for the intention subscale it was 0.75.

Conclusions: The Paediatric Physical Restraint-Theory of Planned Behaviour Questionnaire is an instrument composed of seven factors and 51 items that validly and reliably assesses the intention of paediatric nurses to apply PR in PICUs.

Relevance for Clinical Practice: Having this instrument will help health centres move towards restraint-free care by allowing managers to assess professionals' attitudes, beliefs, and intentions around the use of PR in PICUs.

KEYWORDS
intensive care unit, nursing, paediatric, psychometric studies, restraint physical

1 | INTRODUCTION

The comprehensive care of paediatric patients, in any clinical context (primary, hospital and/or specialized care), requires the performance of various diagnostic and/or therapeutic procedures that, in addition to causing pain and physical discomfort, cause great psychological stress. When the child's behaviour, as a result of a lack of understanding about the intervention being carried out, prevents the application of a treatment and the achievement of the therapeutic goals, care professionals consider the exceptional use of physical restraints (PR) or pharmacological restraints, with the aim of guaranteeing safety.[1,2]

Paediatric intensive care units (PICUs), in particular, provide care for children whose condition puts their lives at real or potential risk. The comprehensive management of these patients is usually invasive, requiring numerous diagnostic and therapeutic procedures.[3] Some authors report that for this reason PR is applied in PICUs to carry out certain painful procedures[1,4–8] and to ensure the maintenance and continuity of life support devices, such as endotracheal tubes, vascular catheters, catheters, or drains. In this way, care professionals try to prevent unplanned adverse effects related to patient safety.[9–11] Even so, the effectiveness of PR with these objectives is still uncertain, so it should only be used when collaborative alternatives have been exhausted.[12,13]

1.1 | Background

The concept of PR in paediatrics is ambiguous.[14,15] It is sometimes called clinical or supportive holding or restraint. The first refers to "positioning a child so that a medical procedure can be carried out in a safe and controlled manner, wherever possible with the consent of child and parent/carer."[16] In contrast, "restraint is used to administer

medication or carry out a procedure to which the child objects, and is carried out in what is considered to be in the child's best interest."[17] At the same time, it is essential to differentiate between PR and physical restriction which is standard practice for certain procedures. Physical restriction is applied in paediatrics to perform invasive procedures, such as safely placing a peripheral venous catheter. Even so, and despite the fact that physical restriction lasts less time than PR, studies by Brenner et al. conclude that its use is very stressful and not beneficial for the child, in addition to leading to feelings of helplessness and vulnerability.[18] Therefore, the shorter duration of physical restriction does not appear to protect against related physical and psychological adverse events.

Demir et al.[1] observed in a study in Turkey that the use of restraints was less common in accompanied patients, in line with another carried out in 40 hospitals in the United States that concludes that the use of PR in PICUs is much less common than that of adult critical care units, where round-the-clock accompaniment by family is not permitted.[19]

Health professionals working in PICUs should be aware that PR leads to adverse physical and psychological events in the paediatric patient, and for this reason, experts are committed to minimizing its use and implementing strategies to practice restraint-free care.[9,12–14] Research shows that informing and involving the family and the child in all decisions and therapeutic procedures—a key function of nurses—is essential to ensure patient collaboration and reduce the use of PR.[20] Even so, there is a gap between the recommendations of clinical practice guidelines and the practices of professionals, especially when it comes to ceasing a specific behaviour, such as the use of PR. For this reason, it is necessary to analyse the factors that influence the behaviour or intention to apply PR. We propose doing so using the framework of the theory of planned behaviour.[9,21]

In the late 1960s, after the realization that a person's attitudes alone cannot predict their behaviour, psychologists began to generate predictive models such as the theory of reasoned action and its extension, the theory of planned behaviour.[6,22] The theory of reasoned action poses that intention is the antecedent to behaviour and that intention is influenced by attitude, by subjective norms, by beliefs about the consequences of the conduct in question, and by the normative beliefs perceived by the individual.[9,22,23] Ajzem & Fishbein (1980) signalled that the theory of reasoned action was useful to describe conducts that are under the control of the person, assuming that the person has absolute control without external pressure to adopt a certain behaviour. Yet, Ajzen (1985) observed that many conducts do not follow this pattern because people's perception of their degree of control over a given behaviour can range from no control to total control. For this reason, Ajzan developed the theory of planned behaviour as an extension of the theory of reasoned action, adding to the original model the notion of perceived behavioural control. One application is in evaluating health professionals' adherence to clinical guidelines or in conducting a procedure with a specific population group.[9,24–26]

This approach has only been used in adult critical patients in Spain,[14] in nurses in Malaysia,[27] and in a study in nursing homes in Israel that evaluates intention through the theory of reasoned action.[28] An advantage of the theory of planned behaviour approach is that behaviour is evaluated according to the TACT principle (target, action, context, and time). Because the original instrument was created for the adult context,[9] it requires adaptation and validation for use in paediatric critical care nurses.

What is known about the topic

- The comprehensive management of critically ill paediatric patients is usually invasive, requiring numerous diagnostic and therapeutic procedures.
- Physical restraint is applied in Paediatric Intensive Care Units to carry out certain painful procedures and to ensure the maintenance and continuity of life support devices.
- Physical restraint leads to adverse physical and psychological events in critically ill paediatric patients.

What this paper adds

- This is the first study to adapt and validate an instrument to assess nurses' intentions to use physical restraint in the paediatric context.
- The availability of this tool will help health centres to move towards restraint-free care by enabling managers to assess the attitudes, beliefs and intentions of professionals regarding the use of physical restraint in PICUs.

2 | THE STUDY

2.1 | Aim

To create and test psychometrically a paediatric version of the Physical Restraint-Theory of Planned Behaviour Questionnaire[9] to assess paediatric critical care nurses' intention to use PR.

2.2 | Materials and methods

2.2.1 | Design

A psychometric, analytical, correlational, and prospective study was carried out from October 2021 to January 2023 in which five PICUs from five hospitals in Spain participated: Sant Joan de Déu Children's Hospital (Barcelona), Vall d'Hebron Hospital (Barcelona), La Paz University Hospital (Madrid), 12 Octubre Hospital (Madrid) and Carlos Haya Regional University Hospital (Málaga) The study took place in three phases. In phase 1, the questionnaire was adapted to critically ill paediatric patients. In phase 2, the content validity of each item was

determined, and a pilot test was conducted. In phase 3, we administered the questionnaire and determined its psychometric properties. It was conducted following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement[29] and the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN) guideline.[30,31]

2.2.2 | Study population and sample

To conduct phases 1 and 2 of the study, we recruited small groups of paediatric nurses from a single centre with a minimum of 5 years working in paediatric critical care. In phase 1, six participants adapted the questionnaire to the context of paediatric critical care and in phase 2, eight participants validated the content and 10 filled out the questionnaire in a pilot test.

For the subsequent psychometric analysis (phase 3), all nurses from the five collaborating centres who met the following selection criteria were asked to fill out the questionnaire:

Inclusion criteria:

- Documented training in paediatrics (master's degree, speciality and/or continuing education courses).
- Minimum work experience in PICU of 2 years.
- Complete informed consent document.

Exclusion criteria:

- Working <30% of full time.
- On sick leave, disability, or leave of absence.

2.2.3 | Study variables

For participants in the psychometric study (phase 3), the following sociodemographic and occupational characteristics were recorded: (i) age (in years); (ii) level of studies (undergraduate, master's, specialty, doctorate); (iii) experience as a nurse (years); (iv) experience in paediatrics (years); (v) experience in PICU (years); (vi) type of contract (fixed term, full-time interim, part-time interim [weekends], temporary or other), (vii) work shift (morning, afternoon, day [12 h], evening or rotating) and (viii) specific training in PR (yes [specify] / no). At the same time, participants' responses to the items of the Physical Restraint-Theory of Planned Behaviour Questionnaire were recorded.

2.2.4 | Data collection tools

The main instrument was the Physical Restraint-Theory of Planned Behaviour Questionnaire on the intention of ICU nurses to use PR in the adult intubated patient from the perspective of the theory of planned behaviour.[9]

The original questionnaire, composed of 48 items, is organized into four subscales according to the constructs of the theoretical model of the theory of planned behaviour (attitudes, subjective norms, perceived behavioural control, and intention to use PR in the intubated adult patient). After the psychometric analysis, adequate reliability and validity data were obtained, with an internal consistency determined by Cronbach's Alpha >0.60 in all its subscales and dimensions and good temporal stability, except for the indirect subjective norm. In addition, confirmatory factor analysis showed a good fit with the theoretical model with nine factors organized in seven dimensions.[9] We adapted and validated the subscales related to attitudes, subjective norms, and perceived behavioural control for use in the PICU, and we designed and validated the intention subscale for use in the PICU.

The scales for attitudes, subjective norms, and perceived behavioural control are formed by a reflective indicator and a corresponding composite formative indicator of beliefs. Each dimension is evaluated individually and, therefore, the scores are specific to each.

2.2.5 | Data collection procedure

The adaptation and validation process was carried out in three phases.

Phase 1: Adaptation of the instrument to the PICU.

To carry out this phase, we used the Delphi method.[32] Participating in this phase were nurses who were experts in the management of paediatric critical patients, with a minimum of 5 years' work experience in the PICU. Potential participants were contacted by email, telephone or in person. Participation was voluntary. Before the first meeting, those who had agreed to participate received via email or post the questionnaire to be evaluated and the informed consent document. Considering that Polit and Beck[33] recommend a minimum of five experts, a total of six participants were selected.

Three meetings were held. The main objective of the first meeting was to qualitatively assess the items to adapt them to the PICU and to design the clinical cases for the intention subscale. These cases were designed based on the clinical situations that motivate the most uses of PR in PICUs, according to our literature review. We included participants of different ages, sex, reason for admission, number of clinical devices, and clinical evolution (sedated patients, those in the process of weaning, unaccompanied and accompanied patients, etc.). Subsequently, a second meeting was held in which the main author of the original instrument was invited to reassess the modified questionnaire. Finally, a third meeting was held in which the information was synthesized, the proposed changes to the instrument were made, and the definitive paediatric questionnaire was developed.

During the content validation process through expert opinions and Delphi methodology, the assessment of the intention to use PR was extended to all critical paediatric patients (not just intubated ones), two items were eliminated from the initial questionnaire, four new items were included, and, in addition, the clinical scenarios of the intention subscale were expanded from three to six (Table 1).

Phase 2: Content validation and pilot testing.

Once the paediatric instrument was created, its content was validated. To this end, we developed an ad hoc document containing all

TABLE 1 Semantic and item differences between the Physical Restraint-Theory of Planned Behaviour Questionnaire and the paediatric version.

Physical Restraint-Theory of Planned Behaviour Questionnaire items	Paediatric version[a]
1. In my opinion, the use of physical restraints in intubated patients is unsafe/safe	1. In my opinion, the use of physical restraints in critically ill paediatric patients is unsafe / safe
2. In my opinion, the use of physical restraints in intubated patients is unnecessary/necessary	2. In my opinion, the use of physical restraints in critically ill paediatric patients is unnecessary / necessary.
3. In my opinion, the use of physical restraints in intubated patients is harmful/beneficial	3. In my opinion, the use of physical restraints in critically ill paediatric patients is harmful / beneficial.
4. In my opinion, the use of physical restraints in intubated patients is unacceptable/acceptable	4. In my opinion, the use of physical restraints in critically ill paediatric patients is unacceptable/acceptable
5. If I use physical restraints in an intubated patient, I will prevent self-extubation.	5. If I use physical restraints in a critically ill paediatric patient, I will prevent self-extubation.
6. If I use physical restraints in an intubated patient, I will prevent self-removal of catheters/tubes.	6. If I use physical restraints in a critically ill paediatric patient, I will prevent self-removal of catheters/tubes.
7. If I use physical restraints in an intubated patient, I will prevent falls.	7. If I use physical restraints in a critically ill paediatric patient, I will prevent falls.
8. If I cannot permanently monitor an intubated patient, I will feel more relieved when they are wearing physical restraints.	8. If I cannot permanently monitor a critically ill paediatric patient, I will feel more relieved when they are wearing physical restraints.
9. If I use physical restraints, I will have more time to perform my tasks.	9. If I use physical restraints, I will have more time to perform my tasks.
10. If I use physical restraints, the intubated patient becomes more agitated.	10. If I use physical restraints, the critically ill paediatric patient becomes more agitated.
11. The use of physical restraints in an intubated patient can cause skin injuries.	11. The use of physical restraints in a critically ill paediatric patient can cause skin injuries.
12. The use of physical restraints in intubated patients upsets me.	12. The use of physical restraints in critically ill paediatric patients upsets me.
13. In my opinion, preventing self-extubation is extremely undesirable/extremely desirable.	13. In my opinion, preventing self-extubation in critically ill paediatric patients is extremely undesirable / extremely desirable.
14. In my opinion, preventing self-removal of catheters and probes is extremely undesirable/extremely desirable.	14. In my opinion, preventing self-removal of catheters and probes in critically ill paediatric patients is extremely undesirable/extremely desirable.
15. In my opinion, preventing intubated patients from falling is extremely undesirable / extremely desirable.	15. In my opinion, preventing intubated critically ill paediatric patients from falling is extremely undesirable/extremely desirable.
16. In my opinion, feeling relieved whenever I cannot monitor an intubated patient is extremely undesirable / extremely desirable.	16. In my opinion, feeling relieved whenever I cannot monitor a critically ill paediatric patient is extremely undesirable/extremely desirable.
17. In my opinion, having more time to perform my tasks is extremely undesirable / extremely desirable.	17. In my opinion, having more time to perform my tasks is extremely undesirable/extremely desirable.
18. In my opinion, if an intubated patient becomes more agitated as a result of the use of physical restraints, it is extremely undesirable/extremely desirable.	18. In my opinion, if a critically ill paediatric patient becomes more agitated as a result of the use of physical restraints, it is extremely undesirable/extremely desirable.
19. In my opinion, if physical restraints injure a patient's skin, it is extremely undesirable/extremely desirable.	19. In my opinion, if physical restraints injure a critically ill paediatric patient's skin, it is extremely undesirable / extremely desirable.
20. In my opinion, if using physical restraints in intubated patients makes me feel unease, it is extremely undesirable/extremely desirable.	20. In my opinion, if using physical restraints in critically ill paediatric patients makes me feel unease, it is extremely undesirable/extremely desirable.
21. I use physical restraints in intubated patients because professionals with whom I work think that they must be used.	21. I use physical restraints in critically ill paediatric patients because professionals with whom I work think that they must be used.
Not included	22. I feel under social pressure when I don't use mechanical restraints in critically ill paediatric patients.
Not included	23. Other professionals in my place use mechanical restraints on paediatric critical patients.
22. I am expected to use physical restraints in intubated patients.	24. I am expected to use physical restraints in critically ill paediatric patients.
23. My nursing colleagues disapprove of me using physical restraints in intubated patients.	25. My nursing colleagues disapprove of me using physical restraints in critically ill paediatric patients.

(Continues)

TABLE 1 (Continued)

Physical Restraint-Theory of Planned Behaviour Questionnaire items	Paediatric version[a]
24. My unit supervisor disapproves of me using physical restraints in intubated patients.	26. My unit supervisor disapproves of me using physical restraints in critically ill paediatric patients.
25. My doctor colleagues disapprove of me using physical restraints in intubated patients.	27. My doctor colleagues disapprove of me using physical restraints in critically ill paediatric patients.
26. Patients' relatives disapprove of me using physical restraints in intubated patients.	28. Patients' relatives disapprove of me using physical restraints in critically ill paediatric patients.
27. My nursing colleagues' approval of my practice towards the use of physical restraints is important to me.	29. My nursing colleagues' approval of my practice towards the use of physical restraints is important to me.
28. My nursing supervisor's approval of my practice towards the use of physical restraints is important to me.	30. My nursing supervisor's approval of my practice towards the use of physical restraints is important to me.
29. My doctor colleagues' approval of my practice towards the use of physical restraints is important to me.	31. My doctor colleagues' approval of my practice towards the use of physical restraints is important to me.
30. Patients' relatives' approval of my practice towards the use of physical restraints is important to me.	32. Patients' relatives' approval of my practice towards the use of physical restraints is important to me.
31. I am confident that I could use physical restraints in intubated patients if I decide to.	33. I am confident that I could use physical restraints in critically ill paediatric patients if I decide to.
32. It is easy for me to make the decision to use physical restraints in intubated patients.	34. It is easy for me to make the decision to use physical restraints in critically ill paediatric patients.
33. The decision to use physical restraints in intubated patients is entirely up to me.	35. The decision to use physical restraints in critically ill paediatric patients is entirely up to me.
Not included	36. The age of the critically ill paediatric patient reduces the use of mechanical restraints. (Eliminated as a result of low factorial load in confirmatory factor analysis)
34. When an intubated patient cooperates, it reduces the use of physical restraints.	37. When a critically ill paediatric patient cooperates, it reduces the use of physical restraints.
35. Whenever a patient is undergoing a weaning or an awakening trial, it increases the use of physical restraints.	38. Whenever a patient is undergoing a weaning or an awakening trial, it increases the use of physical restraints.
36. Family presence at the bedside reduces the use of physical restraints in an intubated patient.	39. Family presence at the bedside reduces the use of mechanical restraints in a critically ill paediatric patient.
37. Pharmacological management of agitation avoids having to use physical restraints in an intubated patient.	40. Pharmacological management of drug withdrawal syndrome reduces the use of mechanical restraints in a critically ill paediatric patient.
38. The reassessment of the patient's medical situation reduces the use of physical restraints.	Item deleted
39. Communication between the multidisciplinary team reduces the use of physical restraints in an intubated patient.	41. Communication between the multidisciplinary team reduces the use of physical restraints in a critically ill paediatric patient.
Not included	42. I am more likely to use physical restraints if the patient is younger. (Eliminated as a result of low factorial load in confirmatory factor analysis)
40. I am more likely to use physical restraints if the intubated patient cooperates.	43. I am more likely to use physical restraints if the critically ill paediatric patient cooperates.
41. I am more likely to use physical restraints if the patient is undergoing a weaning or an awakening trial.	44. I am more likely to use physical restraints if the critically ill paediatric patient is undergoing a weaning or an awakening trial.
42. I am more likely to use physical restraints if a family member is accompanying the patient.	45. I am more likely to use physical restraints if a family member is accompanying the critically ill paediatric patient at the bedside.
43. I am more likely to use physical restraints if I can administer a drug to manage the patient's agitation.	46. I am more likely to use physical restraints if I can administer a drug to manage the critically ill paediatric patient's drug withdrawal syndrome.
44. I am more likely to use physical restraints if I reassess the patient's clinical status.	Item deleted
45. I am more likely to use physical restraints if the patient's clinical status is discussed among the multidisciplinary team.	47. I am more likely to use physical restraints if the patient's clinical status is discussed among the multidisciplinary team.
46. Scenario 1 A 65-year-old male with a past medical history of high blood pressure under treatment and dyslipidemia, who is admitted to the ICU (private room) following a coronary artery triple bypass. Upon admission, he	48. Scenario 1 A 6-year-old male child with Down syndrome and a medical history of atrioventricular canal defect is admitted to the PICU (private room) following surgery to close a ventricular septal defect using sutures and

TABLE 1 (Continued)

Physical Restraint-Theory of Planned Behaviour Questionnaire items	Paediatric version[a]
has an orotracheal tube connected to mechanical ventilation, a central venous catheter in the subclavian artery, radial arterial line, nasogastric tube, urinary catheter, temporary pericardial pacing wires and chest tubes connected to a suction system. The patient's haemodynamic status is stable, and sedation is progressively titrated in order to start weaning. The patient is able to open his eyes to verbal stimulation for less than 10 seconds (RASS-2) and responds to information with his head (yes/no).	an atrial septal defect using a patch. Upon admission, the patient is equipped with an orotracheal tube connected to mechanical ventilation, a central venous catheter inserted through the right jugular, a left radial arterial catheter, a nasogastric tube, a urinary catheter, an external pacemaker lead, and thoracic drains (pleural and pericardial) connected to an aspiration system. Hemodynamically, the patient remains stable, albeit supplemented with low-dose inotropic support. Upon admission to the unit, the process of weaning is initiated with the progressive withdrawal of analgo-sedation. The patient gradually emerges from sedation, displaying responsive behaviours such as eye-opening and consistent movement of all four limbs and the head. The patient intermittently interacts with the orotracheal tube by tactile manipulation and, during one instance, exhibits intentional grasp of the pericardial drainage catheter. The parents are brought to the cubicle. Despite their apprehension, they understand the situation and try to help the patient relax.
47. Scenario 2 A 28-year-old male with a past medical history of smoking (one packet a day) and moderate alcohol abuse, who is admitted to the ICU (private room) with severe traumatic brain injury. During the previous 2 weeks, he has been administered analgo-sedation with midazolam and morphine. In the last week and coinciding with the discontinuation of the sedation, antipsychotic drugs were necessary and he was administered haloperidol. The patient is currently intubated with a tracheostomy tube and nasogastric tube. No central venous catheters or arterial lines have been inserted. The patient does not connect with his surroundings, he is calm, but he continuously moves his arms and legs.	49. Scenario 2 A 16-year-old female patient with no history of pathology is admitted to the PICU (private room) following ingestion of toxic substances and alcohol and a fall from 5 metres. Subsequent imaging reveals a severe head injury necessitating high-impact head trauma management, which includes orotracheal intubation, mechanical ventilation, and a combination of medical and surgical interventions spanning 10 days. Over the past week, concurrent with the withdrawal of analgo-sedation and the initiation of the weaning process, she has required pharmacological intervention with chlorpromazine, diazepam, and quetiapine to mitigate episodes of agitation and disorientation. Presently she remains connected to mechanical ventilation through an endotracheal tube, with parameters set at minimal levels. Additionally, she is equipped with a nasogastric tube and a urinary catheter. While central venous catheters and arterial catheters have not been inserted, two peripheral venous catheters have been placed in the upper extremities. The patient does not connect with her immediate environment and oscillates between periods of agitation alternating and moments of tranquillity.
48. Scenario 3 A 78-year-old female with a past medical history of diabetes mellitus and virus-related liver cirrhosis, who was admitted to the ICU (private room) 5 days ago with a diagnosis of hepatorenal syndrome. She has an orotracheal tube connected to mechanical ventilation and a peripheral intravenous central catheter (PICC), without the need to administer vasoactive drugs. She was calm throughout the day shift but during the night shift she presented acute confusion with lack of attention (CAM-ICU positive), aggressiveness and she tried to get out of bed. The nurse informed the doctor on call of the patient's clinical status, who prescribes an antipsychotic drug. The patient continues to be confused and has psychomotor agitation.	50. Scenario 3 A 12-year-old male patient with no history of pathology is admitted to the PICU as a result of a moderate bronchospasm attack. He is equipped with a peripheral venous catheter and a high concentration mask. Upon admission, he is agitated and displays moderate effort during breathing. In response, non-invasive mechanical ventilation is initiated, featuring an inspiratory pressure of 12cmH2O, an expiratory pressure of 6cmH2O and a FiO2 of 35%. However, as a result of the patient's agitation, the peripheral catheter becomes dislodged and the non-invasive ventilation face mask experiences substantial leakage. Consequently, a new intravenous device is introduced. The parents are distressed by the situation. The attending paediatrician opts to abstain from employing pharmacological interventions and instead endeavours to reassure the patient.
Not included	51. Scenario 4 A 3-month-old female infant, born prematurely at 32 weeks of gestation with a history of moderate bronchopulmonary dysplasia, necessitating a tracheostomy for home respiratory management, is admitted to the PICU presenting symptoms of vomiting, diarrhoea, water-electrolyte imbalance and a Gorelick scale rating of 6, indicative of severe dehydration. Upon admission, she has a 3.5 tracheostomy cannula with an inflated balloon, remaining tethered to her home ventilator. She receives a 4-litre oxygen intake and 35% FiO2 and is also equipped with a urinary catheter, but it is not possible to perform blood tests or peripheral catheter placement. After several attempts and employing physical restraint, the procedure is performed successfully, and a

(Continues)

TABLE 1 (Continued)

Physical Restraint-Theory of Planned Behaviour Questionnaire items	Paediatric version[a]
	catheter is placed in the right upper extremity. Intravenous rehydration using serum therapy is initiated. However, 2 h after the start of this treatment, the patient becomes agitated. The help of the parents is requested in trying to calm the infant, but it is not very effective, and the peripheral catheter and the tracheostomy cannula become dislodged. The cannula is re-inserted without incident, and, after several attempts, a new peripheral catheter is successfully inserted using echocardiography. The patient continues to experience episodes of agitation, heightening the risk of falls. The parents react with distress. The attending paediatrician prescribes levopromazine drops to manage the patient's agitation.
Not included	52. Scenario 5 A male neonate of 10 days is admitted from the emergency department, presenting bronchiolitis. He is equipped with high-flow nasal goggles delivering 8 litres of air per minute. Furthermore, a peripheral venous catheter placed in the child's right hand. He displays signs of moderate respiratory distress. Secretion aspiration is performed to acquire specimens for subsequent microbiological culture. Subsequently, the patient is subjected to non-invasive mechanical ventilation, characterized by an inspiratory pressure of 10cmH2O, an expiratory pressure of 5cmH2O and an FiO2 of 30%. Initially, the infant exhibits agitation in response to the intervention. However, when the care team stops handling him, he calms down and falls asleep with the assistance of the parents.
Not included	53. Scenario 6 A 3-year-old female child, who has recently been extubated following 7 days of orotracheal intubation and invasive mechanical ventilation, is currently managed with a right jugular central venous catheter featuring two lumens. Additionally, she is equipped with a nasogastric tube and a bladder catheter. She is receiving continuous administration of fentanyl at 1mcg/kg/min, while diazepan drops have been discontinued. Within hours of extubation, the patient manifests episodes of agitation, which can be attributed to pharmacological withdrawal syndrome. A score of 8 on the Withdrawal Assessment Tool-1 (WAT-1) scale is recorded. The parents are distressed because they have two more children, the father has to work, and they lack childcare for the other children. For this reason, the patient spends time alone in her cubicle.

[a]The original Physical Restraint-Theory of Planned Behaviour Questionnaire was written and administered in Spanish and translated by a sworn translator for publication in English. See Data S1 for the complete paediatric version of the scale, including instructions and scoring.

items of the questionnaire. Taking into account that Polit et al. (2007)[34] recommend involving a panel of 8–12 experts, eight nurses (different from the six who collaborated in phase 1) participated in this phase, scoring the relevance and wording of each item by means of a Likert-type scale, with scores from 0 (not at all) to 4 (very). Once the content validity of the instrument was established, a pilot test was carried out in which another group of 10 nurses, with training in paediatrics and with at least 5 years of experience in the management of paediatric critical patients. The purpose was to confirm proper comprehension, categorization, and internal order of the items, as well as to anticipate any resistance that potential respondents may have to fill out the questionnaire and the time required to complete it[32].

Phase 3: Psychometric evaluation.

Once the content validation process of the Paediatric Physical Restraint-Theory of Planned Behaviour Questionnaire was completed, the participating nurses from phases 1 and 2 were contacted so that they could distribute it among the eligible PICU nurses at their hospitals. Before participants filled out the questionnaire, they attended an online training session in which we described the research objectives, data collection procedure, questionnaire, and data collection document. The sample size was determined taking into account that the COSMIN recommendations suggest the inclusion of ≥100 patients.[31]

2.2.6 | Statistical analysis

The collected data were stored in a database created with Microsoft Excel®, and patient privacy was preserved. For the management and statistical analysis of all data, we used SPSS® version 23.0 software (Armonk, NY: IBM Corp.).

The numerical variables were described using descriptive statistics (mean, standard deviation, median and quartiles) and were

represented graphically using frequency histograms. Categorical variables were described in frequency tables with percentages and bar graphs.

The content validity of the questionnaire was determined by calculating the item level content validity index (I-CVI) and scale average level content validity index (S/Ave-CVI), according to the recommendations of Lynn (1986)[35] and Polit and Tatano (2006).[36] Values ≥0.8 were considered acceptable.

To establish construct validity, a confirmatory factor analysis of all items was carried out to confirm that the structure corresponds to the theory of planned behaviour model. The number of factors in the instrument was determined using the comparative factor index (CFI >0.90), the Tucker-Lewis index (TLI >0.90) and the root mean square error of approximation (RMSEA <0.08). The adjustment indices were considered satisfactory given the criteria established by Ullman (2006).[37] In addition, a goodness-of-fit analysis was carried out for the latent factors, considering those raised in the original questionnaire, and the relationships between factors were established using Spearman's correlation coefficient. Reliability was assessed using Cronbach's alpha coefficient of each item, which was considered valid >0.60.[38] Finally, the validity of the criteria was established by comparing the psychometric results obtained with those of the original questionnaire. The results were considered statistically significant with $p \leq .05$.

2.2.7 | Ethical considerations

Prior to conducting the study, we obtained approval from the nursing administration and the ethics and clinical research committees of the five hospitals where the study was carried out. We also received the authorization of the main author of the original questionnaire. This research was performed according to the principles set out in the Declaration of Helsinki and subsequent amendments (2009), as well as those of the Belmont Report.

Participation in the study was voluntary, and participants in all phases had sufficient information through oral and written informed consent information. All the data were confidential and privacy was preserved by assigning each participant a code for the statistical processing of the data, as well as adhering to the principles set out in EU Regulation 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of personal data and the free movement of data "and Spain's Organic Law" Organic Law 3/2018 of 5 of December for the Protection of Personal Data and the Guarantee of Digital Rights.

3 | RESULTS

3.1 | Sociodemographic and occupational characteristics of the participants

A total of eight nurses participated in the content validation, with a median age of 34.4 (IQR 25–52) years and a PICU experience of 14.5 (IQR 3–26) years. Content validity scores of the items between 0.75 and 1 were obtained, with an overall content validity index for the full instrument of 0.96 out of 1. No problems emerged during the pilot test and therefore the questionnaire was not modified before phase 3.

A total of 230 paediatric nurses of the 268 that made up the total population of eligible nurses at the five hospitals answered the questionnaire (phase 3), of which 87.7% ($n = 201$) were female with a mean age of 35.56 ± 9.73 years and work experience in PICU of 10.54 ± 8.43 years (Table 2).

3.2 | Structure, content, and construct validity

The Paediatric Physical Restraint-Theory of Planned Behaviour Questionnaire is made up of four subscales (attitude, subjective norms, perceived behavioural control, and intention) subdivided into 7 factors and 51 items (File S1):

- Attitude subscale: 13 items (4 items that directly measure attitude and 9 composite items corresponding to behavioural beliefs by outcome value).
- Subjective norms subscale: 8 items (4 items that directly measure subjective norms and 4 compound items corresponding to normative beliefs by motivation to comply).
- Perceived behavioural control: 7 items (3 items that directly measure perceived behavioural control and 4 composite items corresponding to beliefs of control by the power of influence).
- Intention subscale: 6 clinical scenarios (items 48–53) that evaluate the intention of nurses to apply PR.

After confirmatory factor analysis to determine the construct validity of the 53 items initially included, we decided to eliminate the composite item 36–42 because it had a factorial load of 0.05. At the same time, we observed that the factorial load of the rest of the items was close to or greater than 0.3, except for three items related to behaviour beliefs (Table 3). This could be attributed to both positive and negative beliefs being evaluated. When establishing the matrix of interrelationships between items and considering whether the reliability of the factor would increase, we found that Cronbach's alpha would increase slightly, and we, therefore, decided not to remove the items from the instrument.

Adequate goodness-of-fit indices of the model related to the theory of planned behaviour were observed (Table 4).

3.2.1 | Reliability

Internal consistency

The internal consistency for the attitude subscale obtained a Cronbach's Alpha of 0.80 to 0.73. For the subjective norms subscale internal consistency was 0.72 to 0.89. For the perceived behavioural control subscale, it was from 0.80 to 0.73 and for the intention subscale it was 0.75 (Table 5).

TABLE 2 Sociodemographic and occupational characteristics of the sample ($n = 230$).

Feature	Value
Gender[a]	
Female	201 (87.4%)
Male	28 (12.2%)
Missing	1 (0.4%)
Age (years)[b]	34.4 (25–52)
Experience as a PICU nurse (years)[b]	14.5 (3–26)
Highest academic qualification[a]	
4-year degree in nursing	119 (51.7%)
5-year degree	3 (1.3%)
Postgraduate/master's	71 (30.9%)
Official master's degree/nursing specialty	37 (16.1%)
Doctorate	0 (0%)
Type of employment contract[a]	
Fixed term	111 (48.3%)
Full-time interim	55 (24%)
Part-time interim/weekends	3 (1.3%)
Temporary	51 (22.2%)
Other	8 (3.4%)
Missing	2 (0.8%)
Work shift[a]	
Morning	40 (17.4%)
Afternoon	25 (10.9%)
12-hour daytime	22 (9.6%)
12-hour night-time	49 (21.3%)
Rotating	94 (40.9%)
Combination with care practice[a]	
Care work only	173 (75.2%)
Teaching	35 (15.2%)
Research	5 (2.2%)
Teaching and research	15 (6.5%)
Management	2 (0.9%)
Specific training in physical restraint[a]	
Yes	28 (12.2%)
No	199 (86.5%)
Missing	3 (1.3%)

[a]Frequency (percentage).
[b]Median and interquartile range.

Correlation between factors

The correlation between each of the factors that make up the instrument was positive in all cases and significant, with the exception of normative control beliefs and subjective norms and intention. Figure 1 shows a graphical representation of the structure of the Paediatric Physical Restraint-Theory of Planned Behaviour Questionnaire. When performing the multivariate analysis among all the main components of the instrument, we observed that the model explained 42% of the variance in intention of PICU nurses to use PR (Table 6).

4 | DISCUSSION

There are no other instruments that assess the intention of nurses to apply PR in the paediatric context, so it has only been possible to compare our results with those related to the original questionnaire. The use of PR in PICUs is not limited to a specific type of patient or critical situation since it is associated with the age and non-collaboration of the paediatric patient. Children usually do not understand their clinical situation, which can lead them to view health professionals' actions as hostile, causing them to feel fear and anxiety and, sometimes, become agitated.[10,14] For this reason, unlike the original instrument, which is validated in intubated patients,[9] our paediatric version assesses the intention of nurses to apply PR in critically ill children of any age and clinical situation. Because we wanted to include the most common clinical situations for the use of PR in paediatric critical patients, we expanded the last subscale of intention from three to six clinical scenarios.[9]

The paediatric scale obtained Cronbach's alpha scores of 0.73 for the attitude subscale, 0.78 for subjective norms, 0.69 for perceived behavioural control, and 0.75 for intention. These scores are somewhat higher than those of the original questionnaire for three of the four subscales, which were 0.81, 0.64, 0.68 and 0.60 respectively.[9] The confirmatory factor analysis of the paediatric scale showed that it is structured in seven factors with adequate goodness of fit. This confirms that the paediatric version is a valid and reliable instrument that converges with the precepts raised in Ajzen's theory of planned behaviour.[21] In relation to the correlations between factors, lower values were observed for normative control beliefs and subjective norms and intention, unlike in the original instrument. In addition, in the original instrument, the factor with the most weight was perceived behavioural control, unlike in the paediatric version, in which it was attitude, showing a significant relationship with behavioural beliefs. This finding means that for paediatric nurses, considerations about the safety of the patient and the professional shape attitudes towards the use of PR. A possible explanation is that the difficulty of inserting life support devices (e.g., venous catheters, endotracheal tube, drains), whose accidental removal can cause serious complications,[39] leads paediatric professionals to conclude that PR should be used to increase patient safety.[9,11,14] Finally, the intention to use PR explained 42% of the variance in the paediatric version and a somewhat lower proportion in the original instrument (33%).[9]

The family is a key factor in the care of the paediatric critical patient. When parents stay in the PICU throughout the day and actively participate in the care of their child, anxiety is reduced both for the parents and the child,[40] which could reduce the use of PR. For this reason, three items and some clinical situations described in the intention subscale consider the presence and cooperation of the patient's family.

TABLE 3 Coefficients for each item within the corresponding factor of the questionnaire with the 7 factors.

Dimension	Attitude towards behaviour	Behavioural belief × outcome evaluation	Subjective norms	Normative belief × motivation to comply	Perceived behavioural control	Control belief × power of control	Intention
Item							
Item 1	0.48						
Item 2	0.63						
Item 3	0.55						
Item 4	0.59						
Item 5–13		0.66					
Item 6–14		0.65					
Item 7–15		0.48					
Item 8–16		0.31					
Item 9–17		0.19					
Item 10–18		0.19					
Item 11–19		0.28					
Item 12–20		0.17					
Item 38–44		0.25					
Item 21			0.49				
Item 22			0.51				
Item 23			0.29				
Item 24			0.67				
Item 25–29				0.83			
Item 26–30				0.92			
Item 27–31				0.87			
Item 28–32				0.26			
Item 33					0.70		
Item 34					0.75		
Item 35					0.45		
Item 37–43						0.50	
Item_39–45						0.78	
Item_40–46						0.65	
Item_41–47						0.34	
Item 48: Scenario 1							0.44
Item 49: Scenario 2							0.52
Item 50: Scenario 3							0.27
Item: 51:Scenario 4							0.39
Item 52: Scenario 5							0.48
Item 53: Scenario 6							0.39

Another key factor is analgo-sedation since it reduces the stress of critically ill paediatric patients and facilitates nursing care and adaptation to mechanical ventilation. However, the prolonged use of analgo-sedation entails a series of complications and side effects, including withdrawal syndrome, with an overall incidence in some studies of more than one-third of patients.[14,41] Among the symptoms, we find irritability, anxiety, tremors, insomnia, delirium, hallucinations, and inconsolable crying[41] which may lead, given the lack of patient collaboration and the risk of accidental removal of health care devices, to the use of PR. For this reason, it is essential that paediatric instruments consider both the appropriate use of analgo-sedation and the risk of withdrawal syndrome.

The Physical Restraint-Theory of Planned Behaviour questionnaire in clinical practice can help assess the intention to use PR in paediatric care. Additionally, it can guide the development of quality improvement plans through multi-component interventions to reduce the use of PR and promote safe and high-quality care for critically ill paediatric patients.

TABLE 4 Goodness-of-fit indices of the 7-factor paediatric instrument.

Chi-square	$\chi^2 = 1989.15$; GL = 506; $p < .001$
RMR	0.09
RMSEA	0.09
CFI	0.91
TLI	0.90

Abbreviations: CFI, comparative fit index; RMR, root mean square residual; RMSEA, root mean square error of approximation; TLI, Tucker-Lewis index.

TABLE 5 Internal consistency according to the seven factors.

Factor	Cronbach's alpha	95% CI
Attitude	0.73	0.68–0.78
Attitude towards behaviour	0.80	0.76–0.84
Behavioural belief × outcome evaluation	0.73	0.67–0.78
Norms	0.78	0.73–0.82
Subjective norms	0.72	0.65–0.77
Normative belief × motivation to comply	0.89	0.86–0.91
Control	0.69	0.63–0.75
Perceived behavioural control	0.80	0.75–0.84
Control belief × power of control	0.73	0.67–0.79
Intention	0.75	0.69–0.79

4.1 | Strengths and limitations

The two greatest strengths of this research are the rigorous process by which we adapted the instrument and our multi-centre design. Limitations include our use of convenience sampling and the fact that reproducing the study would require specific training for participants and researchers in the use and interpretation of the scale. It is also important to note that responses may have been conditioned by social desirability bias and participants' beliefs about the ethically acceptable use of PR. Finally, we included eight experts to validate the scale's content. Although Polit et al. (2007) suggest the inclusion of a panel of 8–12 experts to establish the content validity of a scale in the COSMIN Design Checklist, a number of 30–49 experts seems appropriate. Therefore, this was another limitation of the study.

5 | CONCLUSION

The Paediatric Physical Restraint-Theory of Planned Behaviour Questionnaire is an instrument composed of seven factors and 51 items that validly and reliably assesses the intention of paediatric nurses to apply PR in PICUs. This is the first study to adapt and expand to the paediatric context a questionnaire that measures this intention through the theory of planned behaviour—a robust construct that has been amply tested and validated in prior studies. Having this instrument will help health centres move towards restraint-free care by allowing managers to assess professionals' attitudes, beliefs, and intentions around the use of PR in PICUs.

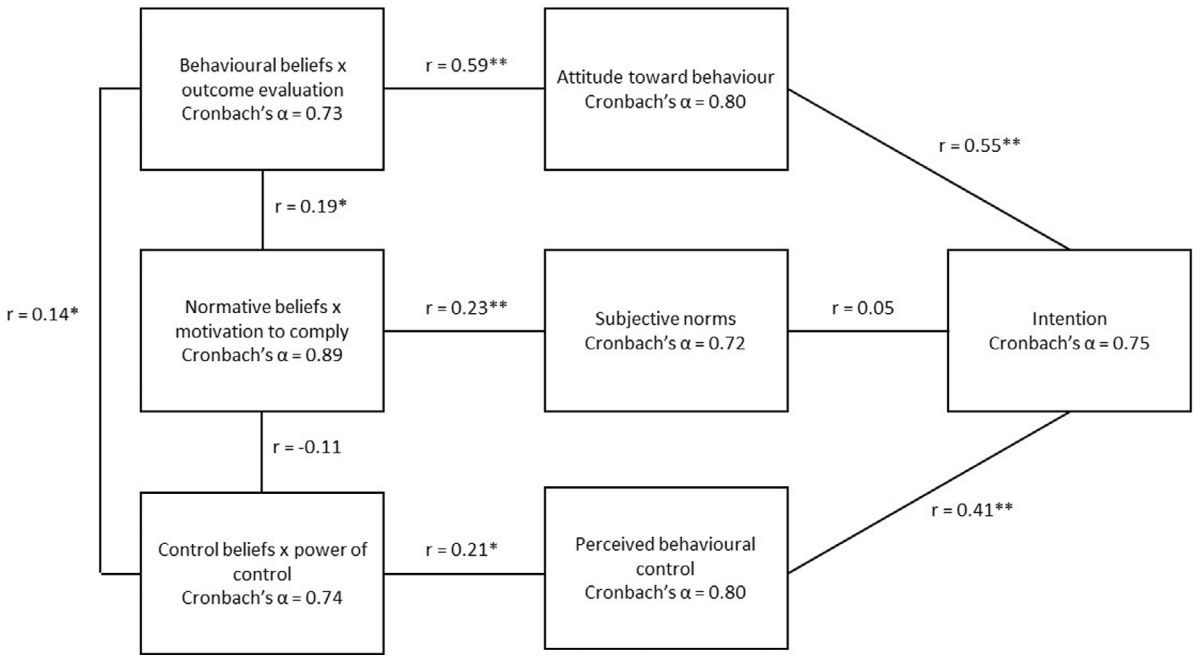

FIGURE 1 Internal consistency and Pearson's *R* correlation between the 7 factors of the Paediatric Physical Restraint-Theory of Planned Behaviour Questionnaire. *r* = Pearson's correlation.* The correlation is significant at 0.05 (bilateral). ** The correlation is significant at 0.001 (bilateral).

TABLE 6 Results of the multivariate analysis of the model.

Subscale	Unstandardised β	95% CI	Standardized β	*p*-value
Attitude towards behaviour	0.42	0.22 to 0.62	0.27	<.001
Behavioural belief × outcome evaluation	0.03	0.02 to 0.05	0.32	<.001
Subjective norms	0.00	−0.12 to 0.12	0.00	.99
Normative belief × motivation to comply	−0.00	−0.02 to 0.01	−0.02	.66
Perceived behavioural control	0.23	0.08 to 0.38	0.16	.00
Control belief × power of control	0.07	0.02 to 0.11	0.16	.00

Abbreviations: β, beta coefficient; CI, confidence interval.
Note: Adjusted R^2 coefficient of determination = 0.423.

AUTHOR CONTRIBUTIONS

P.P-R; P.L-C; E.Z-P; J.C-A; J.M.G-P; S.B-H; S.G-D; M.A.S-R; C.E-L; G. V-C and A.B-A made substantial contributions to the conception, design, or acquisition, analysis and interpretation of data. M.M-A; S.G-R; N.A-M; M.J.E-G; E.M-O; E.C-M; E.L-F; G.L-A; A.G-M; D.M-C; R.F-L; M.M-F; A.M-G and M.S-O collaborated in the acquisition and interpretation of data. All authors involved in drawing the manuscript, revising it, and approve the final version.

ACKNOWLEDGEMENTS

We thank the hospitals and particularly nurses who participated in this study.

DATA AVAILABILITY STATEMENT

Research data are not shared.

ETHICS STATEMENT

Prior to conducting the study, we obtained approval from the nursing administration and the ethics and clinical research committees of the five hospitals where the study was carried out: Sant Joan de Déu Children's Hospital (ethical approval number: PIC-176-21; approved date: 04 November 2021); Vall d'Hebron Hospital (ethical approval number: PR(AMI)07/2022; approved date: 28 January 2022); La Paz University Hospital (ethical approval number: PI-5146; approved date: 10 February 2022); 12 October Hospital (ethical approval number: 22/016; approved date: 17 January 2022) and Carlos Haya Regional University Hospital (ethical ratification/acceptance of the coordinating centre (Sant Joan de Déu Hospital) on 24 November 2021).

ORCID

Patricia Luna Castaño https://orcid.org/0000-0002-5317-5811

REFERENCES

1. Demir A. The use of physical restraints on children: practices and attitudes of pediatric nurses in Turkey. *Int Nurs Rev*. 2007;17:367-374. doi:10.1111/j.1466-7657.2007.00547.x
2. Dorfman P, Hardy M. The immobilization and restraint of pediatric patients during plain film radiographic examinations. *Radiography*. 2004;10:23-31. doi:10.1016/j.radi.2004.01.002
3. Badia M, Vicario E, García Solanes L, Serviá L, Justes M, Trujillano J. Atención del paciente crítico pediátrico en una UCI de adultos, Utilidad del índice PIM. *Med Intens*. 2013;2013(37):83-90. doi:10.1016/j.medin.2012.03.007
4. Dolz Alabau C, Martinez Dolz J, Soriano Prats MA. *Contención física y/o mecánica: plan terapéutico de seguridad en el paciente crítico pediátrico*. Hospital Universitario Politécnico de la Fe de Valencia, Unidad de Cuidados Intensivos Pediátricos; 2013. http://anecipn.org/pdf/congresos/XXXIV/documentos/M23-4.pdf
5. Crutchfield P, Gibb TS, Redinger MJ, Ferman D, Livingstone J. The conditions for ethical application of restraints. *Chest*. 2019;155:617-625. doi:10.1016/j.chest.2018.12.005
6. Via Clavero G. Intención de usar contenciones mecánicas en las unidades de cuidados intensivos: diseño y validación de un instrumento y factores relacionados (Tesis doctoral). 2019. Barcelona: Universidad de Barcelona. http://hdl.handle.net/10803/667920
7. Via Clavero G, Sanjuán Naváis M, Romero García M, de la Cueva Ariza L, Martínez Estalella G, Plata Menchaca E, et al. Eliciting critical care nurses' beliefs regarding physical restraint use. *Nursing Ethics*. 2019;26:1458–1472. doi:10.1177/0969733017752547.
8. Zhang Y, Liu L, Hu J, et al. Assessing nursing quality in paediatric intensive care units: a cross-sectional study in China. *Nurs Crit Care*. 2017;22:355-361. doi:10.1111/nicc.12246
9. Via Clavero G, Guàrdia Olmos J, Gallart Vivé E, Arias Rivera S, Castanera Duro A, Delgado Hito P. Development and initial validation of a Theory of Planned Behavior questionnaire to assess critical care nurses' intention to use physical restraints. *J Adv Nurs*. 2019;75:2036-2049. doi:10.1111/jan.14046
10. Bosch Alcaraz A, Via Clavero G. Can we justify the use of physical and mechanical restraint in pediatric patients admitted to the Intensive Care Unit. *Med Intens*. 2020;44:192-195. doi:10.1016/j.medine.2019.05.008
11. Moyano Hernández M. Sí a las contenciones mecánicas en las unidades de Cuidados Intensivos Pediátricos. Tertulia Pro/contra. ¿Se deben utilizar contenciones mecánicas? Libro de ponencias 33 Congreso Nacional de la Sociedad Española de Cuidados Intensivos Pediátricos. Barcelona, Ergon. 2018. https://secip.com/wp-content/uploads/2018706/12
12. Burry L, Rose L, Ricou B. Physical restraint: time to let go. *Intensive Care Med*. 2018;44:1296-1298. doi:10.1007/s00134-017-5000-0
13. Devlin JW, Skrobik Y, Vice-chair F, et al. Clinical practice guidelines for the prevention and Management of Pain, agitation / sedation, delirium, immobility, and sleep disruption in adult patients in the ICU. *Crit Care Med*. 2018;46:e825-e873. doi:10.1097/CCM.0000000000003299
14. Via Clavero G, Guàrdia Olmos J, Falcó Pegueroles A, Gil Castillejos D, Lobo Cívico A, De La Cueva Ariza L, et al. Factors influencing critical care nurses intentions to use physical restraints adopting the theory of planned behaviour: A cross-sectional multicenter study. *Austr Crit Care*. 2020;33:426-435. doi:10.1016/j.aucc.2019.09.003
15. De Hert M, Dirix N, Demunter H. Prevalence and correlations of seclusion and restraint use in children and adolescents: a systematic

review. *Eur Child Adolesc Psychiatry*. 2011;20:221-230. doi:10.1007/s00787-011-0160-x
16. Lambrenos K, McArthur E. Introducing a clinical holding policy. *Paediatr Nurs*. 2003;15:30-33. doi:10.7748/paed2003.05.15.4.30.c852
17. Jeffery K. Therapeutic restraint of children: it must be always justified. *Paediatr Nurs*. 2002;14:20-22. doi:10.7748/paed.14.9.20.s20
18. Brenner M. Child restraint in the acute setting of pediatric nursing: an extraordinarily stressful event. *Issues Compr Pediatr Nurs*. 2007;30:29-37. doi:10.1080/01460860701366658
19. Mion LC. Physical restraint in critical care settings: Physical restraint in critical care settings: will they go away? *Geriatr Nurs*. 2008;29:421-423. doi:10.1016/j.gerinurse.2008.09.006
20. Ofoegbu BN, Playfor SD. The use of physical restraints on paediatric intensive care units. *Pediatr Anesth*. 2005;15:407-411. doi:10.1111/j.1460-9592.2004.01551.x
21. Ajzen I. The theory of planned behavior: frequently asked questions. *Hum Behav Emerg Tech*. 2020;2:314-324. doi:10.1002/hbe2.195
22. Ajzen I, Fishbein M. *Understanding Attitudes and Predicting Social Behaviour*. Prentice Hall; 1980.
23. Fishbein M, Ajzen I. *Belief, Attitude, Intention and Behaviour: an Introductory to Theory and Research*. Addison-Wesley; 1975.
24. Godin G, Bélanger-Gravel A, Eccles M, Grimshaw J. Healthcare professionals' intentions and behaviours: a systematic review of studies based on social cognitive theories. *Implement Sci*. 2008;3:36. doi:10.1186/1748-5908-3-36
25. Godin G, Kok G. The theory of planned behaviour: a review of its applications to health-related behaviors. *Am J Health Promot*. 1996;11:87-98. doi:10.4278/0890-1171-11.2.87
26. McEachan RRC, Conner M, Taylor NJ, Lawson RJ. Prospective prediction of health-related behaviours with the theory of planned behavior: a meta-analysis. *Health Psychol Rev*. 2011;5:97-144. doi:10.1186/1748-5908-3-36
27. Eskandari F, Abdullah KL, Zainal NZ, Wong LP. Use of physical restraint: Nurses' knowledge, attitude, intention and practice and influencing factors. *J Clin Nurs*. 2017;26:4479-4488. doi:10.1111/jocn.13778
28. Werner P, Mendelsson G. Nursing staff members' intentions to use physical restraints with older people: testing the theory of reasoned action. *J Adv Nurs*. 2001;35:784-791. doi:10.1046/j.1365-2648.2001.01911.x
29. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC. Strengthening the reporting of observational studies in epidemiology (STROBE): explanation and elaboration. *Int J Surg*. 2014;12:1495-1499. doi:10.1016/j.ijsu.2014.07.014
30. Mokkink LB, Prinsen CAC, Bouter LM, de Vet HCW, Terwee CB. The COnsensus-based standards for the selection of health measurement INstruments (COSMIN) and how to select an outcome measurement instrument. *Braz J Phys Ther*. 2016;20:105-113. doi:10.1590/bjpt-rbf.2014.0143
31. Mokkink LB, Prinsen CAC, Patrick DL, et al. COSMIN study design checklist for patient-reported outcome measurement instruments. 2019. https://www.cosmin.nl/wp-content/uploads/COSMIN-study-designing-checklist_final.pdf
32. Ludwig B. Predicting the future: have you considered using the Delphi methodology? *J Extens*. 1997;35(5):35. http://www.joe.org/joe/1997october/tt2.html
33. Polit D, Beck C. *Essential of Nursing Research: Methods, Appraisal and Utilization*. 6th ed. Lippincott Williams and Wilkings; 2006.
34. Polit DF, Tatano Beck C, Owen SV. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. *Res Nurs Health*. 2007;30:459-467. doi:10.1002/nur.20199
35. Lynn MR. Determination and quantification of content validity. *Nurs Res*. 1986;35:382-385. doi:10.1097/00006199-198611000-00017
36. Polit D, Tatano C. The content validity index: are you sure you know what's being reported? Critique and recommendations. *Res Nurs Health*. 2006;29:489-497. doi:10.1002/nur.20147
37. Ullman JB. Structural equation modeling: reviewing the basics and moving forward. *J Pers Assess*. 2006;87:35-50. doi:10.1207/s15327752jpa8701_03
38. Nunnally J, Bernstein I. *Psychometric Theory*. 3rd ed. McGraw-Hill; 1995.
39. Al-Abdwani R, Williams CB, Dunn C, et al. Incidence, outcomes and outcome prediction of unplanned extubation in critically ill children: an 11 year experience. *J Crit Care*. 2018;44:368-375. doi:10.1016/j.jcrc.2017.12.017
40. Arona Olmo S, Rodriguez AM. La humanización de los cuidados enfermeros en unidades de críticos neonatales y pediátricos. *Àgora de Salut*. 2022;8:189-203. doi:10.6035/AgoraSalut.2022.8.17
41. Fernández Carrión F, Pérez A. Síndrome de abstinencia en la UCIP *Protoc Diagnós Terapéut Pediatr*. 2020;3:3-15. https://www.aeped.es/sites/default/files/documentos/01_sindrome_ucip.pdf

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Bosch Alcaraz A, Piqueras Rodríguez P, Corrionero Alegre J, et al. Adaptation and validation of the Physical Restraint-Theory of Planned Behaviour Questionnaire to the paediatric context. *Nurs Crit Care*. 2024;1-14. doi:10.1111/nicc.13066