Department of Clinical Sciences and Community Health

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Coordinator: Prof. LA VECCHIA Carlo

Doctoral Thesis

Nursing Sensitive Outcomes in Intensive Care Unit.

A focus on the family engagement in healthcare

SSD: Nursing Sciences (MED/45)

Supervisor:

Prof. Anne Lucia Leona DESTREBECQ

PhD Candidate:

Matteo DANIELIS

Matricola n° R12288

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Abstract

Driven by the current need of achieving high-reliability and patient-focused organization, several efforts have been enacted with the purpose of identifying and qualifying nursing care's contribution to patients' outcomes in Intensive Care Unit (ICU). The main aim of this thesis was to advance knowledge in critical care nursing with regard to nursing outcomes in the ICU.

Thirty-five Nursing Sensitive Outcomes (NSOs) have been identified from a scoping review. Pressure ulcers, ventilator-associated pneumonia, and physiological parameter changes have been the top three reported outcomes, while those related to the physical dimension (such as bowel status) and the experience of being in intensive care (such as family participation in care) have been rarely reported. In addition, as an expression of both the structural and process dimensions of care, a total of 21 nursing factors have been studied to date. Early mobility programmes, the use of algorithms, checklists and specific assessment tools, nurse staffing and compliance with care bundles have been largely studied as being able to affect NSOs in the ICU. Conversely, little research investigating family member's contributions to care in ICU, including its outcomes on family itself and on patient care, has been rendered available.

Thus, the aim of the Family ENgagement in Intensive Care Environments (FENICE) project was to assess the effects of a family engagement program on family members' satisfaction and on patients' well-being and quality of life post-discharge. When questioned, relatives of critically ill patients discharged from an ICU experienced a mix of negative and positive feelings in the early stages. Three main themes summarized the experience of relatives in the first three months after ICU discharge: 'Being shaken following ICU discharge'; 'Returning to our life that is no longer what it used to be' and 'Feeling powerless due to the COVID-19 pandemic'.

Finally, from an educational perspective, ICUs were perceived as good learning environments where undergraduate nursing students reported learning a high degree of competences compared with other clinical rotations. Therefore, this context of care can promote positive attitudes regarding the NSOs, by moving nursing care from a task orientation to an outcomes focus since the undergraduate education.

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Preface

The availability of a codified knowledge in the nursing field is the result of the lively scientific discussion among thinkers, researchers and philosophers that began in the late nineteenth and early twentieth century. Its origin dates back to the nursing tradition of studying the determinants of health, drawing on Florence Nightingale's *Notes on Nursing* in 1860 (Kagan, 2014). Although futuristic insights and misconceptions were combined traits in such a character, her main goal was to make a specific and significant contribution as a nurse to achieving a healthy society. Nightingale also bequeathed posterity the concept of a well-educated workforce of nurses as the essential requirement for leading nursing practice to become a professional and evolutionary experience.

From a theoretical point of view, the concept of caring has been widely explored. Questions such as 'what is the being of caring?' and 'who is the nurse?' have been answered by those scholars – Leininger, Heidegger and Watson, just to name a few examples – interested in ontological, epistemological, and methodological assumptions (Cheung, 1998; McFarlane, 1976). The second crux of reflection was about the practice of nursing. The effort to shaping and defining what nursing care is by responding to 'what does the nurse do?' found enthusiastic supporters among nurses of the twentieth century, such as Peplau, Henderson and Orem (Mudd, Feo, Conroy, & Kitson, 2020). Lastly, the prevailing question nowadays is 'what does the nurse actually produce?', which reflects the main idea that the specific features required by the profession should be located in the array of patients' outcomes nursing can pursue (Coster, Watkins, & Norman, 2018).

In the long course of the evolution of nursing (which is still not complete), new concepts, definitions and paradigms, such as the Nursing Process, the Evidence-Based Nursing and best practices, the Quality Management (Foth, Lange, & Smith, 2018), have been gradually introduced. More importantly, these theoretical notions made nursing interventions quantifiable: patients' outcomes are based on analytical cause-effect strategies. Historically, the major nursing outcomes have been defined as patients' mortality, absence of adverse events, patients' satisfaction and actual health status changes (Pierce, 1997).

The task of studying nursing outcomes is challenging. First, focusing on outcomes alone may be insufficient if these are analysed in isolation from the context of care (Pierce, 1997). Secondly, an outcome is achievable only by emphasising patients' active participation in the planning of their care (Foth et al., 2018). Third, some nursing activities are inseparable

elements within the multidisciplinary team, while others are relatively invisible and difficult to measure (Canzan, Heilemann, Saiani, Mortari, & Ambrosi, 2014). In contrast to disciplines with highly technical practice with specific, recognizable and immediate result, some nursing interventions do not occur in a singular space or time, and their effects spread them out over time (e.g., nurse-patient education activities).

With regard to the acute care settings, nursing practice in Intensive Care Units (ICUs) differs from other units for a variety of reasons. Whilst instrumental care – which focuses on physical health needs and employs interventions based on evidence – is a strong dimension of caring for critically ill patients, addressing the psychosocial needs also gains magnitude, and sometimes becomes a priority in this context (Romero-Martin et al., 2019). In an ICU, nurses are typically assigned to one/two patients based on higher acuity, frequency of observation and measurements, and multiple other aspects of care – from basic nursing to technical and advanced nursing – which patients require (Penoyer, 2010). In addition, patient involvement has only recently received attention in ICUs, with a considerate look at both family members, as a valid proxy in a beloved's decision-making process, and visitors who are approached with a more open attitude. As nurses, we should not forget that patients (and families alike) have more direct control over outcomes than any of the members of the nursing team.

All these considered, this thesis and the work behind it are intended to move a little step forward in the field of nursing outcomes, trying to advance knowledge in critical care nursing.

1. Introduction

1.1 Structure of the thesis

To better understand the research context, a brief introduction of what nursing outcomes are (hereinafter, Nursing Sensitive Outcomes [NSOs]) is here described in the Introduction. This chapter aims to define the theoretical framework that provides a reference for analysing the contribution of nursing care toward patient outcomes. In addition, the aims and the underpinning methodologies of the present thesis are here reported, as well as the general planning of the literature review. In the first phase of the project, the work starts with two reviews of literature. Chapter 2 synthesises the evidence of 35 NSOs that have been conceptualized and measured in critically-ill patients to date. The second review, illustrated in Chapter 3, summarises 21 nursing care factors investigated to date in ICUs in relation to NSOs. The second phase concentrated on the conceptualization of a research protocol (Chapter 4) of a quasi-experimental study whose underlying concept is family involvement in ICUs. Chapter 5 explains how the COVID-19 pandemic has introduced substantial changes in the critical environments of the ICUs in terms of resources and workload, not to mention the dramatic research disruption. Chapter 6 refocuses the attention on the research project by reporting the results of a preliminary step: the experiences of relatives of critically ill patients discharged from non-COVID ICUs after a three-month period. Lastly, Chapter 7 includes a critical reflection on the quality of ICU environments and the level of competences learned by students during their clinical rotations. Finally, Chapter 8 reports an overview of the results obtained and the concluding remarks. The structure of the thesis is depicted in Figure 1.1.

Most of the results presented in each chapter were already or are being published (or under review) in international, peer-reviewed journals. The content of each chapter corresponds to the related paper with some additional results or, in some cases, extended text.

1.2 Aims of the thesis

The main aim of this thesis was to advance knowledge in critical care nursing with regard to nursing outcomes in the ICU. Other specific aims are addressed in each chapter.

The first specific aim was to (a) map all primary studies conducted in the field of NSOs in ICUs, to overcome the selection limits applied by available systematic reviews; and (b)

classify NSOs in the ICU, hence providing a summary of the evidence published to date and highlighting outcomes requiring further research.

The second specific aim was to identify nursing care factors that have been associated with NSOs, with the intent of summarising those investigated to date and highlighting those in need of further research investments.

The third aim was to plan and conduct a research project, called FENICE (Family ENgagement in Intensive Care Environments), with the goal of assessing the effects of a family engagement program on family members' satisfaction and on patients' well-being and quality of life (QoL).

The fourth aim was to (a) describe the organizational changes in the ICUs due to the coronavirus pandemic (COVID-19); (b) explore the peculiarities of nursing care for the critically ill COVID-19 patients; and (c) investigate the major challenges perceived by ICU nurses during the pandemic.

The fifth aim was to explore and describe the experiences of a relative who had to face the day-to-day life during the first three months after a patient's discharge from non-COVID-19 ICU (preliminary results from the FENICE study).

The sixth aim was to (a) explore students' perceived quality of the ICU environment during their clinical rotations, (b) compare these perceptions with those reported by students attending other settings, and (c) assess correlations, if any, between the perceived quality of the environment attended and the competences gained.

1.3 Underpinning methods

To identify the questions to be researched and clarify their importance, a literature review protocol was designed and implemented between 2018 and 2019. According to the framework proposed by Arksey and O'Malley (Arksey & O'Malley, 2005), further refined by Levac and colleagues (Levac et al., 2010) and the Joanna Briggs Institute (JBI, 2017), and following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (Moher et al., 2009), a scoping review of literature was subsequently conducted in 2019. At that point, in accordance with the methodological process inspired by Tricco and colleagues (Tricco, Langlois, & Straus, 2017) which was further developed by Langlois et al (2019), a rapid review was performed in 2020. Subsequently, a protocol for a quasi-experimental study with two non-randomized groups was developed by following the

CONSORT (CONsolidated Standards Of Reporting Trials) guidelines (Schulz, Altman, Moher, & Grp, 2010). The protocol was registered in ClinicalTrials.gov, (Identifier: NCT04311190) on March 17, 2020.

Then, three study designs were implemented using different methodologies:

a. An exploratory study was conducted via an online survey available from May 11th to July 10th, 2020.

b. A descriptive qualitative study (Sandelowski, 2010) was held from August 2020 to January 2021. Methods and findings were reported according to the COnsolidated criteria for REporting Qualitative research principles (Tong, Sainsbury, & Craig, 2007).

c. A secondary analysis of a previous cross-sectional national research was conducted in 2020 by following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cross-sectional studies (von Elm et al., 2014).

1.4 Theoretical framework and thesis rationale

Most of the content of this section has been published.

> Danielis, M., Destrebecq, A., Terzoni, S., & Palese, A. (2019). Nursing Sensitive Outcomes in the Intensive Care Unit: a scoping review protocol. SCENARIO: Official Italian Journal of ANIARTI, 36(3).

More than twenty years after the release of the Institute of Medicine's landmark report, To Err Is Human: Building a Safer Health System (Kohn, Corrigan, & Donaldson, 2000), the debate is moving the focus from recognizing and reporting errors to improve patient safety and quality of care. Nowadays, both the overall quality of patient care and the contribution of different health care professions on patient outcomes are monitored through a number of mechanisms such as the international accreditation programs, which often stimulate not only quality enhancement activities and organizational improvement (Alkhenizan & Shaw, 2011; Desveaux, Mitchell, Shaw, & Ivers, 2017), but also an international debate on their actual healthcare benefits (Brubakk, Vist, Bukholm, Barach, & Tjomsland, 2015; Lam et al., 2018).

In this framework, nurses are trying to quantify and qualify the contribution of their care toward patient outcomes, since this provides the background for measuring the effect of any

changes to nurse variables such as nurse staffing levels, nurse skill mix and nurse practice environment on patients outcomes (Aiken et al., 2012; Myers, Pugh, & Twigg, 2018). The work of Maas and colleagues (1996) is considered one of the first attempts to clearly highlight the relationship between nursing activities and patient outcomes (Maas, Johnson, & Moorhead, 1996). In their report, the authors enlightened in depth the strategies used to develop and validate a list of Nursing Sensitive Outcomes (NSO). From the perspective of the authors, which has been subsequently universally recognized, a NSO is a "variable patient or family caregiver state, behaviour, or perception responsive to nursing intervention" (Maas et al., 1996). Over the years, NSOs have been measured to assess nursing quality, identify areas in need of improvement, and measure the success of patient safety enhancement program (Burston, Chaboyer, & Gillespie, 2014). Available data suggests that lower nurse-to-patient ratio (Needleman et al., 2011), higher proportion of nurses with a baccalaureate level education (Kendall-Gallagher, Aiken, Sloane, & Cimiotti, 2011) and better nurse work environments (Aiken, Clarke, Sloane, Lake, & Cheney, 2009) are associated individually and exponentially with lower mortality and failure-to-rescue (Aiken, Cimiotti, et al., 2012; Aiken et al., 2014).

When looking at patients' outcome, literature commonly include a wide range of indicators such as pressure ulcer, falls and falls with injury, medication error, nosocomial infection, pneumonia, vein system complication, failure to rescue, sepsis, gastrointestinal bleeding, shock, restraint, patient/family satisfaction with nursing care, patient/family satisfaction with pain management, mortality, length of stay and health-related quality of life (Ingersoll, McIntosh, & Williams, 2000; Kane, Shamliyan, Mueller, Duval, & Wilt, 2007; Myers et al., 2018; Needleman et al., 2011; Riera et al., 2016; Smith & Jordan, 2008).

While all of these are important, the focus of this thesis is on those indicators sensitive to nursing practice in a highly specialized setting, such as the ICU. Outcomes following critical illness vary widely between ICUs, in part because of differences in patient related factors, including severity of illness, comorbidities conditions, and disease-specific issues (Vincent et al., 2009), in part because of organizational issues, including hospital and ICU volume, closed or open ICU policy, availability of ICU specialists, and nurse staffing characteristics (Sakr et al., 2015). All the elements of nursing care, from *fundamentals* that may seem basic and non-technical, such as bathing and positioning a patient in bed, to *advanced*, such as managing highly technical devices, enable the intensive care nurse to gather vital

information about the patient and to improve his/her recovery. Moreover, nurses provide the constant surveillance and decision-making that is required to optimize outcomes and reduce complications in the critically ill patient (Chamberlain, Pollock, Fulbrook, & Grp, 2018).

The theoretical framework, to which this thesis refers, starts from the Donabedian three-dimensional model for measuring the healthcare quality, defined as the application of medical science and technology in a manner that maximizes its benefit to health without correspondingly increasing the risk. According to the model, three distinct components of quality care have been conceptualized: a) the *Structure*, which consists of the setting in which care is provided and covers variables both at the patients-level, and at nurses- and organizational-level; b) the *Process*, which comprehends all the activities of the healthcare professionals; and c) the *Outcome*, which refers to the actual change in patient's health status.

Ten years later, Irvine and colleagues (Irvine, Sidani, & Hall, 1998) enriched the model by separating the process component into nurses' independent (without a physician order), dependent (medical care-related) and interdependent (team-related) role functions. Then, with Doran's works (Doran, Sidani, Keatings, & Doidge, 2002; Doran et al., 2006), the relationship between nursing process (with a focus on the nurses' independent role) and patient's outcome has begun to be examined systematically. The authors reported two important statements: firstly, some outcome measures were really sensitive to nursing interventions; secondly, data on NSO can be routinely collected and integrated in clinical documentation (Doran et al., 2006).

The last review on NSOs in high acuity area has been conducted in 2017 (Myers et al., 2018). The authors examined the literature in order to identify suitable indicators for measuring the impact of nurse staffing and skill mix variations on patient outcomes in stand-alone high acuity settings, including ICU, step-down unit (with an intermediate level of care), high dependency units and Emergency Department (ED).

The indicators found were mortality, length of stay, central-line-associated bloodstream infection, ventilator-associated pneumonia, sepsis, falls with injury, reintubation, and medication errors. However, they concluded that there was still the need to clarify the definitions for each of the indicators and noted methodological limitations as grey literature was not included. The goal of this work is to overcome these limits with the different

approach of scoping review. Moreover, while the high acuity is a general concept which refers to the high level of care required by a patient regardless of the place, ICU is a specific physical space in which critically ill patients with life-threatening conditions are supported by advanced technology, placed under continuous monitoring and cared by a multidisciplinary team specially qualified (Marshall et al., 2017). To date, there is no existing synthesis on NSOs for Intensive Care Unit and further research is needed to clarify the definitions of the existing indicators.

Based on these premises, it is assumed that nurses related factors – directly tied to structural components – and the actual nursing care delivered to a patient – the process part – are closely related to the outcome measures called NSOs. Lastly, three ideas underpin this review work: first, the growing focus on quality improvement in health care; second, the concerns being expressed about the identification of suitable outcomes for ICU patients in relation to nursing; and, third, the impulsion towards data collection on NSOs to direct clinical practice.

1.5 Planning the review

Review questions

This review questions were:

What is the current state of research in the field of NSOs in the ICU?

What are the ICU's nursing outcomes that have been conceptualized and measured to date?

What are the structure and process variables associated to these NSOs?

Inclusion criteria

Participants

The scoping review will map studies concerning adult (≥ 18 years old) critically ill patients admitted and cared for in an ICU. Therefore, those studies regarding paediatric population (<18 years old) and patients receiving palliative care in the ICU will be excluded.

Concepts

The central focus of the review will be the NSOs. According to Maas and colleagues, which has been subsequently universally recognized (Myers et al., 2018) a NSO is considered as any

change in a patient's health state, behaviour and/or perception associated with nursing care interventions, as performed by nurses.

With regards to the NSOs, this work work will consider the classification developed by Doran (Doran, 2011), who categorised nursing outcomes in: (a) clinical (e.g., deterioration of pain and vital signs) (Lillibridge, Botti, Wood, & Redley, 2017), (b) functional (e.g., duration of early morning stiffness, fatigue) (Minnock et al., 2018), (c) safety (e.g., urinary tract infection, pressure ulcers and pneumonia) (Odgaard, Aadal, Eskildsen, & Poulsen, 2018), and (d) perceptive outcomes (e.g., patients' perceptions of nursing care received) (Aiken et al., 2018). With regards to the nursing interventions, this work will consider Irvine et al. framework who have categorised nurses role functions in (a) independent (without a physician order or prescription); (b) dependent (medical care-related); and (c) interdependent (team-related) (Irvine et al., 1998). Moreover, alongside the process variables (e.g., independent, dependent), emerged factors affecting NSOs will be also categorised in structural variables (Doran, 2011) (e.g., the nurse-to-patient ratio) when appropriate.

Therefore, all studies that refer to any of NSO for patients admitted to the ICU will be included in the scoping review. In particular, all clinical, functional, safety and perceptive NSOs will be considered when associated with nurse's independent, dependent and interdependent role functions. When documented, data on nurse-related structural and process variables and NSOs will also be considered.

Context

The context will include: (a) general ICUs where patients from medical, surgical and ED are admitted and cared for, and (b) specialty ICUs where specific care for select populations of critically ill patients is delivered. For the intent of the scoping review, an ICU is defined as a multidisciplinary and inter-professional environment in which patients having or at risk of developing life-threatening organ dysfunction are cared for. No country restrictions will be applied in order to scope the full number of existing studies in the field.

Types of studies

The following studies will be included: (a) primary (all methods, both quantitative and qualitative) and secondary studies as reviews and meta-analyses, (b) published in indexed

journals or as grey literature, and (c) written in the English language. No limitation in the time frame of publication will be applied. The following studies will be excluded (a) conference abstracts, book chapters, commentaries and editorials; and (b) studies written in a language other than English according to the language background of the research team.

Methods

A scoping review design will be performed by following the framework proposed by Arksey and O'Malley in 2005 (Arksey & O'Malley, 2005), which has been further developed by Levac et al. in 2010 (Levac, Colquhoun, & O'Brien, 2010) and enhanced in rigor and clarity by the Joanna Briggs Institute in 2015 (Institute, 2015). Moreover, this protocol is conducted in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analysis - Scoping Reviews (PRISMA-ScR) statement (Tricco et al., 2018).

Search strategy

Following the Joanna Briggs Institute guideline (JBI, 2017), the search strategy will be a three-step process. First of all, a preliminary and fast search will be conducted on at least two online databases relevant to our topic (MEDLINE and Cumulative Index to Nursing and Allied Health Literature [CINAHL]), combining the following terms: nursing sensitive outcomes, critically ill patients and intensive care unit, with the aim of identifying other keywords and index terms to develop a full search strategy. Subsequently, multiple databases will be examined in the second step.

The search strategy has been designed with the assistance of a librarian; its implementation will be assisted by the same expert librarian. In the final step, researchers will scan the references of all relevant studies identified for additional sources of inclusion. Also in the case of reviews, the reference lists will be screened by hand, with the aim of retrieving relevant studies to add for their evaluation against the inclusion criteria. Moreover, in case of doubts regarding the study inclusion due to data not reported in the full-text, authors will be contacted via email with at least three attempts to obtain missed information.

Information sources

Information sources to be consulted in-depth will include MEDLINE (via PubMed), Cochrane Database of Systematic Reviews, CINAHL, Joanna Briggs Library, Web of Science and Scopus

databases. Additionally, freely accessible web search databases (e.g., Google Scholar), websites of governmental and professional organizations about ICU care, such as the European Society of Intensive Care Medicine (ESICM), as well as OpenGrey for unpublished studies will be hand-consulted.

Study selection

All identified studies will be uploaded into the bibliographic management software EndNote® (Clarivate Analytics, PA, USA) and duplicates will be removed. In the first level of study screening, study titles and abstracts will be screened and evaluated for their eligibility against the inclusion criteria by two researchers, independently. All studies considered relevant will be included; disagreements will be resolved by discussion with a third researcher. In the second level of screening, an independent full-text review will be performed by two researchers to determine if studies meet the inclusion criteria. Even in this step, in cases of disagreements, a third researcher will be involved. The reasons given for excluded articles will be summarized in the PRISMA-ScR flow diagram, which will provide the flow process of study's search and selection process. According to Arksey and O'Malley, no assessment of methodological quality of the studies included will be performed.

Data extraction

A Microsoft Excel® spreadsheet will be used to extract data from the included studies. Data extraction will be performed independently by two researchers. The following will be extracted: (a) the study's general information (author, journal/source, publication/data collection year, and country); (b) the study's main features as: study design, setting(s) involved (e.g., type of ICU), aims, participants' inclusion criteria, participants included and their main characteristics; (c) a description of the reported NSOs in terms of: definition, instruments, metrics and procedures, and timeframe; and (d) the nursing care variables (as structure and process variables, when reported) that have been associated with NSOs, and the key findings of the study.

Then, a pilot test will be performed to assess the capability of the form to capture the proper information by reading and extracting at least 10% of the studies retrieved by two researchers, before independently and then agreeing on the findings. The final data

extraction sheet will be reviewed by all authors to eliminate discrepancies and ensure consistency in the data included.

Data presentation

When data extraction is completed, the researchers will have provided the following:

- a description of the state of the research in the field (e.g., countries involved, types of ICUs, and methodologies used), thus offering a comprehensive map on how studies have been designed and performed to date;
- NSOs as measured in the ICU to date, reporting their definitions, measures, instruments and timeframes (Levac et al., 2010);
- independent variables related to NSOs as measured in the ICU, categorised in (a) process variables as independent, dependent and interdependent role functions, and in (b) structure variables (Doran, 2011). These categorizations will be performed by two researchers, firstly independently and then agreeing upon the findings.

Discrepancies will be resolved by discussion in group. Moreover, tables, charts and maps will be used for presenting the findings. Graphic representations will be accompanied by narrative summaries.

Figure 1.1 Thesis flow

Scoping review research protocol

1. Introduction

Scoping review

2. Nursing Sensitive Outcomes in Intensive Care Unit

Rapid review

3. Nursing care factors influencing NSO

Quasi-experimental study research protocol

4. Family ENgagement in Intensive Care Environments (FENICE)

Cross-sectional study

5. Effects of coronavirus on the ICU

Qualitative study

6. The experiences of relatives

Secondary analysis of a cross-sectional study

7. Intensive Care Units as learning environment

2. Nursing Sensitive Outcomes in Intensive Care Unit

Most of the content of this section has been published.

This article has been chosen for the Società Italiana di Scienze Infermieristiche (SISI) Researcher 2021 (SISI Award 2021).

2.1 Introduction

In recent years, increased attention to the quality of patient care and the impact of different healthcare professions on patient outcomes has emerged among researchers, clinicians, and managers (Brubakk et al., 2015; Lam et al., 2018). In this context, it has been widely recognized that caring for critically-ill patients in the ICU is challenging, due to both the acute condition of the patient at the time of admission and the peculiarities of the ICU environment (Marshall et al., 2017). Acute illness, which requires constant surveillance, as well as medical treatments, are always accompanied by increased physiological and psychological needs that demand from nurses comprehensive and holistic care (Naef, Ernst, Burgi, & Petry, 2018). Moreover, patients in the ICU typically receive care from a multidisciplinary team, surrounded by a high-technology environment (Marshall et al., 2017). Thus, measuring and quantifying nurses' contributions is more challenging because of the complexity of nursing practice as well as the lack of reliable instruments capable of accurately measuring nursing care outcomes. In addition, the combined independent (as interventions failing in the nursing domain), dependent (as the medical care-ordered), and interdependent (team care-related) functions (Doran, 2011) in the ICU make the debate on nursing sensitive outcomes more complex.

The term "nursing sensitive outcome" was first introduced by Maas and colleagues (1996) and then universally acknowledged as each change in patient's state, behaviour, and perception associated with a nursing intervention (Maas et al., 1996). Many studies over the last decades have focused on the relationship between patient outcomes and some nursing

structure variables, such as skill mix, staffing, education level, and work environment, suggesting that mortality, patient complications, and the length of stay in hospital are influenced by the quality of nursing care delivered (Aiken, Cimiotti, et al., 2012; Aiken et al., 2014; Griffiths et al., 2018; Seligardi, Bassi, & Mongardi, 2017). However, in the ICU context, only five reviews have been developed to date, documenting the following outcomes associated with nursing care variables: mortality (Kane, Shamliyan, Mueller, Duval, & Wilt, 2007; McGahan, Kucharski, Coyer, & Winner, 2012; Myers et al., 2018; West, Mays, Rafferty, Rowan, & Sanderson, 2009), ICU and in-hospital length of stay (Kane et al., 2007; Myers et al., 2018; West et al., 2009), infections and pathogen transmission, such as central line-associated bloodstream infections and ventilator-associated pneumonias (Kane et al., 2007; McGahan et al., 2012; Myers et al., 2018; West et al., 2009), unplanned extubations and reintubations (Kane et al., 2007; Myers et al., 2018; West et al., 2009), falls (Myers et al., 2018), medication errors (Myers et al., 2018), and pressure ulcers (McGahan et al., 2012). Moreover, all authors concluded that there was still the need to clarify the definitions for each of these indicators, establishing common metrics and tools across studies. In addition, given that grey literature was excluded, a potential bias could have affected these findings.

Furthermore, other outcomes of nursing care, such as sleep quality (Ding et al., 2017), oral health (Chipps et al., 2016), hygiene status, and anxiety (Klein, Bena, Mulkey, & Albert, 2018), that have also been reported as being important for the patient's experience (Stalpers, De Vos, Van Der Linden, Kaljouw, & Schuurmans, 2017) have been neglected to date, most likely due to the complexity of the nursing discipline in the ICU and the lack of measures capable of portraying the effects of nursing care on the behaviour and perceptions of critically-ill patients. As a consequence, the set of nursing sensitive outcomes that should be considered while designing studies in the field are limited and have not been well defined.

Based on these premises, developing a scoping review covering a broad spectrum of literature on nursing sensitive outcomes for critically-ill patients in the ICU setting would provide highly relevant data capable of offering a comprehensive map of (a) studies performed in the field, thus overcoming the selection limits applied by the systematic reviews available, and (b) nursing sensitive outcomes measured in the ICU, providing a summary of the evidence published to-date and highlighting outcomes requiring further studies.

2.2 The review

Aims

The aims of this scoping review were (a) to explore the characteristics of the available studies on nursing sensitive outcomes in the ICU and (b) to identify all reported outcomes used to date, to measure the contribution of nursing care in this setting.

The review questions were the following: What is the state-of-the-science in research in the field of nursing sensitive outcomes in the ICU? What nursing sensitive outcomes have been conceptualized, used, and studied up to now in ICU settings?

Design

A scoping review was conducted according to the framework proposed by Arksey and O'Malley (Arksey & O'Malley, 2005), further refined by Levac and colleagues (Levac et al., 2010) and the Joanna Briggs Institute (JBI, 2017). The scoping review research protocol was first developed and approved by the research team (Danielis et al., 2019). Then, the following steps were undertaken: (1) identifying the research question according to the Patient, Concept and Context framework (JBI, 2017); (2) identifying relevant studies; (3) selecting studies; (4) charting the data; and (5) collating, summarizing, and reporting the results. Findings are reported here, following the Preferred Reporting Items for Systematic reviews and Meta-analysis extension-Scoping Reviews (PRISMA-ScR) statement (Tricco et al., 2018).

Patient, Concept and Context framework

The Patient, Concept and Context framework was the following:

(a) Participants: critically-ill adult patients admitted to the ICU.

(b) Concept: nursing sensitive outcome, defined as any patient's health state, behaviour, or perception that responds to one or more interventions (Maas et al., 1996) performed by nurses in ICU or any other outcome variable identified by researchers as sensitive to nursing care. Nursing sensitive outcomes were categorised according the Doran's taxonomy (Doran, 2011) in (a) *safety* (=adverse occurrences), (b) *clinical* (=symptom control), (c) *functional* (=physical and psychosocial functioning and self-care abilities), and (d) *perceptive* (=satisfaction with nursing care / subjective experience of the illness) outcome dimensions. Moreover, outcomes have been categorised according to Doran's

nurses' functions of care (Doran, 2011) in (i) outcomes achieved with *independent* functions (=without a physician order), and (ii) outcomes achieved with *dependent* functions (=medical care-related) and *interdependent* outcomes (=team-related or multidisciplinary).

(c) Context: ICU, defined as a highly specialized setting in which a critically-ill patient is cared for by a multidisciplinary team (Marshall et al., 2017). In this review, studies regarding both general ICUs, which include a wide range of diagnoses and procedures, and specialty ICUs, which include diagnosis-specific care for selected populations of critically-ill patients (for example, cardiosurgical ICUs) were considered.

Data sources and search strategy

In accordance with the Joanna Briggs Institute (JBI, 2017), a three-step process was performed by two authors, experts in critical care, who designed the search strategy, further verified by a librarian. First, an initial search in the MEDLINE (via PubMed) and CINAHL databases was performed in January 2019 allowing authors to identify subject headings and keywords for the well-refined search strategy. Secondly, the electronic databases MEDLINE (via PubMed), CINAHL, Web of Science, and Scopus were examined in February 2019. Thirdly, a freely accessible web database (e.g., Google Scholar) has been hand searched by authors.

The following terms have been considered: (1) "Outcome Assessment (Health Care)"[Mesh] OR "Patient Outcome Assessment"[Mesh] OR "Treatment Outcome"[Mesh] OR "Quality of Health Care"[Mesh] OR "Critical Care Outcomes"[Mesh] OR "Outcome Measures"; (2) "Intensive Care Units"[Mesh] OR "Critical Illness"[Mesh] OR "Critical Care"[Mesh] OR "Critical Care Nursing"[Mesh] OR "Critically ill patient"; (3) "Nursing"[Mesh] OR "Nursing Care"[Mesh] OR "Contribution of nursing care" OR "Nursing sensitive outcome" OR "Nurse sensitive indicator". All these terms and free-text words were combined into the search strings with the Boolean Operator 'AND'. In the final step, the reference list of included articles was screened, with the purpose of identifying all additional and relevant articles not recognized from the electronic databases. Duplicate articles were automatically removed through EndNote®.

Study selection criteria and process

Primary studies were included according to the following inclusion criteria: (a) concerning adult patients admitted and cared for in ICU settings; (b) based on all quantitative and qualitative study designs, as well as secondary studies based on all types of reviews; and (c) published in English, at any time.

Studies published concerning (a) the paediatric population (<18 years of age), (b) terminally-ill patients, or (c) peri-operative settings (e.g., recovery rooms), (d) not focused on the contribution of nursing care on patient outcomes in the ICU (e.g., appropriate antimicrobial therapy, optimizing the medication dose); (e) published in language other than English; (d) as conference abstracts, book chapters, best practice guidelines, commentaries, and editorial(s) were excluded.

First, two researchers screened article titles and abstracts according to the inclusion criteria, in an independent fashion. All relevant articles were included, and disagreements were solved using consensus and consultation with an additional researcher. Secondly, an independent full-text assessment was performed by two researchers to identify and select the articles to include in the review. Also at this stage, disagreements were solved by cooperation with a third researcher. In the case of reviews, the primary research included was screened, with the aim of retrieving relevant studies to add after evaluating them against the inclusion criteria.

Given the nature of the study, the publications included were considered for their consistency with the research questions rather than for their methodological quality (Arksey & O'Malley, 2005) that was not evaluated.

Data extraction

In a preliminary fashion, a pre forma grid was designed as a Microsoft Excel® spreadsheet, piloted in 10% of the studies included by one researcher. Given its power to contribute to the aims of this scoping review, data extraction was initiated and conducted by the first author and supervised by the last author. The following data were extracted from each study and populated in the grid: (a) general information, such as author(s), journal, publication year, and country; (b) main methodological features, such as study design, type of ICU, aims, and participants' characteristics; (c) a description of the reported nursing sensitive outcomes, such as end point of dependent variable in terms of definition and metrics; (d) a

brief description of nursing care as independent variable(s), when reported; and (e) the key findings. An example of the data extraction grid and process is reported in Table 2.1.

Data synthesis

Two authors independently summarized and synthesized the findings (Arksey & O'Malley, 2005) in accordance with the aims of the review, before independently agreeing on each of the synthesis's findings.

With regards to the first scoping review question, a synthesis of literature available on nursing sensitive outcomes was performed. Specifically, nursing sensitive outcomes were grouped according to their similarities (e.g., pressure sores, pressure ulcers). Then, studies were classified such as (a) primary research (meta-analyses, systematic reviews, and literature reviews), which focuses on multiple data sources from other studies, and (b) secondary research, in which data are gathered from original studies, including observational (retrospective and prospective cohort, case-control), interventional (randomized controlled trials [RCTs], crossover, quasi-experimental, before-and-after studies), mixed and qualitative methods, and case reports. Countries in which studies were conducted were categorized into six geographical areas: United States of America and Canada, Europe, Australia and New Zealand, Asia, Middle East, and Central and South America. The intensive care settings were categorized in general, cardiovascular, neurological, medical/surgical, and medical ICUs, as reported by the authors.

With regards to the second scoping review question, a thematic categorization (Sasseville, Chouinard, & Fortin, 2018) was used to allocate the nursing sensitive outcomes into outcome domains and sub-domains. With the aim of increasing specificity, each nursing sensitive outcome was grouped according to common clinical themes under the most similar sub-domain as reported below:

(a) safety: (1) healthcare associated infections, which included infections that occur while receiving critical care (Haque, Sartelli, McKimm, & Abu Bakar, 2018), and (2) critical incidents, unintended circumstances related to the process of care that may result in unfavourable patient outcomes (Runciman, 2006);

(b) clinical: (1) goal assessment and monitoring, which embraced all the outcomes that involve a close surveillance from nurses, understood as monitoring, evaluating, and acting on the emerging signs of a patient's change in status at the

bedside (Kutney-Lee, Lake, & Aiken, 2009), and (2) general health, whose outcomes captured different issues of critical illness and patient recovery and involved numerous healthcare professionals;

(c) functional: (1) psychosocial dimension, which referred to outcomes that can lead the patient to suffer from unpleasant emotional and cognitive reactions, and (2) functional dimension, understood as the degree of mobility and ability to perform activities of daily living; and

(d) perceptive: the experience of being in intensive care, which encompass the outcomes generated by the intense environment of an ICU.

Lastly, the nursing sensitive outcomes identified in this review were categorized according to the three-role nurses' functions of care: independent, dependent and interdependent (Doran, 2011).

2.3 Results

Studies included

Figure 2.1 maps out the literature retrieved and the process of study inclusion. Initially, 4,231 records were identified, from which 205 were assessed for eligibility after duplication removal and a relevance screening process. Thereafter, 93 studies were excluded due to the following reasons: main focus on a setting other than the ICU (e.g., high-dependency units) (n=22), not reporting outcomes related to nursing care (e.g., medical procedures) (n= 20), publication type not meeting the inclusion criteria (e.g., editorials) (n=20), non-eligible critically-ill patients (e.g., those receiving palliative care) (n=17), and care not provided by nurses (e.g., nursing assistants) (n=14).

Finally, 112 studies fully met the inclusion criteria.

Of the 112 articles included the majority (n=86, 76.8%) were published in nursing journals and the remainder (n=26, 23.2%) in medical journals. The first study was published in 1996, with 2019 being the latest publication year included. Only four articles (3.6%) were published before 2000. Thirty-two (28.6%) were published between 2001 and 2010, and more than two thirds (67.8%) were published after 2010.

Settings

Publications were mainly authored in the United States of America and Canada (n=44; 39.2%), followed by Europe (n=21, 18.8%), Australia and New Zealand (n=18, 16.1%), Asia (n=15, 13.4%), the Middle East (n=10, 8.9%), and Central and South America (n=4, 3.6%). Studies were conducted in general ICUs (n=83, 74.1%), followed by cardiovascular (n=10, 8.9%), medical (n=8, 7.1%), medical and surgical (n=6, 5.4%), and neurological ICUs (n=5, 4.5%).

Study designs

Almost all studies included were data-based, using predominantly a quantitative method (n=90). Of these, 62 (55.3%) were observational in design, including cross-sectional, case-control, prospective, and retrospective cohort studies. Other quantitative studies included were experimental and quasi-experimental (n=26, 23.2%) and mixed-method (n=2, 1.8%) in their design. Of the remaining, 17 (15.2%) were literature reviews, including systematic and narrative reviews. Only four (3.6%) were qualitative studies, and one was a case report. The study design employed to document the nursing sensitive outcomes, as well as the countries where the studies were performed and the type of ICU, are shown in Table 2.2.

Report of Nursing Sensitive Outcomes

As reported in Table 2.3, the 112 included studies documented a total of 233 nursing sensitive outcomes, categorized into 35 outcomes, on average two per study included. The most studied outcome was pressure ulcers (n=20), followed by ventilator-associated pneumonias (n=19), physiological parameters (n=14), and delirium (n=13). The least often studied nursing sensitive outcomes were quality of life, secretion clearance, patient-ventilator desynchrony, and post-extubation dysphagia, all reported in only one study respectively.

The measurement systems used included instruments/tools (e.g., Confusion-Assessment Method-ICU), direct clinical measures (e.g., level of glycemia), administrative data (e.g., length of stay), and patients' narratives (e.g., interviews and informal conversations). However, 22 studies did not report a description of the metric used of the outcome assessed (e.g., hygiene status).

According to Doran's outcome classification (Doran, 2011), the outcomes most often studied to-date are those regarding safety (n=77, 33.1%), followed by clinical (n=72, 30.9%), functional (n=70, 30.0%), and perceptual (n=14, 6.0%) domains, as reported in Table 2.3.

Safety domain

Several studies (n=77, 33.1%) documented outcomes negatively influencing patient safety, including critical incidents (five nursing sensitive outcomes) and healthcare-associated infections (three nursing sensitive outcomes) sub-domains. When looking at the critical incident sub-domain, the most commonly reported outcome was pressure ulcers (n=20) and falls and unplanned extubation rates, documented in six publications. Adverse events outcome (four studies) was reported in a number of different ways, including airway-, medication-, procedures-, lines- and environment- related incidents. Lastly, only three publications reported incontinence-associated dermatitis.

Among healthcare associated infections, the ventilator-associated pneumonia incidence was the most frequently reported outcome (n=19), followed by central line-associated bloodstream infections (n=12) and catheter-associated urinary tract infection (n=7).

Nursing sensitive outcomes in the safety domain were measured predominantly with prevalence/incidence, reporting the number of cases as documented in the clinical records or databases.

Clinical domain

Several studies (n=72, 30.9%) documented outcomes related to symptoms and disease control, such as goal assessment and monitoring (seven nursing sensitive outcomes) and general health (six nursing sensitive outcomes). Within these outcomes, physiological parameter alteration was the most reported outcome (n=14). Pain was documented in nine studies, mostly with validated tools (e.g., Visual Analogue Scale, Critical-care Pain Observational Tool). Then, in order of frequency, glycaemic levels were documented in five articles; deep vein thrombosis in two; and patient-ventilator desynchrony, post-extubation dysphagia, and secretion clearance in one study, respectively. Mortality, hospital or intensive care unit length of stay, ICU readmissions, length of mechanical ventilation, and the patient reported quality of life were considered general health outcomes. The most reported outcome was mortality, being present in 11 studies with three different metrics (ICU, in-

hospital, and 30-day mortality), followed by ICU length of stay in nine studies, length of mechanical ventilation in eight, hospital length of stay in seven, ICU readmissions in three, and quality of life in one single study.

Functional domain

Studies evaluating the functional domain (n=70, 30.0%) documented nursing sensitive outcomes in their psychosocial (four nursing sensitive outcomes) and physical dimensions (seven nursing sensitive outcomes). Delirium was reported in 13 studies, using predominantly the Confusion Assessment Method-ICU to evaluate its occurrence. A total of 11 studies instead reported anxiety, mostly measured with the State Trait Anxiety Inventory and the Beck Anxiety Inventory. Moreover, 11 studies investigated the patient's bedside monitor or personal experience, followed by five studies investigating the cognitive status, focusing on the acute change or fluctuation of a patient's mental status measured with different tools (e.g., Ramsay Sedation Scale, Richmond Agitation-Sedation Scale).

The most frequently reported outcome in the physical dimension category was sleep quality, being present in 11 studies, using a miscellaneous method of assessment (e.g., patient's subjective experience, the Richards-Campbell Sleep Questionnaire, or polysomnography recordings).

The functional status was reported in five studies. Nutritional and oral health status was measured in four studies, while bowel, eye health, and hygiene status were measured in two. These last outcomes were measured predominantly with direct observation, except for oral health, which was evaluated with specific assessment scales (e.g., Beck Oral Health Assessment scale).

Perceptive domain

Studies reporting outcomes regarding the patient's experience of being in the ICU (n=14, 6.0%) were rare. Specifically, patients' satisfaction was studied in seven studies using patient narratives. Moreover, comfort was documented in five studies using both patients' narratives and validated tools (e.g., Sickness Impact Profile), while the family's degree of participation in professional care was documented by two studies. As these outcomes are related to individual perception, observations, interviews, informal conversations, and self-reported questionnaires were the most commonly used methods to assess them.

Nursing sensitive outcomes as expression of nurses' role functions

The 35 nursing sensitive outcomes emerged were classified into independent, interdependent, and dependent, according to (Doran, 2011) (Table 2.4). The interdependent outcomes influenced by ICU multi-professional interventions (e.g., ventilator-associated pneumonias) were the largest, being represented by 20 (57.1%) nursing sensitive outcomes. The independent outcomes reflecting the end point of autonomous interventions performed by nurses (e.g., prevention and/or care of pressure ulcers) were less often studied (n=8, 22.9%). Dependent outcomes in which the nurses' interventions are used to be performed in response to a medical prescription (e.g., length of mechanical ventilation) were studied by a limited number of studies (n=7, 20.0%).

2.4 Discussion

This is the first scoping review summarizing the state of research by providing an overview of nursing sensitive outcomes studied among patients cared for in ICU settings. The first attempt in the field of measuring the nursing sensitive outcome in the ICU was provided by Laight in 1996.

Studies included

A total of 112 studies have emerged, mainly published in nursing journals over 23 years, expressing an average of five/papers per year. In other words, the interest in this field of research seems to be recent, as also demonstrated by the fact that most articles have been published in the last nine years. In general, the majority of studies have been conducted in the United States, followed by Europe. No studies have emerged from the African continent, suggesting that differences in research production may reflect differences in health care systems and resources. However, international–cross continental studies are suggested in this field given the different technologies and nurse-to-patient ratios that can both influences critically-ill patients' outcomes.

General ICUs have been the most studied settings to date, while specific ICUs, such as neurological and cardiological, have been less investigated. This can be interpreted under different lights, as the tendency of hospitals to aggregate patients under different critical conditions in general ICUs on one hand and as limited access to research by specific ICUs on

the other hand. Both possible explanations suggest the consideration of further implications, such as measuring nursing sensitive outcomes in patients with extreme variable critical conditions in the first case and the lack of evidence produced for specific sub-groups of patients in the second case.

The majority of studies have been conducted with quantitative methods; however, a relatively small number of experimental studies (n=26) emerged suggesting two possible implications: first, given that the majority of studies were observational in design, data can still be insufficient to demonstrate a strong relationship between some nursing interventions and nursing sensitive outcomes. Secondly, a few intervention studies measuring changes in the ICU nursing practice have been documented to date, suggesting that more quasi or experimental study designs are required in this field.

Report of nursing sensitive outcomes

Thirty-five nursing sensitive outcomes across the studies emerged and could be used to monitor the quality of patient care in the ICU. In addition to the mortality, ICU and in-hospital length of stay, infections and pathogen transmission, unplanned extubations and reintubations, falls, medication errors, and pressure ulcers reported in previous systematic reviews (Kane et al., 2007; McGahan et al., 2012; Myers et al., 2018; West et al., 2009), a wide range of nursing sensitive outcomes has emerged. According to Doran (2011), the majority of studies evaluated safety outcomes, suggesting the attempt to establish best practices capable of ensuring patient safety in the ICU. As ICUs are considered high-risk areas for incidents, errors, and adverse events due to the patients' severe conditions and the great number of procedures performed, patient safety is a tangible concern in intensive care environments and a key driver for quality of care.

In order of frequency, as the second main domain of nursing sensitive outcomes measured to date, studies evaluated clinical outcomes, thus strictly connected to the complexity of the patients' health condition; then, the functional domain (e.g., anxiety, functional dependence, delirium) has been measured with less frequently while perceptual outcomes have almost been neglected. Specifically, despite the relevance attributed recently to the fundamentals of care (e.g., sleep quality, nutritional status, and patient satisfaction) (Kitson, 2018) and to the need for symptom control (e.g., comfort, anxiety, pain assessment, and

management) (Su et al., 2018), these types of outcomes seems to be understudied among ICU patients.

With regards to the metrics, while some studies did not report the systems used to assess specific outcomes (e.g., hygiene status, comfort), a large variability of direct and indirect measures emerged across the remaining ones. Moreover, while for some nursing sensitive outcomes a substantial homogeneity in the measures used emerged (e.g., glycaemic levels, falls), in others, a wide variety was present (e.g., patient satisfaction). This seems to suggest that a lack of agreement and validated tools shared by clinical nurses and researcher teams is still present, thus making the assessment of nursing sensitive outcomes a challenge (La Sala et al., 2017). Therefore, more research aimed at establishing a validated measurement system for each nursing sensitive outcomes, also in the form of international consensus, is strongly recommended.

Nursing sensitive outcomes as expression of nurses' role functions

According to the findings to date, researchers have mostly studied outcomes requiring an interprofessional collaboration (e.g., physiological parameters, adverse events, mortality), thus reflecting interdependent nurses' functions (Doran, 2011). The ICU is a multifaceted environment in which complex and multi-professional interventions are required every day. In ICU settings, nurses and physicians work together and the decision-making process is often driven by multi-professional protocols and guidelines (Marshall et al., 2017). In fact, collaborative team members have less individual autonomy, as interprofessional collaboration requires interdependent practice (Rose, 2011).

2.5 Recommendations for research and practice

To date, 35 outcomes have been studied in the ICU as associated with nursing care. However, from the research point of view, given the diverse approaches and metrics used, further consensus to develop valid and homogeneous conceptual and operative definitions of each nursing sensitive outcome in the ICU settings is strongly recommended. Moreover, increasing efforts in establishing perceptual outcomes or those close to the fundamental of nursing care are suggested with the aim of portraying the specific contribution of ICU nurses. Furthermore, outcomes at the family level, which have been reported as being important in the ICU, should be considered in the future, alongside the need of providing a holistic

approach to the patient. For this reason, communities of academics, clinicians as well as educators and scientific nursing societies can offer a great contribution.

From a clinical point of view, the set of the nursing sensitive outcomes emerged can be used by nurses and nurse managers to develop an ICU minimum data set. For this purpose, it is strongly advisable to proactively develop functional and perceptive outcomes, such as self-care, functional, and psychosocial status, which have all been reported as being essential according to patient experiences (Aiken et al., 2012). The 35 nursing sensitive outcomes identified can be also used in clinical practice to (a) detect clinically recognizable outcomes among critically ill patients in an ICU environment, (b) achieve clinical meaningfulness by monitoring all dimensions of health status influenced by nursing care (both physical and psychosocial), and (c) provide evidence of the critical care nurses' contribution to patients' outcomes.

From an educational level point of view, the set of outcomes emerged can be considered core contents of the programmes by articulating them at the undergraduate level (e.g., safety outcomes) and at the advanced level of education (e.g., perceptual outcomes).

Finally, for what concerns policy making, outcomes emerged can be considered as the basis of administrative databases capable of collecting data regarding the nursing care delivered and the associated outcomes in ICU. Designing and implementing robust databases across units and hospitals, both at the national and at the international levels, can be valuable both for clinical and research purposes.

2.6 Limitations

There are several limitations of this scoping review. While a comprehensive search strategy and an inclusive approach were employed, there is no guarantee that all eligible studies were identified. Moreover, other potentially relevant publications could have been missed because searches were limited to (a) studies written only in the English language, (b) specific databases, excluding some relevant data sources (e.g., Embase) thus introducing a potential selection bias.

The lack of clear definitions of nursing sensitive outcomes through included studies determined a challenging process in study identification, eligibility and inclusion. For example, in the specific field of pressure sores, the researchers have also considered as a nursing sensitive outcome, as that evaluated with the Norton and Braden scale even if these

tools are intended to measure the risk of pressure sores and not the actual occurrence of pressure sores. However, we have considered these as outcomes according to the aim of this scoping review as well as the fact that nursing interventions can be also considered in light of the risk reduction or prevention as applied at the patient level (e.g. malnutrition, mobilization).

In addition, due to the high number of publications included and the heterogeneity of the research methods used, also in accordance with Arksey and O'Malley (2005), the researchers did not assess the methodological quality of the studies.

Furthermore, the researchers considered all studies where some nursing care variables were measured in their influences on patients' outcomes. The researchers did not consider if studies were led by nurses by and/or included nurses in the team of researchers because this was out of the established aims of the scoping review.

2.7 Conclusions

The purpose of this scoping review was to map the literature on nursing outcomes that have been conceptualized and measured in critically-ill patients to date, in the available literature. Based on 112 studies, our review identified 35 nursing sensitive outcomes that could be further considered in measuring the quality of care in the ICU, as well as in intervention studies aimed at evaluating the effectiveness of specific nursing care actions. According to the findings, while some outcomes are well represented (e.g., safety, clinical, and functional), others remain less explored (e.g., perceptual). Moreover, most of the nursing sensitive outcomes studied reflect the end point of team care activities; a smaller number of outcomes reflecting the independent role of nurses in ICU have been studied to date.

Figure 2.1 Scoping Review Flow Diagram (Tricco et al., 2018)

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┌─────────────────────────────────────┐     ┌─────────────────────────────────────┐
│ Records identified through database   │     │ Additional records identified through │
│ searching:                            │     │ other sources (web search, Google     │
│ MEDLINE (n=612), CINAHL (n=1,032),    │     │ Scholar, reference lists of articles) │
│ Web of Science (n=1,146) and Scopus   │     │ (n=10)                                │
│ (n=1,441)                             │     │                                       │
└─────────────────────────────────────┘     └─────────────────────────────────────┘
                        │                                      │
                        └──────────────────┬───────────────────┘
                                           ▼
                          ┌─────────────────────────────────┐
                          │ Records after duplicates removed  │
                          │ (n = 3,982)                       │
                          └─────────────────────────────────┘
                                           │
                                           ▼
                          ┌─────────────────────────────────┐     ┌─────────────────────────────────┐
                          │ Records screened                  │────▶│ Records excluded (n = 3,777)      │
                          │ (n = 3,982)                       │     │ irrelevant titles and abstracts   │
                          └─────────────────────────────────┘     └─────────────────────────────────┘
                                           │
                                           ▼
                          ┌─────────────────────────────────┐     ┌─────────────────────────────────────┐
                          │ Full-text articles assessed       │     │ Full-text articles excluded, with     │
                          │ for eligibility                   │────▶│ reasons (n = 93)                      │
                          │ (n = 205)                         │     │ main focus not in ICU: n=22           │
                          └─────────────────────────────────┘     │ not reporting NSOs: n=20              │
                                           │                       │ publication type not meeting the      │
                                           ▼                       │ inclusion criteria: n=20              │
                          ┌─────────────────────────────────┐     │ non-eligible patients: n=17           │
                          │ Studies included in the           │     │ care not provided by nurses: n=14     │
                          │ scoping review                    │     └─────────────────────────────────────┘
                          │ (n = **112**)                     │
                          └─────────────────────────────────┘
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CINAHL, Cumulative Index to Nursing and Allied Health Literature; NSOs, Nursing Sensitive Outcomes; ICU, Intensive Care Unit.

Table 2.1 Data extraction process: an example of the steps performed

Study main characteristics						Nursing sensitive outcomes measured and metrics	Nursing care intervention(s) as independent variable(s)	Key findings
First author, year and country	*Journal*	*Design*	*Setting*	*Aim(s)*	*Participants' profile*			
Aktas et al., 2016 (Turkey)	Nursing in Critical Care	Randomized controlled trial	Cardiovascular ICU	To examine the effect of music therapy on pain, sedation and physiologic parameters during endotracheal suctioning of mechanically ventilated patients	66 patients (33 experimental and 33 control), who were scheduled for a coronary artery bypass graft surgery or valve replacement that met these inclusion criteria	- Cognitive status (Ramsay Sedation Scale); - Pain (Critical-Care Pain Observation Tool); - Physiological parameters (patient bedside monitor)	Music therapy	Music therapy can be effective nursing practice in to reduce pain and control sedation levels in patients on mechanical ventilators during endotracheal suctioning
Al Ashry et al., 2014 (US)	Journal of Intensive Care Medicine	Before-and-after study	General ICU	To assess whether nursing compliance with filling an 18-item ICU checklist is associated with improvement in clinical outcomes in mechanically and no mechanically ventilated ICU patients	A consecutive series of 349 patients admitted to the ICU between December 2012 and June 2013	- ICU length of stay (number of ICU days); - Hospital length of stay (number of hospital days); - Length of mechanical ventilation (number of ventilator days)	Nurse-led ICU checklist	Compliance with completion of a nurse-led ICU checklist was associated with prolonged ICU stay, hospital stay, and ventilator stay
Almerud et al., 2003 (Sweden)	Intensive and Critical Care Nursing	Mixed method study	General ICU	To ascertain whether music therapy had a measurable relaxing effect on patients who were temporarily on a respirator in an ICU and after completion of respirator treatment investigate those patients' experiences of the music therapy	20 ICU patients who were temporarily in need of mechanical ventilation and whose condition was physically stable	- Anxiety (patients' experience); - Comfort (patients' experience collected by validated tools or qualitative interviews); - Physiological parameters (patient bedside monitor)	Music therapy	A significant reduction in systolic and diastolic blood pressure during music therapy sessions and an increase of them after treatment cessation were observed. ICU nursing staff can beneficially apply music therapy as a non-pharmacological intervention
Alm-Kruse et al., 2008 (Norway)	BMC Nursing	Before-and-after study	General ICU	To evaluate the existing degree of glycemic control, and to implement strict glycemic control safely in ICU through a nurse-led implementation of an algorithm for intensive insulin-therapy	5009 blood glucose samples from 494 patients, during the 32 months of the Study	- Glycemic levels (blood glucose samples)	Nurse-led algorithm	Through the implementation of strict glycemic control, the fraction of samples within the new target range increased from 33% to 45.8%. There was also a significant decrease in severe hypoglycemic episodes.

Table 2.2 Summary of ICU nursing sensitive outcomes as studied to date in the available literature

Nursing sensitive outcomes	Paper (n.)	Metrics of nursing sensitive outcomes (n.)	Study design (n.)[a]	Setting: geographical area (n.)	Setting: ICU type (n.)	References
Pressure ulcers	20	Prevalence and/or incidence rate (15) Prevalence and/or incidence (1) Discharge codes (1) Norton Scale (risk identification) (1) Braden Scale (risk identification) (1) Not reported (1)	Meta-analysis (1) Systematic review (1) Literature review (3) Randomized controlled trial (2) Quasi-experimental study (2) Before-and-after study (3) Cross-Sectional study (4) Cohort study (3) Cohort study protocol (1)	Asia (1) Australia and New Zealand (4) Central and south America (1) Europe (6) Middle East (1) United States of America and Canada (7)	General (15) Cardiovascular (2) Medical/surgical (2) Medical (1)	(Ballesteros, 2017; Caldini et al., 2017; Castellan, Sluga, Spina, & Sanson, 2016; de Laat, Schoonhoven, Pickkers, Verbeek, & van Achterberg, 2006; Driscoll et al., 2018; Elliott, McKinley, & Fox, 2008; Fraser, Spiva, Forman, & Hallen, 2015; Heslop & Lu, 2014; Jackson et al., 2011; Krapohl, Manojlovich, Redman, & Zhang, 2010; Malbrain et al., 2010; Manojlovich, Antonakos, & Ronis, 2009; Ozyurek & Yavuz, 2015; Riera et al., 2016; Dewi Stalpers, de Brouwer, Kaljouw, & Schuurmans, 2015; D. Stalpers et al., 2017; Stone et al., 2007; Sutton & Jarden, 2017; Winkelman et al., 2012; S. Yang et al., 2019)
Ventilator associated pneumonia	19	Prevalence and/or incidence rate (19)	Meta-analysis (1) Literature review (3) Quasi-experimental study (2) Before-and-after study (7) Cohort study (1) Cross-Sectional study (4) Cohort study protocol (1)	Asia (1) Australia and New Zealand (3) Europe (2) United States of America and Canada (13)	General (15) Medical/surgical (2) Medical (1) Cardiovascular (1)	(Bingham, Ashley, De Jong, & Swift, 2010; Blot et al., 2011; Boulila et al., 2016; Cutler & Sluman, 2014; Driscoll et al., 2018; Fraser et al., 2015; Hatler et al., 2006; Idemoto & Kresevic, 2007; D. Kelly, Kutney-Lee, Lake, & Aiken, 2013; Krapohl et al., 2010; Lawrence & Fulbrook, 2011; Manojlovich et al., 2009; Micik et al., 2013; Riera et al., 2016; Ross & Crumpler, 2007; Stone et al., 2007; Winkelman et al., 2012; S. Yang et al., 2019; Zurmehly, 2013)
Physiological parameters	14	Patient bedside monitor (14)	Systematic review (1) Literature review (2) Randomized controlled trial (4) Quasi-experimental study (3) Crossover study (1) Mixed method study (2) Qualitative study (1)	Asia (3) Australia and New Zealand (1) Europe (4) Middle East (3) United States of America and Canada (3)	General (10) Cardiovascular (2) Medical/surgical (1) Neurological (1)	(Aktas & Karabulut, 2016; Almerud & Petersson, 2003; Chan, Chung, Chung, & Lee, 2009; Chan et al., 2006; Cox & Hayes, 1999; Jagan, Park, & Papathanassoglou, 2019; Ledwith et al., 2010; Lindgren et al., 2013; Liou, Shih, Tang, Lai, & Chen, 2008; Marklew, 2006; Minton, Batten, & Huntington, 2018; Papathanassoglou, 2010; Papathanassoglou et al., 2018; Winkelman et al., 2012)

		Tool/Measure	Study design	Geographical location	ICU type	References
Delirium	13	Confusion-Assessment Method-ICU (6) Intensive Care Delirium Screening Checklist (2) Neecham tool and/or Confusion-Assessment Method-ICU (1) Automatic Prediction of Delirium in Intensive Care Units (1) Not reported (3)	Systematic review (1) Literature review (3) Quasi-experimental study (2) Before-and-after study (6) Cohort study (1)	Asia (3) Central and south America (1) Europe (2) United States of America and Canada (7)	General (6) Medical/surgical (3) Cardiovascular (3) Medical (1)	(Alway, Halm, Shilhanek, & St Pierre, 2013; Andrews, Silva, Kaplan, & Zimbro, 2015; Black, Boore, & Parahoo, 2011; H.-y. Cho, Song, Piao, Jin, & Lee, 2015; Idemoto & Kresevic, 2007; Kram, DiBartolo, Hinderer, & Jones, 2015; Martinez, Donoso, Marquez, & Labarca, 2017; Mullin, Chrostowski, & Waszynski, 2011; Piao, Jin, & Lee, 2018; Dewi Stalpers et al., 2015; Stuck, Clark, & Connelly, 2011; Winkelman et al., 2012; Zhang et al., 2017)
Central Line-Associated Bloodstream Infections	12	Prevalence and/or incidence rate (11)	Meta-analysis (1) Systematic review (2) Literature review (2) Before-and-after study (2) Cross-Sectional study (4) Cohort study protocol (1)	Asia (1) Australia and New Zealand (2) Europe (1) United States of America and Canada (8)	General (10) Medical (1) Cardiovascular (1)	(Driscoll et al., 2018; Hatler et al., 2006; Idemoto & Kresevic, 2007; D. Kelly et al., 2013; Krapohl et al., 2010; Manojlovich et al., 2009; McMullan et al., 2013; Ramritu, Halton, Cook, Whitby, & Graves, 2008; Riera et al., 2016; Stone et al., 2007; West et al., 2009; S. Yang et al., 2019)
Anxiety	11	State Trait Anxiety Inventory tool (4) Beck Anxiety Inventory tool (2) Patients' experience (1) Faces Anxiety Scale (1) Brief Symptom Inventory tool (1) Numeric Rating Scale (1) Not reported (1)	Systematic review (1) Literature review (1) Randomized controlled trial (6) Quasi-experimental study (1) Before-and-after study (1) Mixed method study (1)	Asia (1) Europe (2) Middle East (4) United States of America and Canada (4)	General (8) Neurological (2) Cardiovascular (1)	(Almerud & Petersson, 2003; Demir & Khorshid, 2010; Han et al., 2010; Jagan et al., 2019; Karadag, Samancioglu, Ozden, & Bakir, 2017; Klein et al., 2018; Lindgren et al., 2013; Mulkey, Bena, & Albert, 2014; Papathanassoglou et al., 2018; Saadatmand et al., 2013; Tracy & Chlan, 2011)
Psychological status	11	Patient bedside monitor (4) Patients' experience (2) Brief Symptom Inventory tool (2) Numeric Rating Scale (1) Sickness Impact Profile tool (1) Not reported (1)	Literature review (1) Randomized controlled trial (5) Quasi-experimental study (2) Before-and-after study (1) Mixed method study (1) Qualitative study (1)	Asia (2) Australia and New Zealand (1) Europe (3) Middle East (3) United States of America and Canada (2)	General (7) Neurological (2) Medical (1) Cardiovascular (1)	(Black et al., 2011; Cox & Hayes, 1999; Han et al., 2010; Irurita, 1999; Klein et al., 2018; Lindgren et al., 2013; Mulkey et al., 2014; Papathanassoglou, 2010; Papathanassoglou et al., 2018; Saadatmand et al., 2013; C. P. Su et al., 2013)
Sleep quality	11	Patients' experience (2) Patients' experience, Verran-Synder-Halpern Sleep scale, Richards-Campbell Sleep Questionnaire, Sleep Assessment tool and	Systematic review (1) Literature review (4) Randomized controlled trial (3) Cohort study (1) Mixed method study (1)	Asia (1) Australia and New Zealand (1) Europe (1) Middle East (3) United States of America and Canada (5)	General (8) Medical (2) Cardiovascular (1)	(Alway et al., 2013; Casida, Davis, McKee, Zalewski, & Yang, 2018; Cox & Hayes, 1999; Dick-Smith, 2017; Ding, Redeker, Pisani, Yaggi, & Knauert, 2017; Jagan et al., 2019; Karadag et al., 2017; Papathanassoglou, 2010;

		polysomnographic recordings (1) Richards-Campbell Sleep Questionnaire or polysomnographic recordings (1) Polysomnographic recordings (1) Pittsburgh Sleep Quality Index (1) Numeric Rating Scale (1) Visual Analogue Sleep scale (1) Total sleep time, Modified Groninger's Sleep Quality scale, polysomnographic recordings, Electroencephalography and electromyography data (1) Not reported (2)	Qualitative study (1)			Papathanassoglou et al., 2018; C. P. Su et al., 2013; Tracy & Chlan, 2011)
Mortality	11	ICU mortality (3) 30-day mortality (4) In-hospital mortality (3) In-hospital, ICU, 30-day mortality (1)	Meta-analysis (1) Systematic review (1) Randomized controlled trial (1) Quasi-experimental study (1) Before-and-after study (1) Cohort study (3) Cross-Sectional study (3)	Asia (2) Australia and New Zealand (1) Europe (1) United States of America and Canada (7)	General (10) Neurological (1)	(Amaravadi, Dimick, Pronovost, & Lipsett, 2000; Anifantaki et al., 2009; Boulila et al., 2016; S. H. Cho, Hwang, & Kim, 2008; Driscoll et al., 2018; D. M. Kelly, Kutney-Lee, McHugh, Sloane, & Aiken, 2014; Klein et al., 2018; Morita et al., 2017; Sales et al., 2011; Stone et al., 2007; West et al., 2009)
Pain	9	Critical-Care Pain Observation Tool (1) Critical-Care Pain Observation Tool and/or Numeric Rating Scale (1) Faces Pain Thermometer, Brief Pain Inventory , Critical-Care Pain Observation Tool, Visual Analogue Scale (1) Visual Analogue Scale and McGill Melzack Pain Questionnaire (1) Visual Analogue Scale (1) Veterans' administration pain	Systematic review (2) Literature review (2) Randomized controlled trial (4) Cohort study protocol (1)	Asia (1) Europe (2) Middle East (3) United States of America and Canada (3)	General (7) Cardiovascular (2)	(Aktas & Karabulut, 2016; Chan et al., 2006; Demir & Khorshid, 2010; Idemoto & Kresevic, 2007; Jagan et al., 2019; Papathanassoglou et al., 2018; Riera et al., 2016; Dewi Stalpers et al., 2015; Tracy & Chlan, 2011)

		scale (1) Universal pain assessment tool (1) Not reported (2)			
ICU length of stay	9	Number of ICU days (9)	Randomized controlled trial (2) Quasi-experimental study (1) Before-and-after study (5) Cohort study (1)	Asia (1) Australia and New Zealand (1) Europe (1) United States of America and Canada (6)	General (7) Medical/surgical (1) Neurological (1)	(Al Ashry, Abuzaid, Walters, & Modrykamien, 2016; Anifantaki et al., 2009; Dammeyer et al., 2013; Fraser et al., 2015; Klein et al., 2018; Knowles, McInnes, Elliott, Hardy, & Middleton, 2014; Liou et al., 2008; Winkelman et al., 2012)
Length of mechanical ventilation	8	Number of ventilator days (8)	Randomized controlled trial (2) Quasi-experimental study (1) Before-and-after study (4) Cohort study (1)	Asia (1) Europe (2) United States of America and Canada (5)	General (7) Medical/surgical (1)	(Al Ashry et al., 2016; Anifantaki et al., 2009; Dammeyer et al., 2013; Falk & Wallin, 2016; Kram et al., 2015; Liou et al., 2008; Swadener-Culpepper, Skaggs, & Vangilder, 2008; Winkelman et al., 2012)
Hospital length of stay	7	Number of hospital days (7)	Randomized controlled trial (1) Before-and-after study (5) Cohort study (1)	Europe (2) United States of America and Canada (5)	General (6) Neurological (1)	(Al Ashry et al., 2016; Amaravadi et al., 2000; Anifantaki et al., 2009; Dammeyer et al., 2013; Fraser et al., 2015; Klein et al., 2018; Kram et al., 2015)
Catheter Associated Urinary Tract Infections	7	Number of events (7)	Meta-analysis (1) Literature review (1) Before-and-after study (1) Cohort study protocol (1) Cross-Sectional study (2) Case-Control study (1)	Asia (1) Australia and New Zealand (1) Europe (1) United States of America and Canada (4)	General (5) Medical/surgical (1) Medical (1)	(Driscoll et al., 2018; Fraser et al., 2015; Galiczewski & Shurpin, 2017; D. Kelly et al., 2013; Riera et al., 2016; Stone et al., 2007; S. Yang et al., 2019)
Patients' satisfaction	7	Patients' experience (1) Nurses' experience (1) Patient Satisfaction Survey (1) Questionnaire with Likert scale (1) Not reported (3)	Randomized controlled trial (1) Literature review (3) Cross-Sectional study (2) Qualitative study (1)	Asia (1) Australia and New Zealand (3) Europe (1) Middle East (1) United States of America and Canada (1)	General (7)	(Boev, 2012; Heslop & Lu, 2014; Irurita, 1999; Jakimowicz & Perry, 2015; Liou et al., 2008; Papathanassoglou, 2010; D. Stalpers et al., 2017)
Unplanned Extubations	6	Prevalence and/or incidence rate (5) Nurses' experience (1)	Meta-analysis (1) Literature review (2) Cohort study (1) Cross-Sectional study (1) Qualitative study (1)	Asia (2) Australia and New Zealand (1) Europe (3)	General (6)	(M. Danielis, Chiaruttini, & Palese, 2018; Driscoll et al., 2018; Falk & Wallin, 2016; Kiekkas, Aretha, Panteli, Baltopoulos, & Filos, 2013; S. Yang et al., 2019; Yeh, Lee, Ho, Chiang, & Lin, 2004)

Falls	6	Number of events (6)	Systematic review (2) Literature review (1) Before-and-after study (1) Cohort study (1) Cohort study protocol (1)	Australia and New Zealand (2) Europe (2) United States of America and Canada (2)	General (4) Cardiovascular (1) Medical/surgical (1)	(Driscoll et al., 2018; Fraser et al., 2015; Heslop & Lu, 2014; Mullin et al., 2011; Riera et al., 2016; Dewi Stalpers et al., 2015)
Comfort	5	Patients' experience (2) Sickness Impact Profile tool (1) Not reported (2)	Literature review (2) Quasi-experimental study (1) Mixed method study (1) Qualitative study (1)	Australia and New Zealand (1) Europe (2) Middle East (1) United States of America / Canada (1)	General (4) Cardiovascular (1)	(Almerud & Petersson, 2003; Black et al., 2011; Idemoto & Kresevic, 2007; Minton et al., 2018; Papathanassoglou, 2010)
Cognitive status	5	Ramsay sedation scale (1) Richmond Agitation-Sedation Scale (1) 5-point Likert scale (1) Japan Coma Scale and Level of Cognitive Functioning Assessment Scale score (1) Glasgow Outcome Scale Extended (1)	Quasi-experimental study (2) Randomized controlled trial (1) Before-and-after study (1) Cross-Sectional study (1)	Asia (2) Europe (1) Middle East (1) United States of America and Canada (1)	General (2) Neurological (2) Cardiovascular (1)	(Aktas & Karabulut, 2016; Andrews et al., 2015; Langhorn, Holdgaard, Worning, Sorensen, & Pedersen, 2015; E. Lee, Park, Whyte, Kim, & Park, 2014; Okubo, 2012)
Glycemic levels	5	Blood glucose samples (5)	Randomized controlled trial (1) Quasi-experimental study (2) Before-and-after study (2)	Europe (2) Middle East (1) United States of America and Canada (2)	General (2) Medical (2) Cardiovascular (1)	(Alm-Kruse, Bull, & Laake, 2008; Dodson, Simpson, & Feinstein, 2014; DuBose et al., 2009; Khalaila et al., 2011; Lindgren et al., 2013)
Functional status	5	Six Minute Walk Test, Barthel Index, Functional Independence Measure (1) Barthel Index (1) A 16 levels of mobility tool (1) Number of ambulation sessions (1) Number of patients' mobilization (1)	Systematic review (1) Quasi-experimental study (1) Before-and-after study (3)	Asia (1) Australia and New Zealand (2) United States of America and Canada (2)	General (3) Neurological (1) Cardiovascular (1)	(Freeman & Koerner, 2018; Klein et al., 2018; Okubo, 2012; Sosnowski, Lin, Mitchell, & White, 2015; Sutton & Jarden, 2017)
Adverse events	4	Number of airway/ventilations, medication, procedures/lines and equipment, environment events (4)	Systematic review (1) Cohort study (2) Case report (1)	Australia and New Zealand (1) Central and south America (1) United States of America and Canada (2)	General (3) Medical/surgical (1)	(George, Henneman, & Tasota, 2010; Morrison, Beckmann, Durie, Carless, & Gillies, 2001; Toffoletto et al., 2016; West et al., 2009)

Oral health status	4	Oral mucosa assessment scale (1) Beck Oral Health Assessment scale (1) Oral Assessment Guide (1) Throat instrument (1)	Randomized controlled trial (2) Quasi-experimental study (1) Before-and-after study (1)	Asia (2) United States of America and Canada (2)	General (3) Medical/surgical (1)	(Chipps et al., 2016; Hsu, Liao, Li, & Chiou, 2011; Jang & Shin, 2016; Ross & Crumpler, 2007)
Nutritional status	4	Time to start of enteral feeding (2) Time to start of enteral feeding and caloric target (1) Not reported (1)	Systematic review (1) Before-and-after study (3)	Australia and New Zealand (1) Europe (2) Middle East (1)	General (3) Medical (1)	(Friesecke, Schwabe, Stecher, & Abel, 2014; Orinovsky & Raizman, 2018; Dewi Stalpers et al., 2015; Sutton & Jarden, 2017)
ICU readmissions	3	Number of events (3)	Systematic review (1) Before-and-after study (1) Cohort study (1)	Europe (1) United States of America and Canada (2)	General (2) Medical/surgical (1)	(Falk & Wallin, 2016; Fraser et al., 2015; West et al., 2009)
Incontinence-associated dermatitis	3	Incontinence-associated Dermatitis and Its Severity instrument (1) Clinical assessment (1) Number of events (1)	Narrative review (1) Cohort study (1) Descriptive/correlational (1)	Asia (2) United States of America and Canada (1)	General (3)	(Bliss et al., 2011; Wang, Zhang, Zhang, Zhao, & Xian, 2018; S. Yang et al., 2019)
Family participation	2	Observations, interviews, informal conversations, field notes and document review (1) Not reported (1)	Cohort study (1) Qualitative study (1)	Australia and New Zealand (1) Europe (1)	General (2)	(Castellan et al., 2016; Minton et al., 2018)
Deep vein thrombosis	2	Reports of related diagnostic tests (e.g., duplex sonography of lower extremities, computerized tomography of the chest and ventilation-perfusion scan) (1) Not reported (1)	Systematic review (1) Quasi-experimental study (1)	Australia and New Zealand (1) United States of America and Canada (1)	General (1) Medical/surgical (1)	(Driscoll et al., 2018; Winkelman et al., 2012)
Eye health status	2	Schirmer test (1) Not reported (1)	Literature review (1) Case-Control study (1)	Australia and New Zealand (1) Europe (1)	General (2)	(Laight, 1996; A. P. Marshall, Elliott, Rolls, Schacht, & Boyle, 2008)
Hygiene status	2	Not reported (2)	Mixed method study (1) Cohort study (1)	Australia and New Zealand (1) Europe (1)	General (1)	(Castellan et al., 2016; Coyer, O'Sullivan, & Cadman, 2011)
Bowel status	2	Time to first bowel open, incidence of constipation and/or diarrhea (1) Diarrhea days (1)	Before-and-after study (2)	Australia and New Zealand (2)	General (2)	(Ferrie & East, 2007; Knowles et al., 2014)
Quality of life	1	Not reported (1)	Systematic review (1)	Australia and New Zealand (1)	General (1)	(Sosnowski et al., 2015)
Secretion clearance	1	Number of airway suction episodes (1)	Cross-Sectional study (1)	Australia and New Zealand (1)	General (1)	(Ntoumenopoulos et al., 2018)

Pt-ventilator desynchrony	1	Ventilator graphics (1)	Literature review (1)	United States of America and Canada (1)	General (1)	(Mellott, Grap, Munro, Sessler, & Wetzel, 2009)
Post-extubation dysphagia	1	Water swallowing test and a food test (1)	Cohort study (1)	Asia (1)	Medical/surgical (1)	(Omura, Komine, Yanagigawa, Chiba, & Osada, 2019)

Table 2.3 Overview of identified nursing sensitive outcomes in ICU

Outcome domain (n.) (Doran, 2011)	Outcome sub-domain (n.)	Reported outcomes from publications (n.)
Safety (77)	Critical incidents (39)	Pressure ulcers (20)
		Falls (6)
		Unplanned extubations (6)
		Adverse events (4)
		Incontinence-associated dermatitis (3)
	Healthcare-associated infections (38)	Ventilator Associated Pneumonia (19)
		Central Line-Associated Bloodstream Infections (12)
		Catheter Associated Urinary Tract Infections (7)
Clinical (72)	General health (39)	Mortality (11)
		ICU length of stay (9)
		Length of mechanical ventilation (8)
		Hospital length of stay (7)
		ICU readmissions (3)
		Quality of life (1)
	Goal assessment and monitoring (33)	Physiological parameters (14)
		Pain (9)
		Glycemic levels (5)
		Deep vein thrombosis (2)
		Patient-ventilator desynchrony (1)
		Post-extubation dysphagia (1)
		Secretion clearance (1)
Functional (70)	Psychosocial dimension (40)	Delirium (13)
		Anxiety (11)
		Psychological status (11)
		Cognitive status (5)
	Physical dimension (30)	Sleep quality (11)
		Functional status (5)
		Nutritional status (4)
		Oral health status (4)
		Bowel status (2)
		Eye health status (2)
		Hygiene status (2)
Perceptual (14)	Experience of being in intensive care (14)	Patient's satisfaction (7)
		Comfort (5)
		Family participation (2)

Table 2.4 Classification of nursing sensitive outcomes according to the functions of nurses (Doran, 2011)

Care function / Classification / nursing sensitive outcomes	Pressure Ulcers	Ventilator Associated Pneumonia	Physiological parameters	Delirium	Central Line-Associated Bloodstream Infections	Anxiety	Psychological status	Sleep quality	Mortality	Pain	ICU length of stay	Length of mechanical ventilation	Hospital length of stay	Catheter Associated Urinary Tract Infections	Patients' satisfaction	Unplanned Extubations	Falls	Comfort	Cognitive status	Glycemic levels	Functional status	Adverse events	Oral health status	Nutritional status	ICU readmissions	Incontinence-associated dermatitis	Family participation	Deep vein thrombosis	Eye health status	Hygiene status	Bowel status	Quality of life	Secretion clearance	Patient-ventilator desynchrony	Post-extubation dysphagia
Independent	*					*	*											*					*			*			*	*					
Interdependent		*	*	*	*			*	*	*				*	*	*	*	*			*	*					*	*				*	*	*	*
Dependent											*	*	*						*					*	*						*				

3. Nursing care factors influencing NSO

Most of the content of this section has been published.

> Danielis, M., Destrebecq, A.L.L., Terzoni, S., & Palese, A. (2021). Nursing care factors influencing patients' outcomes in the intensive care unit: Findings from a rapid review. International Journal of Nursing Practice, e12962.

3.1 Introduction

The literature regarding the relationship between nursing care and patient outcomes has increased in recent years (Myers et al., 2018) with the intent to promote high quality of care and to demonstrate the value of nursing care (Di Giulio, Clari, Conti, & Campagna, 2019; Salmond & Echevarria, 2017). Theoretically, the quality of care has been conceptualised by Donabedian (Donabedian, 1988) as composed of three distinct dimensions or levels, namely: a) structure, consisting of the setting where the care is provided and covering organisational variables; b) process, including all interventions as performed by healthcare professionals; and c) outcome(s), as the change(s) measured in the patients' health status.

In the specific field of nursing care, 'structure' has been reported as including, for example, the nurse-to-patient ratio (Blot et al., 2011), while 'process' has been described as including interventions performed independently or under physicians' prescription (e.g., weaning from mechanical ventilation) (Al Ashry et al., 2016). With regard to outcomes, in line with Doran's definition (Doran, 2011), a nursing-sensitive outcome (NSO) has been defined as any change in a patient's health state, behaviour or perception, associated with or sensitive to the nursing care received (e.g., reduced pressure injury with preventive nursing care) (Karadag et al., 2017). Recently, a total of 35 NSOs have been identified as appropriate in Intensive Care Unit (ICU) contexts (Danielis et al., 2019). According to their features, these outcomes have been categorised as (a) clinical (general health, and goal assessment and monitoring), (b) functional (psychosocial and physical dimensions), (c) safety (critical incidents and healthcare-associated infections) and (d) perceptive (experience of being in ICU). However, NSOs have been documented to vary across patients and settings (Danielis et al., 2019; Myers et al., 2018), and also according to nursing care factors.

Several nursing care factors expressing the structural and the process dimensions have been documented as having an influence on NSOs (Myers et al., 2018). Among the first, higher

patient mortality, infections, postoperative complications and missed nursing activities have been associated with lower levels of nurse staffing (Cho, Lee, You, Song, & Hong, 2019; Lee et al., 2017; Penoyer, 2010). Several studies have also documented the role of the work environments and that of staff workloads in affecting patients' safety (Kelly et al., 2013; Ulrich, Barden, Cassidy, & Varn-Davis, 2019). Additional research has shown that some structural dimensions of nursing care are associated with outcomes among critically ill patients in open or closed ICUs, and the availability of clinical nurse specialists (Checkley et al., 2014). Nurses with advanced competence in ICU have been documented to enhance patient satisfaction, to decrease mortality rates and the length of stay (LOS), thus saving on the costs associated with care (Woo, Lee, & Tam, 2017).

With regard to the process dimensions, available studies have documented that rounding practices (e.g., daily meetings between physician and charge nurse) and the use of protocols (e.g., regarding mobility, delirium management) have been associated with lower ICU mortality (Checkley et al., 2014). Moreover, an early and timely start of enteral feeding (Orinovsky & Raizman, 2018) and intensive glycaemic control (Khalaila et al., 2011), both considered as nursing care interventions, have also been documented to improve NSOs.

Despite the rich debate, no reviews mapping those nursing care factors investigated for their influence on NSOs have been published in the ICU field. Therefore, no summaries about the state of the science in intervention studies have been produced, nor are there any critical reflections on the most studied or understudied nursing care factors. Among the various reasons for this lack of evidence, one may be due to the predominance of multidisciplinary processes in the ICU settings that lead to diverse implications of professional and research approaches. Given that multidisciplinary interventions prevail, firstly, nursing care is sometimes overshadowed in its capacity to affect NSOs (Needleman, 2017). Secondly, intervention studies in the field have a high degree of complexity, given that the contribution of nursing care is not easily discernible from other factors affecting patient outcomes (Myers et al., 2018). The main intent of this review is to overcome these challenges by providing a summary of the state of the art in the field of the nursing care factors affecting NSOs in ICU.

The main aim of the study was to summarise the structural and process nursing care factors that have been studied to date and their influence on the outcomes of critically ill patients.

3.2 The review

Study design

A rapid review, as a form of knowledge synthesis, is capable of providing timely information (O'Leary et al., 2017) and was performed in March 2020. As this approach uses a streamlined systematic review methodology, the present study design was conducted as a pragmatic approach to provide information to ICU clinical nurses, managers and decision-makers (O'Leary et al., 2017). According to the methodological process inspired by Tricco and colleagues (Tricco, Langlois, & Straus, 2017) and then further developed by Langlois et al (2019), the following seven-stage process was performed: 1) needs assessment and topic selection, 2) study development, 3) literature search, 4) screening and study selection, 5) data extraction, 6) risk-of-bias assessment and 7) knowledge synthesis. In line with the study design and aims, no quality appraisal of the studies was performed, and a selective process of data extraction was applied.

Needs assessment and topic selection

The primary need was to map the nursing care factors associated with NSOs, with the intent of summarising those factors investigated to date and highlighting those in need of further research investments. Thus, the review question was:

What nursing care factors at the structure and the process levels, capable of influencing outcomes of critically ill adult patients cared for in ICU, have been studied to date?

Study development

Following the Preferred Reporting Items for Systematic reviews and Meta-Analysis (PRISMA) guidelines (Moher, Liberati, Tetzlaff, Altman, & Group, 2009), the search was performed according to Population, Intervention, and Outcome (PIO) statements (Eriksen & Frandsen, 2018) as follows: (P) population: critically ill adult patients admitted and cared for in ICU; (I) intervention(s): any nursing care factors at the structure and process levels of care delivered to a patient (Donabedian, 1988); and (O) outcome(s): any outcome influenced by nursing care factors in ICU.

Literature search

The MEDLINE (via PubMed), the CINAHL, and the Scopus databases, as well as the grey literature, were searched up to March 2020. The authors set this time with the intention of including those nursing factors documented before the COVID-19 pandemic caused by SARS-CoV-2 (Cucinotta & Vanelli, 2020). Consequently, the search strategy combined terms from three main themes: (1) "Intensive Care Units"[Mesh] OR "Critical Illness"[Mesh] OR "Critical Care"[Mesh] OR "Critical Care Nursing"[Mesh] OR "Critically ill patient"; (2) "Nursing"[Mesh] OR "Nursing Care"[Mesh] OR "Contribution of nursing care" OR "Nursing interventions"; and (3) "Patient Outcome Assessment"[Mesh] OR "Outcome Assessment (Health Care)"[Mesh] OR "Treatment Outcome"[Mesh] OR "Critical Care Outcomes"[Mesh] OR "Outcome Measures". All these terms and free-text words were combined into search strings with the Boolean Operator 'AND'.

Screening and study selection

Studies were included when they (a) assessed NSO(s) as associated with nursing factors at the structural and process levels, (b) were performed in adult (≥18 years old) ICU patients, (c) as primary (e.g., randomised control trials) and secondary study designs (e.g., systematic reviews) and (d) published in English. Therefore, those studies concerning (a) the paediatric population (<18 years), (b) terminally-ill patients, or (c) settings other than ICU (e.g., recovery rooms), (d) not focused on the specific contribution of nursing care, and (e) published in languages other than English, were all excluded.

In the first level of screening, the titles and abstracts of retrieved studies were evaluated for their eligibility against the inclusion criteria by two researchers independently. A third reviewer was included to resolve disagreements, if any. Then, an independent full-text review was performed to determine if the studies meet the inclusion criteria. Also in this step, in case of doubt, a third researcher was involved. At the end of the process, 93 studies were retrieved, as reported in the PRISMA flow diagram (Moher et al., 2009) (Fig. 3.1).

Data extraction

The following data were extracted from each included study and reported in a Microsoft Excel® spreadsheet: (a) author(s), journal, publication year and country; (b) study design, type of ICU (e.g., general, specialised), the study aims and participant profiles; (c) nursing

care factors(s) as evaluated in their association with NSOs: each nursing care factor was briefly described together with the outcomes linked to it, and (d) key findings. Secondary research designs (e.g., systematic reviews) were also included and discussed as a single study. This process was completed by the first author with the supervision of the last author. According to the nature of the rapid review, selected studies were considered to scope the available literature rather than to evaluate the effects of specific nursing care factors. No quality appraisal of the studies was performed.

Risk of bias assessment

The following strategies were applied to prevent bias: (a) the review team shared each step of the study inclusion and exclusion process; (b) MEDLINE (via PubMed), CINAHL, and Scopus were accessed as major scientific databases; (c) the data extraction was performed at by at least two reviewers; and (d) the summary table, as well as the narrative synthesis, were both reviewed by a third independent researcher.

Knowledge synthesis

With regards to the rapid review question, a narrative synthesis of the available studies was performed. Nursing care factors were first categorised according to their common organisational or clinical significance (e.g., hours of nursing care per day, music therapy, care bundle compliance) by two researchers, one an expert in ICU care. Then, these factors were classified according to the Donabedian model dimensions , namely, structure and process. Therefore, by combining the first and the second categorisation, the following classification emerged:

Structure dimension: factors at 1) organisational level, which included organisational and workplace culture and 2) nursing staff level, embracing all metrics for measuring nursing staff characteristics.

Process dimension: factors of 3) nurse-led programmes, understood as all interventions carried out by nurses, but shared and scheduled with a physician, 4) nurses' independent interventions, which refer to interventions planned and performed according to the nursing role and 5) nurse behaviours, understood as the health-promoting behaviours of nursing staff.

The categorisation of the studies is reported in Table 3.1.

3.3 Results

Literature synthesis

As reported in Table 3.2, most studies (n = 74, 79.6%) were published in nursing journals. The earliest study was published in 1999 and more than two-thirds of the articles (n = 72; 77.4%) were published after 2010. Studies were mainly authored in the US and Canada (n = 36; 38.7%) and included mainly general (n = 68, 73.1%) ICU settings. With regards to study methods, 51 (54.8%) were observational in design, including cross-sectional, case-control, prospective, and retrospective cohort designs.

Nursing factors investigated to date

As reported in Table 3.3, a total of 21 nursing care factors measured against the 35 NSOs (Danielis et al., 2019) have been studied to date. Among them, early mobility programmes (n = 16, 45.7%) have been largely studied as being able to affect NSOs, followed by the use of algorithms, checklists and specific assessment tools (n = 14, 40.0%), nurse staffing (n = 12, 34.2%) and compliance with care bundles (n = 11, 31.4%). However, nurse orientation programmes and night-time care routine interactions were studied only once, each regarding their influence on NSOs. According to Donabedian's model (Donabedian, 1988), the most frequently studied nursing care factors focus on the process dimension (n = 78, 65.0%), followed by the structure dimension (n = 42, 35.0%).

Structure dimension

As reported in Table 3.3, in terms of the structure dimension, nursing factors influencing NSOs have been investigated both at an organisational level and at the personnel level.

Factors at the organisational level were widely studied with regard to their influence on 21 NSOs. Specifically, the work environment has been documented in terms of its influence on ten NSOs (e.g., healthcare-associated infections and falls); magnet hospital proprieties have been studied against five outcomes (e.g., catheter-associated urinary tract infections, mortality), followed by nurse-physician communication measured regarding three NSOs (e.g., pressure ulcers and central line-associated bloodstream infections), while material availability has been studied for its ability to influence the occurrence of pressure ulcers, delirium and the sleep quality.

Factors at the personnel level have been investigated with regard to 21 NSOs; specifically, nurse staffing has been studied regarding 12 (e.g., the length of mechanical ventilation and ICU readmissions), followed by the nurse specialist role explored in terms of its effect regarding six (e.g., delirium and falls occurrences) and nurse experience regarding three NSOs (e.g., unplanned extubations and adverse events).

Process dimension

As reported in Table 3.3, studies that evaluated the nursing care factors at the process dimension included nurse-led programmes, nurses' independent interventions and nurse behaviours.

Nurse-led programmes were described regarding their effect on 37 NSOs. These included, particularly, early mobility programmes, studied in relation to 16 NSOs (e.g., hospital length of stay, patient-ventilator desynchrony); followed by checklists, algorithms and specific assessment tools in relation to 14 NSOs (e.g., nutritional and bowel status). Then, in order of frequency, programmes facilitating family participation in patient care were studied for their influence on four NSOs (e.g., comfort), educational programmes for two NSOs (ventilator-associated pneumonia and oral health status) and a reality orientation programme for cognitive status.

Independent nursing interventions have been investigated in relation to 29 NSOs. The most-reported factor was music therapy, influencing seven NSOs (e.g., comfort and pain), followed by massage interventions focused on six NSOs (e.g., sleep quality and physiological parameters), relaxation and guided imagery for five NSOs (e.g., anxiety and pain), body positioning in relation to four NSOs (e.g., ventilator-associated pneumonia and physiological parameters), therapeutic touch for three NSOs (e.g., psychological status), aromatherapy and cold application for two outcomes (e.g., sleep quality and pain, respectively).

Lastly, nurse behaviours have been studied in relation to 12 NSOs. The most-reported factor was care bundle compliance, which has been measured regarding its influence on 11 NSOs (e.g., patient satisfaction, secretion clearance), followed by night-time care routine interactions for their capacity to affect sleep quality.

3.4 Discussion

A total of 93 studies emerged, mainly in nursing journals in a span of 20 years, with on average just over four articles per year. Most articles were published in the last nine years, suggesting that intervention studies are attracting increased interest in the last years. In this regard, no comparison can be performed with other fields of nursing care because, to the best of our knowledge, no similar rapid review has been performed to date. Twenty one nursing care factors have been investigated to date, and according to the categorisation applied (Donabedian, 1988), most were at the process level and fewer at the structural level.

Structure dimension

At the structure level, the nursing work environment and staffing characteristics were studied mainly in relation to similar outcomes such as the occurrence of ventilator-associated pneumonia, pressure ulcers, central line-associated bloodstream infections and mortality. Communication between nurses and physicians have been examined in relation to ventilator-associated pneumonia, pressure ulcers, and central line-associated bloodstream infections. These factors have been largely studied also in other contexts as mediating NSOs, thus not directly influencing outcomes, although they have been documented as improving job satisfaction (Ulrich et al., 2019) and enabling nurses to improve their performance, the quality of their clinical surveillance and their compliance with aseptic techniques (Stone et al., 2007).

Within the structure dimension, regarding personnel level categorisation, three factors have been investigated in relation to different NSOs. The numbers of nursing staff have been reported as hours of nursing care per patient day (Heslop & Lu, 2014), as staff skill mix (Sales et al., 2011), and as the nurse to patient ratio (Yeh et al., 2004). Nurse staffing has been considered regarding its influence on outcomes such as length of mechanical ventilation, hospital LOS, the occurrence of catheter-associated urinary tract infections, and others. Less emphasis has been devoted to date to the nurse specialist roles and experience. A recent meta-analysis that included 35 studies published between 2006 and 2017 involving 175,755 patients showed that a higher nurse staffing level decreased the risk of in-hospital mortality by 14% in specialist ICUs (Driscoll et al., 2018), suggesting the availability of a strong body of knowledge. In contrast, the types of specialty certifications, different degrees of advanced nursing practice, job descriptions, and nurses' work experience of ICU, seem to require

further research with the intent of clarifying their contributions to patient outcomes and to inform policy-development concerning the requirements in terms of the professional profile of ICU nurses.

Process dimension

In the process dimension (Donabedian, 1988), three different factors emerged. The most investigated were programmes led by nurses (e.g., educational programmes), followed by independent nursing interventions (e.g., music therapy), and those regarding nurse behaviours (e.g., care bundle compliance). Considering the programmes led by nurses, most studies reported the implementation of early mobility programmes and the use of checklists, algorithms and specific assessment tools to improve outcomes such as ventilator-associated pneumonia and mortality rates. Nowadays, accumulating evidence is suggesting that nurse-led approaches are more suitable, effective and cost-saving for disease management (Klein et al., 2018; Orinovsky & Raizman, 2018). This is the case where, for example, nurse-led weaning programmes led to a reduction in the length of mechanical ventilation (Kram et al., 2015). With regard to independent nursing interventions, the use of music therapy has been largely documented (Aktas & Karabulut, 2016), followed by massage, relaxation and guided imagery, body positioning, therapeutic touch, aromatherapy and cold application. Accordingly, these interventions were assessed in relation to different NSOs; however, the number of studies available was limited, possibly due to the prevailing multidisciplinary nature of the work care processes in the ICU (Marshall et al., 2017). Nurse behaviours, such as care bundle compliance, have been studied in relation to various outcomes including the incidence of ventilator-associated pneumonia, preventing infections associated with care practices and patient mortality.

On the other hand, night-time care routine interactions have been less investigated. This lack of studies can be interpreted along two lines of reasoning: (1) measuring behaviours in clinical practice is challenging, as it requires a long engagement in the research process (Lambert & Housden, 2017) and (2) measuring the outcomes of violations in care delivery when strong recommendations are available, is less important than understanding why and in which organisational condition nurses fail to maintain their compliance to bundles of care or good practice. In other words, while it is important to continue to study the relevance of this factor in relation to its implications for NSOs, the focus should be on the variables

underlying poor compliance or on those which are able to maximise the quality of care delivered.

Implications of the findings

A total of 21 nursing factors have been assessed in relation to 35 ICU NSOs to date. First, the set of nursing factors that emerged could be considered as the basis for further research, especially regarding those poorly investigated. Periodically assessing what interventions, in relation to which outcomes have been studied could direct future research to fill in gaps as well as to explore similar interventions and outcomes, thus accumulating further evidence. Secondly, at the clinical level, having a map of the interventions assessed, as well as which outcomes were studied, could stimulate nurses' participation in scientific development of nursing knowledge, for instance, of interventions performed on a daily basis and not to date considered by researchers (Smith, Dale, Mehta, Pinto, & Rose, 2016). Thirdly, the set of nursing care factors can be used as a blueprint to design and develop educational programmes both at the undergraduate and postgraduate levels. Moreover, as both structure and processes dimensions of nursing care are capable of affecting NSOs, this information might be useful to inform managerial decision-making.

Strengths and limitations

This rapid review contributes new knowledge in summarising the state of the science on nursing care factors influencing patient outcomes in ICU. An established rapid review method (Tricco et al., 2017) was performed; however, although its findings can inform researchers and clinicians on emergent issues (Langlois, Straus, Antony, King, & Tricco, 2019), these should be considered within the limitations of this review design, which does not specifically assess the study characteristics, specific ICU settings, patients or the effectiveness of the interventions. In accordance with O'Leary et al. (2017), the methodological quality of the studies included was not assessed. Secondly, although a systematic approach was followed according to the study design, some selection and information bias may have occurred, and some studies missed. Lastly, some reviews have been included with the intent of covering a broad spectrum of literature and intercepting all nursing care factors investigated to date. Some reviews might have analysed primary studies

already included in this rapid review, thus introducing a potential bias regarding the duplicates.

3.5 Conclusions

This rapid review highlighted that, to date, a broad set of interventions has been assessed against the NSOs, with a greater number at the process levels and fewer at the structural dimension levels. Findings suggest that researchers are attracted mainly to modifiable variables with the intent to establish effective nursing care processes; however, structural variables are also capable of influencing patient outcomes. Overall, the set of nursing factors that emerged can be used as a map for researchers, educators, managers and clinicians in their various roles. Future studies should try to combine factors at the structural and process levels in their capacity to influence NSOs, given that, according to the findings, they have been investigated separately.

According to the findings, mobility programmes, the use of algorithms, checklists, and specific assessment tools, appropriate nurse staffing and compliance with care bundles have been largely studied as they are able to affect the NSOs of critically ill patients. However, interventional studies aimed at evaluating the effectiveness of specific nursing care factors (e.g., body positioning, family involvement and educational programs) are needed; similarly, nurse specialist roles and nurse experience in ICU should be fully documented with details on their capacity to affect patients' outcomes. Moreover, periodically repeating an assessment of the nursing care factors investigated in relation to NSOs might support the analysis of emerging trends.

Figure 3.1 Review Flow Diagram (Moher et al., 2009)
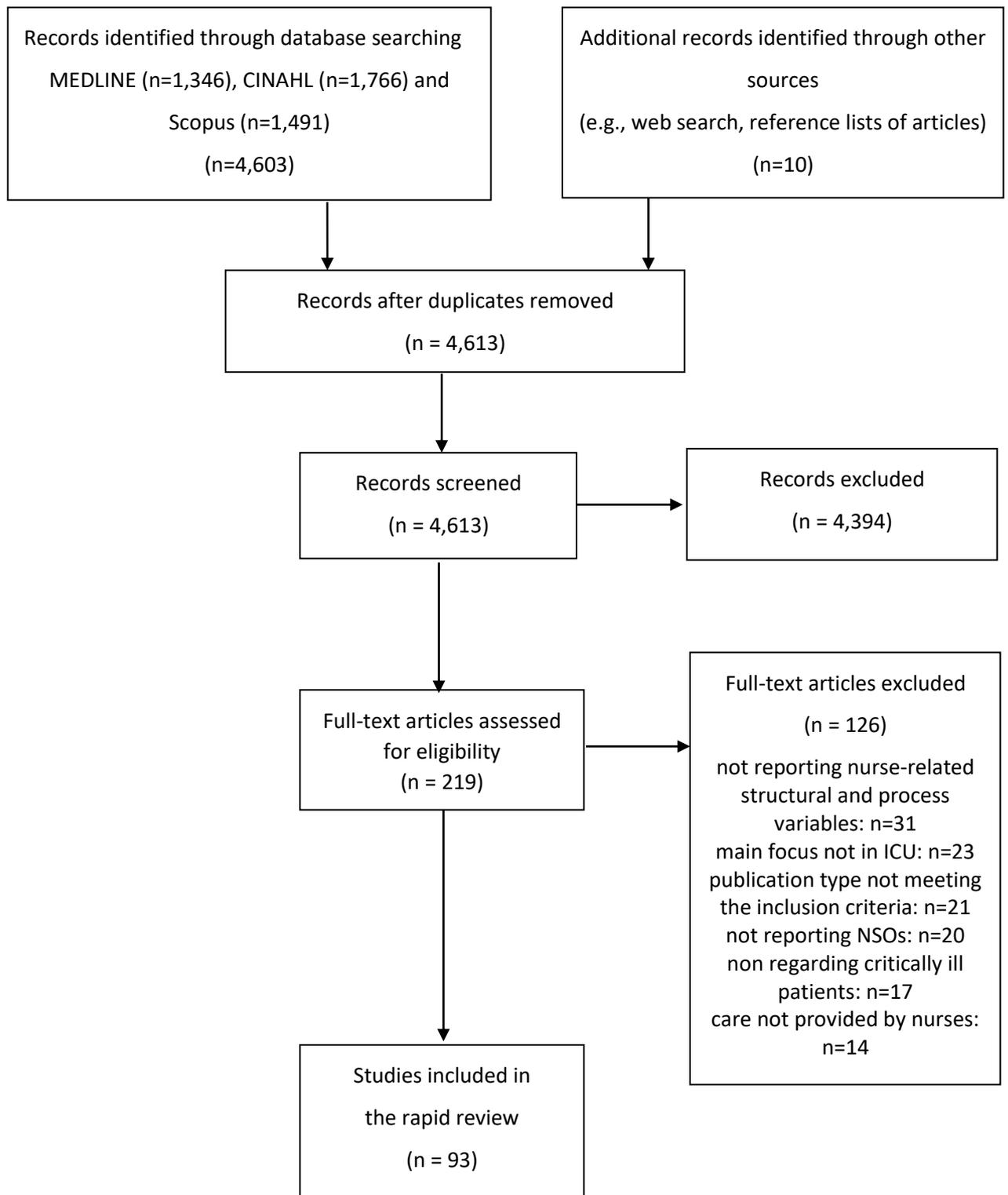
CINAHL, Cumulative Index to Nursing and Allied Health Literature; ICU, Intensive Care Unit; NSOs, Nursing Sensitive Outcomes.

Table 3.1 Study categorisation

Donabedian model component (Donabedian, 1988)	Categorisation	Nursing care factor with its definition[a]	Study example
Structure	Organisational level	*Work environment*, as the organisational characteristics of the workplace that facilitate or confine nursing care practice	Patients in critical care units with better nurse work environments experienced 11% lower odds of 30-day mortality than those in worse nurse work environments (Kelly et al., 2014).
		Magnet-hospital properties, as nurse participation in hospital management, nursing foundations for quality of care, nurse manager abilities, staffing and resource adequacy, shared decision making between RN and MD	The associations found between hospital profitability and patient outcomes were mixed. In the CAUTI, VAP and decubiti models there were significant positive relationships; hospitals with the lowest profit margin had less adverse outcomes than profitable ones (p<0.05). The effects of magnet accreditation were not consistent (Stone et al., 2007).
		Communication RN vs. MD, as a mix of four core elements: openness, timeliness, accuracy and understanding	Timeliness of communication was inversely related to pressure ulcers (r=-0.38; p=0.06), and workplace empowerment and scores on the Acute Physiology and Chronic Health Evaluation III were positive predictors of ventilator-associated pneumonia (R2=0.36; p=0.005) (Manojlovich et al., 2009).
		Material availability, resources such as earplugs, eye masks, pressure redistributing mattresses	Seven studies assessed the effect of using the earplug or eye mask intervention on sleep in the ICU. The results for the intervention groups showed a beneficial impact (p<0.05) for increased REM sleep and decreased REM latency in two of the six studies (Alway et al., 2014).
	Personnel level	*Nurse staffing*, as hours of nursing care per patient day, staff mix, skill mix and nurse-to-patient ratio	In this study that included 27,372 ICU patients discharged from 42 tertiary and 194 secondary hospitals, every additional patient per RN was associated with a 9% increase in the odds of dying (OR=1.09, 95% CI=1.04-1.14) (Cho et al., 2008).

Process				

		Nurse specialist, a nurse with a formal recognition of specialised knowledge, skills and clinical practice experience	The presence of a certified nurse specialist in critical care was associated with lower ICU mortality (OR=0.52, 95% CI=0.36-0.73, p<0.001) and fewer patients receiving mechanical ventilation in the ICU (OR=0.20, 95% CI=0.15-0.26, p<0.001) (Fukuda et al., 2020).
		Nurse experience, as working experience in years	Unplanned extubations occurred more frequently in the care of nurses with less experience, while experienced nurses (>4 working years) encountered unplanned extubations less frequently (Yeh et al., 2004).
Process	Nurse-led programmes	*Early mobility programs*, as early mobility interventions from a dedicated mobility team	The 66 patients who received the mobility intervention had significantly fewer falls, ventilator-associated events, pressure ulcers and CAUTIs than the 66 patients in the routine care group. The mobility group also reported lower hospital costs, fewer delirium days, lower sedation levels and improved functional independence (Fraser et al., 2015).
		Checklists, algorithms and specific assessment tool, as a pre-defined instrument to achieve standardisation of processes	Following a feeding protocol, enteral nutrition started significantly earlier (28±20 h versus 47±34 h, p<0.001), within 24 h in 64% versus 25% (p<0.0001); and for each of the first 5 days, the proportion of patients meeting their nutritional goal was significantly higher (Friesecke et al., 2014).
		Family participation in patient care, as promotion of family access to patient by effective planning of routine care	Patients receiving nurse-facilitated family participation demonstrated better psychological recovery and wellbeing than the control group at 4, 8 and 12 weeks after admission to a critical care setting (Black et al., 2011).
		Educational programs, as consistent approach to quality patient care thereby resulting in less variability by sharing research-based information	The intervention group who received the clinical nursing practice guideline had significantly shorter starting time of EN and a reduced duration of mechanical ventilator than those in the control group (p<0.001) (Koontalay et al., 2020).
		Reality orientation nursing program, as cognition-orientated technique for patients with memory loss and spatial and temporal disorientation	Results from this quasi-experimental study indicated that patients who received the reality orientation program had a higher mean of the Glasgow Outcome Scale Extended than those receiving the usual care, despite that the groups differed significantly (p=0.01) in post-

traumatic amnesia duration (Langhorn et al., 2015).

Nurse's independent interventions	*Music therapy*, as complimentary treatment in a therapeutic context	In the music group, there were statistically significant reductions (p=0.001) in heart rate, respiratory rate and oxygen saturation than the control participants at 45 minutes (Chan et al., 2006).
	Massage, as non-pharmacological hand activity with different techniques	In eight of 12 randomised control studies there was a high level of evidence of favourable effects with respect to improvements in vital signs and a reduction in pain and anxiety (Jagan et al., 2019).
	Relaxation and guided imagery, as a cognitive-behavioural technique in which the patient employs a mental process that uses images to alter a physical/emotional state	Among the 60 randomised critically ill adults in the sample, the intervention group experienced significant decreases in the incidence (p=0.003) and ratings of pain (p<0.001), systolic arterial pressure (p<0.001), anxiety (p=0.01) and improved quality of sleep (p=0.02) (Papathanassoglou et al., 2018).
	Body positioning, as current positioning practices and degree of bed elevation	Intracranial pressure decreased with supine head of bed 45° (p<0.01) and knee elevation, head of bed 30° and 45° (p<0.05) and increased (p<0.05) with right and left lateral head of bed 15°. Hemodynamic parameters were similar in the various positions (Ledwith et al., 2010).
	Therapeutic touch, as non-pharmacological intervention indicates the use of hands on the patient's body	Repeated measures analysis of variance indicated no significant increases or decreases in any of the physiologic variables measured between pre-, during and post-time segments for therapeutic touch. The most frequently occurring words and phrases to describe the subjects' feelings were warmth, relaxation, tingling, calmness, sleepiness and the sensation of falling asleep (Cox et al., 1999).
	Aromatherapy, as essential oils from plants administered via inhalation, massages and orally	Comparison of the Pittsburgh Sleep Quality Index and the Beck Anxiety Inventory scores at the patient's levels in the control and intervention groups before and after the intervention, showed statistically significant differences in the change in favour of the intervention group (p<0.05) (Karadag et al., 2015).
	Cold application, as ice therapy on an injured area	Patients in the cold group had significantly lower pain intensity than the placebo group. The application of cold prolonged the length of

		time until analgesics were needed after the chest tube removal (Demir et al., 2010).
Nurse's behaviours	*Care bundle compliance*, as the multidisciplinary approach to patient care based upon a set of evidence-based activities	Implementation of the bundle decreased average patient hospital length of stay by 1.8 days, reduced the length of mechanical ventilation by an average of 1 day, and established a baseline delirium prevalence of 19% over a three-month time period (Kram et al., 2015).
	Night-time care routine interactions, as the major environmental factor affecting the sleep of critically ill patients	Out of eight night-time care routine interactions, only one (post-operative exercises) was significantly associated to sleep variables ($r>0.40$, $p<0.05$) (Casida et al., 2018).

[a] These definitions were developed by a combination of a priori knowledge of the research subject and a content analysis of the included studies.

Abbreviations: RN, registered nurse; MD, medical doctor; ICU, intensive care unit; CAUTI, catheter-associated urinary tract infections VAP, ventilator-associated pneumonia; EN, enteral nutrition; REM, rapid eye movement; OR, odds ratio; CI, confidence interval.

Table 3.2 Summary of study characteristics

Study characteristic	Number of studies (n = 93) n. (%)
Journal source	
Nursing	74 (79.6)
Medical	19 (20.4)
Year of publication	
From 1999 to 2009	21 (22.6)
From 2010 to 2020	72 (77.4)
Continent	
US and Canada	36 (38.7)
Asia	19 (20.4)
Europe	17 (18.2)
Australia and New Zealand	10 (10.8)
Middle East	9 (9.7)
Central and South America	2 (2.2)
Setting (ICU type)	
General	68 (73.1)
Medical	8 (8.6)
Cardiovascular	7 (7.5)
Medical and surgical	6 (6.5)
Neurological	4 (4.3)
Study design	
Observational	51 (54.8)
Experimental and quasi-experimental	30 (32.3)
Literature review	11 (11.8)
Mixed-method	1 (1.1)

ICU, Intensive Care Unit; US, United States.

Table 3.3 Structure and process nursing care factors studied to date regarding their influence on NSOs (n=93 studies)

Classification/NSO (n.)		Factor	VAP (11)	Sleep quality (9)	Mortality (8)	Physiological parameters (7)	Pressure Ulcers (7)	Delirium (6)	CLABSIs (6)	Anxiety (6)	Psychological status (6)	Pain (5)	Length of mechanical ventilation (5)	Cognitive status (4)	Nutritional status (4)	Hospital LOS (4)	CAUTIs (4)	ICU LOS (3)	Patients' satisfaction (3)	ICU readmissions (3)	Falls (3)	Unplanned Extubations (2)	Comfort (2)	Glycaemic levels (2)	Functional status (2)	Oral health status (2)	Eye health status (2)	Deep vein thrombosis (2)	Bowel status (2)	Adverse events (1)	Incontinence-associated dermatitis (1)	Family participation (1)	Hygiene status (1)	Quality of life (1)	Secretion clearance (1)	Patient-ventilator dysynchrony (1)	Post-extubation dysphagia (1)
Structure (42)	Organisation level (21)	Work environment (10)	*		*		*	*	*			*			*		*		*		*																	
		Magnet hospital properties (5)	*		*		*		*								*																				
		Communication RN vs. MD (3)	*				*		*																													
		Material availability (3)		*			*	*																														
	Personnel level (21)	Nurse staffing (12)	*	*	*		*					*			*	*		*	*	*	*							*									
		Nurse specialist (6)	*				*	*	*									*				*															

Process (78)

Nurse-led programmes (37)

Nurse experience (3)	* ... * ... *
Early mobility programmes (16)	* * * * * * * * * * * * * * * *
Checklists, algorithms and specific assessment tools (14)	* * * * * * * * * * * * * *
Family participation in patient care (4)	* * * *
Educational programmes (2)	* *
Reality orientation nursing programmes (1)	*

Nurse's independent interventions (29)

Music therapy (7)	* * * * * * *
Massage (6)	* * * * * *
Relaxation and guided imagery (5)	* * * * *
Body positioning (4)	* * * *
Therapeutic touch (3)	* * *

Category	Sub-category														
	Aromatherapy (2)		*			*									
	Cold application (2)					*	*								
Nurse's behaviours (12)	Care bundle compliance (11)	*		*	*			*	*	*	*	*	*	*	*
	Night-time care routine interactions (1)		*												

NSOs, nursing sensitive outcomes; ICU, intensive care unit; LOS, length of stay; VAP, ventilator associated pneumonia; CLABSIs, central line-associated bloodstream infections; CAUTIs, catheter associated urinary tract infections; RN, registered nurse; MD, medical doctor.

4. Family ENgagement in Intensive Care Environments (FENICE)

Most of the content of this section has been published.

4.1 Introduction

The well-being of patients and their relatives is considered fundamental in the care of critically ill adult patients and one of the top five research priorities among intensive care nurses (Blackwood, Albarran, & Latour, 2011). The concept of "family engagement" in ICU has expanded to the point where Health Care Professionals (HCPs) should now consider the role of the family as no longer of passive consultation, but rather of active involvement (Haines, 2018).

A recent scoping review has investigated the extent of literature on patient and family involvement in ICUs between 2003 and 2014 (Olding et al., 2016). The authors identified five components of family participation, that focused on involvement as: a) being present; b) receiving care and meeting needs; c) communicating and receiving information; d) participating in the decision-making process; and e) contributing to care (Olding et al., 2016). A more recent clinical review in 2018 has summarized the concept of "engagement" by defining it as a mechanism to act with people and to share with them information and decisions, and a way to achieve patient- and family-centred care (Burns et al., 2018). In addition, authors designated as "family" each family member, close relative, and caregiver with whom the patient spent most of the time (Burns et al., 2018).

Where "family involvement" has been documented, the contributions have primarily considered family's attendance in ICU rounds (Au et al., 2018; Stelson et al., 2016; Stickney, Ziniel, Brett, & Truog, 2014), followed by the participation in fundamental care, such as bathing and massaging (Mitchell, Chaboyer, Burmeister, & Foster, 2009), in psychological

patients' care (Black et al., 2011), in ventilator weaning programs (Burns, Devlin, & Hill, 2017), and in research experiences (Dotolo, Nielsen, Curtis, & Engelberg, 2017).

Regarding the outcomes, the family members' involvement in the ICU patient care seems to improve patients' psychological recovery, well-being, and satisfaction levels,(Huffines et al., 2013) while their post-traumatic disorders and depression were found to be reduced (Oczkowski, Mazzetti, Cupido, & Fox-Robichaud, 2015). Recently, family engagement in professional care has been recognized as a Nursing Sensitive Outcome (NSO) (Castellan et al., 2016; Minton et al., 2018), that is a patient or caregiver's state, behavior, or perception associated to nursing interventions (Maas et al., 1996). Accordingly, assessing family members' satisfaction should be considered a way to improve the quality of critical care provided to families of patients in ICU environments (Frivold, Slettebo, Heyland, & Dale, 2018).

To date, little research investigating family members' contributions to care in ICUs, including its outcomes on family itself and on patient care, is available (Olding et al., 2016). We hypothesized that engaging families in the care of critically ill patients could improve outcome both at family and at patient levels. Thus, the aim of this project is to assess the effects of a family engagement program on family members' satisfaction and on patients' well-being and quality of life (QoL).

4.2 Materials and methods

Research hypothesis and expected outcomes

1) At family level

Families of critically ill patients in the family engagement group will show a higher general satisfaction as compared to those families in the control group.

2) At patient level

The family-involved patients' group will show (a) an increased sense of well-being after the daily visiting period, and (b) a better QoL after ICU discharge (three and six months) as compared than the control group.

Study Design

A quasi-experimental study with two non-randomized groups will be performed by following the CONSORT (CONsolidated Standards Of Reporting Trials) guidelines (Schulz, Altman,

Moher, & Grp, 2010). Fig. 4.1 shows the flow chart of the study protocol: enrollment, allocation, follow-up and analysis steps.

Setting

This study will be conducted in two general ICUs of an Academic Hospital in the Northeast of Italy equipped with 900 beds. ICU A and B (beds = eight/each) provide care for both ventilated and non-ventilated patients and mixed medical, surgical, and trauma patients admitted directly through the ED or other hospital wards. Each ICU environment is a traditional open space, in which beds are separated by curtains. Staff is composed of registered nurses (RNs), with a nurse-to-patient ratio of 1:2, medical doctors (MD) and nursing assistants (NAs). Generally, the average ICU length of stay (LOS) is 5.0 days, and the average ICU occupancy rate is 80.2%.

Sampling and sample

This study will involve two groups of family members of patients who will be admitted to two ICUs. Specifically, in the intervention group, family members will be actively involved in the care of their relative; in the control group, patients will receive the usual care provided only by the nurses. Given the setting of the ICUs, with one open space shared by patients and visitors, participant randomization is not feasible. Moreover, to reduce the risk of inter-group contamination, ICU-A will be assigned to the intervention group and ICU-B to the control group.

A consecutive sampling method will be adopted to recruit the expected family members of adult patients ($\geq$ 18 years) in both the intervention and the control groups in the same period, from July 2020 to June 2021. Inclusion and exclusion criteria for the study population are shown in detail in Table 4.1. Patients' withdrawal criteria will be as follows: discharge from ICU, transfer to another hospital, or death. The withdrawal criterion for family members will be the unexpected suspension of daily visiting.

Sample size calculation

The sample size calculation is based on the target population of the study, which is composed of family members. Yet, no studies have evaluated the specific effect of the implementation of a family involvement program in ICUs on family's' perceived satisfaction.

However, previous studies estimated the effect of structured communication and support programs on the satisfaction of family members of critically ill patients with the FS-ICU tool (Abvali, Peyrovi, Moradi-Moghaddam, & Gohari, 2015; Othman, Subramanian, Ali, Hassan, & Haque, 2016), in which the mean of FS-ICU total score before intervention was 55.3 (± 10.3) and after intervention was 61.4 (± 17.7). Based on this, a sample of 188 patients (94 per each group) is the adequate requirement for the present study. This will result in a mid-scale effect size of 0.41, at a 5% significance level with a power of 80% and an allocation rate of 1:1. The sample size of this study was calculated with the software G*Power (version 3.1.9.4) (Faul, Erdfelder, Lang, & Buchner, 2007). Thus, each family member will be included together with his/her loved one who is being taken care for in ICU (94 per each group).

Despite light sedation being considered a routine therapy in the ICU settings of this study, a variety of reasons, including neurological, physiological, and communicative disabilities, can prevent patients' accurate estimation of their well-being by means of self-reported measures. This group of patients may include unconscious, deeply sedated and intubated patients, as well as those with a cognitive impairment or a head and maxillofacial trauma. For this reason, the researchers could not extend the sample size evaluation to the patient' well-being outcome.

Intervention and control group

The intervention will be carried out in a single ICU (ICU-A) and will engage family members in the care of their loved one with bed physical exercises and simple care tasks, as reported in Table 4.2. Trained nurses will provide families with written and verbal information about their involvement in the above-mentioned care activities (day 1: patient's admission to ICU) and will strictly supervise their engagement during the daily visiting hours (from day 2 to the transferring into another unit/ward). No intervention will be implemented without the approval of nurses and physicians who daily evaluate patients' conditions. Each session of family involvement will last for at least one hour per patient/day. In the case of signs of respiratory, hemodynamic or neurovegetative distress, the session will be immediately suspended by any HCP and the reasons of such decision will be appropriately communicated to the family member.

The intervention group will be formed of maximum eight patients, corresponding to the ICU-A bed availability. In the ICU-B, patients will receive the usual care consisting of a once-daily visit of at least one hour by family members without their formal involvement in simple care.

Family members' recruitment and involvement

Table 4.3 illustrates the recruitment and the involvement processes for family members.

Data collection and measurements

All data will be collected daily by two researchers, together with the nursing and medical staff of the Department of Anaesthesia and Intensive Care (Udine University Hospital), and professionally trained medical and nursing students. Data collection will include both clinical information and paper-based questionnaires. The anonymized paper data will be stored by the researchers.

Sociodemographic and clinical data

At the time of admission to ICU, within the routinely admission assessment, patients' demographics (age, gender), clinical characteristics (diagnosis, comorbidities, Glasgow Coma Scale [GCS] and Richmond Agitation-Sedation Scale [RASS] scores), anthropometric measures (weight and height, both required to calculate the body mass index [BMI]), and previous habits (e.g., cigarette smoking) will be assessed. Simultaneously, the family member's information, including age, gender, education, relation to patient and profession, will be collected with an *ad hoc* form.

Intervention

Every day, each activity performed by the family member in the intervention group will be recorded in a pre-established form. The grid will report data, time, type of activities, and their duration (in minutes). In case of clinical deterioration during the intervention, this will be immediately stopped by the nurse and/or physician in charge of the patient's care. The intervention group will be formed of maximum eight patients, corresponding to the ICU-A bed availability.

Outcomes

At family level:

a. Family satisfaction, assessed with the FS-ICU tool (Heyland, Tranmer, & Kingston Gen Hosp, 2001; Wall, Engelberg, Downey, Heyland, & Curtis, 2007), will be self-reported by family members within 48 hours after a patient's discharge from ICU.

At patient level:

a. A patient's sense of well-being will be measured with a visual analogue scale (VAS) within 30 minutes after the family involvement for the intervention group and in the same span of time after the ICU visiting hours for the control group (Lolaty, Bagheri-Nesami, Shorofi, Golzarodi, & Charati, 2014);

b. The QoL will be investigated with the SF-12 (Apolone & Mosconi, 1998) questionnaire within the first 48 hours after admission to assess pre-admission QoL (Hofhuis, Spronk, Van Stel, Schrijvers, & Bakker, 2007), at three and six months after ICU discharge by telephone (patient or family members).

FS-ICU

The FS-ICU questionnaire includes 24 items; 14 inquire about families' satisfaction with care and 10 explore their satisfaction with decision-making (Wall et al., 2007). All items are scored on a five-point Likert scale (from 1=very dissatisfied to 5=very satisfied) except one item which is dichotomous (yes/no). All questions included the "not applicable" optional response. Data will be collected from all participants via self-administered questionnaires (written).

SF-12

Originally developed from the Medical Outcomes Study (MOS) 36-item Short-Form Health Survey (SF-36), the SF-12 tool consists of 12 questions and measures eight domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health (Apolone & Mosconi, 1998; Ware, Kosinski, & Keller, 1996). A score ranging from 0 (indicating the worse health status) to 100 (the best health status) is assigned to each domain. Domain scores can be summarized into a Physical Component Score (PCS) and Mental Component Score (MCS). Data will be collected on all participants via

a combination of self-administered questionnaires (written) during the ICU-stay and telephone interviews post-discharge.

Data analysis

Collected data will be entered into a Microsoft Excel® worksheet. All statistical analysis will be performed using the SPSS software version 25 (SPSS Institute Inc., USA) and the statistical significance set at $p<0.05$. Continuous variables (e.g., age, LOS) will be displayed as mean and standard deviation (SD) if normally distributed or median and quartiles otherwise. Normality will be assessed by using the Kolmogorov-Smirnov test. Nominal variables (e.g., gender, reason of admission) will be calculated as absolute numbers and percentage. Student's unpaired t-test will be used to analyze comparisons between means; Blom's transformation will be used if normality test fails. Categorical variables will be analyzed using the chi-squared test for independence. A continuity-corrected chi-squared statistic or Fisher's exact test to evaluate the null hypothesis of this study in case of expected frequencies <5 in contingency tables will be applied. Moreover, the scores of FS-ICU and SF-12 obtained from the two groups will be examine using the analysis of covariance (ANCOVA). Once half of the sample is reached (47 per each group), an ad interim analysis will be performed to assess (a) whether the intervention is feasible in terms of family members acceptability and willingness to participate in the study, and (b) whether a statistically significant difference regarding family satisfaction between groups is already noticeable (p-value set to 0.05). According to the results (e.g., study dropout rates and consent refusal, treatment difference larger or smaller than expected), the intervention and/or sample size calculation will be changed, and a new research protocol will be developed. However, this study has not stopping rules.

Ethical considerations

The current study will be conducted according to the criteria set by the declaration of Helsinki; each patient legally authorizes a representative and/or a family member will provide written informed consent for all study procedures. Family members will be informed about withdrawing from the study at any time without affecting the care provided. The participants' privacy and personal information will be protected, and data will be anonymously analyzed. In addition, both ICUs are equipped to ensure patients' privacy

during the visiting and intervention time (e.g., large spaces, beds separated by curtains). Lastly, this protocol was approved by the Regional Ethics Committee of the Friuli Venezia Giulia (CEUR-2020-Sper-012) (Appendix 1).

Trial registration

ClinicalTrials.gov, Identifier: NCT04311190. Registered on March 17, 2020. https://clinicaltrials.gov/ct2/show/NCT04311190?term=fenice&draw=2&rank=1.

4.3 Discussion

To date, very few works (Abvali et al., 2015; Othman et al., 2016) have studied the relationship between engaging families' interventions and NSOs in ICUs. This protocol constitutes a significant step in a research agenda aimed at deepening the NSOs' reliability across the ICUs and useful to proxy monitoring the quality of hospital care. The results of this study might have the potential to provide additional evidence for family participation in bedside care in ICUs, and a better understanding of how family members and critically ill patients may benefit from the involvement itself.

Regarding dissemination, the results of the present study will be firstly presented and discussed at professional meetings by conducting a stakeholders' consultation. Then, research findings will be disseminated in scientific journals and at national and international conferences.

4.4 Conclusions

Despite international bodies prioritizing the well-being of families and patients in ICU, current literature lacks practical underpinnings and examples to promote the involvement of family in the care of the critically ill patients. This study protocol aimed at examining the effect of a family engagement program on NSOs at both family- and patient-level. The results will provide valuable insight into the quality of care delivered. ICU nurses and physicians need to become convinced that families can be routinely involved in care activities; family engagement can optimize patients' outcomes including well-being and quality of life and increase family satisfaction with care in ICU.

Figure 4.1 Flow chart of the study protocol
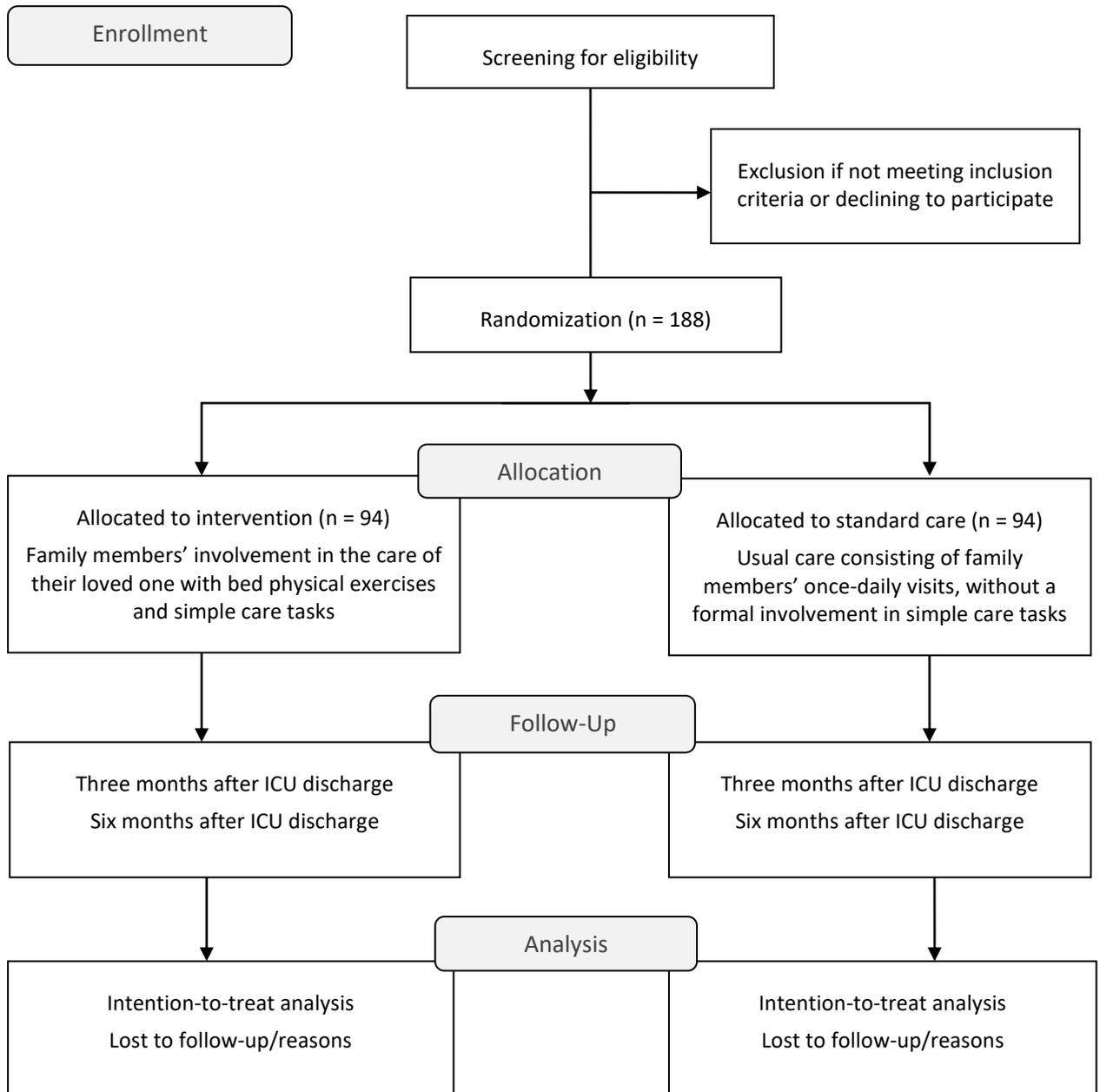
Table 4.1 Inclusion and exclusion criteria for patients and family members

	Include	Exclude
Patient	Adult (18 years of age and older)	Pediatric population (< 18 years old)
	Expected to stay in ICU at least three days to ensure adequate exposure to ICU environment Suffering from either high or low acuity conditions	If patient meets any of the following criteria: **Airways** - Unsafe airways - Hypoventilation/hyperventilation **Breathing** - PaO2/FiO2 < 200mmHg - pH < 7.30 - SpO2 < 92% - Respiratory rate > 35/min - Heart rate < 50/min - Heart rate > 130/min **Circulation** - Mean arterial pressure between 60 to 80 mmHg - Having mechanical heart/blood pressure support (e.g., intra-aortic pump balloon) - Intense diaphoresis - Prone position - Intracranial pressure monitoring **Disability** - Hypersensitivity to touch (e.g., epileptic status) - Psychomotor agitation or anxiety status (e.g., RASS scores +1 to +5) - Suppurating/infective/inflammatory/burned skin conditions **Exposure** - Unstable fractures - Peripheral intravenous line on the hands - Terminally ill conditions
Family member	Adult (18 years of age and older)	Pediatric population (< 18 years old)
	Being the patient's spouse, or in a blood relation, or next of kin, and/or a person with whom the patient spends most of the time Willing to visit the patient daily Willing to participate in the study	Lack of propensity or interest in participating in the study

RASS, Richmond Agitation Sedation Scale.

Table 4.2 Family involvement: care activities

High acuity patients	Low acuity patients
(when a patient is mechanically ventilated and under analgosedation)	(when a patient is awake and collaborative)
Open and close the fingers	Massages
Open and close the toes	Arms and legs position changes
Physical presence with touch at least 60 minutes/day	Washing face
Hair brushing	Assisting with rehabilitation exercises
Reading texts of interest to the patient (e.g., newspapers)	Encouraging/assisting with eating and drinking under nurses' strict supervision

Table 4.3 Details of the intervention protocol

Step 1 – Day one (patient's admission to ICU)

The researcher[a] verifies if the patient meets the inclusion criteria.
If yes, the researcher[a] proceeds with step 2.

Step 2 – Day one (family members' first visit to the ICU)

The researcher[a] verifies if the family member meets the inclusion criteria.
If yes, the researcher[a] provides information about the intervention (including how to talk to the patient, advice on where to sit or stand at the bedside and on how to open and close the interaction, as well as on the activities in which family members can be involved). The education session will last at least half an hour. Moreover, the researcher[a] discusses the study details with the family, identifies with them a family member as a reference, and ascertains decisions regarding consent.
If the written consent is provided, data collection starts with step 3.

Step 3 – Day two to transfer to ward (during the ICU-stay)

The researcher[a] actively seeks opportunities to promote the family access to the patient, maximizing the time available for the family to be with s/he and encouraging them to interact by talking and holding the patient's hand. In addition, the researcher[a] promotes the implementation of the activities described in Table 2 by recording them in the ad hoc grid.
On daily basis, the researcher[a] evaluates both the availability of the family member to participate, and the patient's clinical conditions before engaging the family member. Furthermore, the researcher[a] supervises all activities performed by the family member and provides feedback of encouragement.

ICU, Intensive Care Unit.

[a] The authors and/or a member of the research team.

5. Effects of coronavirus on the ICU

Most of the content of this section has been published.

5.1 Introduction

At the beginning of January 2020, the World Health Organization defined COVID-19 as a viral respiratory disease with extensive and rapid infectiousness (The Lancet Infectious, 2020). COVID-19 refers to "coronavirus disease 2019" and has to date 214,468,601 cases and 4,470,969 deaths globally, correct for the 27 of August 2021. As of 27 August 2021, a total of 4,953,887,422 vaccine doses have been administered.

In Europe, the availability of beds in ICUs varies considerably: from 4.2 beds per 100.000 inhabitants in Portugal to 29.2 beds in Germany (Rhodes et al., 2012) and to 8.8 beds in Italy before the COVID-19 pandemic – in line with the data from the main European countries – with a 50% increase during the pandemic (Zangrillo & Gattinoni, 2020).

The reorganization of ICUs' services has had consequences on both organizational and care levels, with a 33% increase in the workload of nursing staff and an important impact on the healthcare staff with the spread of symptomatology such as loss of appetite (59%), fatigue (55%), difficulty in falling asleep (45%), irritability (28%), and suicide sometimes (2%) (Shen, Zou, Zhong, Yan, & Li, 2020). ICUs had to change the organization of work trying, on one hand, to compensate for patients' loneliness and the isolation by strengthening the skills of group working, on the other hand, to comply with care protocols, such as the pronation of sedated patients under mechanical ventilation, or the communication with family members through video calls (Ambrosi et al., 2020; Bower & He, 2020; Galazzi, Brioni, Mistraletti, Roselli, & Abbruzzese, 2020).

Despite the substantial scientific production on COVID-19 of the last six months, studies that describe, from an international perspective, how the ICUs have changed to adapt to the care needs of critically ill COVID-19 patients are not available. The data reported in Europe so far mostly include general hospitals, mainly in a single country, and with limited scopes.

5.2 Objectives

The objectives of the study were: (1) to describe the organizational changes in the ICUs due to the COVID-19 pandemic; (2) to explore the peculiarities of nursing care for the critically ill COVID-19 patients; and (3) to explore the major challenges perceived by ICU nurses during the pandemic.

5.3 Methods

An exploratory study was conducted via an online survey available from May 11th to July 10th, 2020. Nurses who assisted patients with COVID-19 in an ICU in one of the 27 member states of the European Union were invited to participate. The link to the questionnaire was disseminated through the main social media platforms (Facebook® and Twitter®) and shared in the main international groups of ICU nurses.

The questions were elaborated after a literature review on the effects of COVID-19 on patients and on healthcare organizations. The questionnaire consisted of 56 questions.

This chapter reports data on (1) the actions at corporate level taken to tackle the pandemic, (2) the peculiarities of nursing in an ICU during the pandemic, and (3) the most important challenges perceived by nurses.

As to data analysis, descriptive statistics were used and central dispersion index (mean, standard deviation [SD]), frequencies, and percentages were processed. Student's t test was used to verify the differences between the means of some variables before and after the spread of COVID-19 (e.g., number of beds). The data were collected on a Microsoft Excel® spreadsheet and processed with SPSS Software, version 26 (SPSS Institute Inc., USA).

5.4 Results

Sixty-two nurses responded, most of them were female (n = 31, 60.8%) with an average age of 37.5 years (SD 10.8). Almost all of them were clinical nurses and with > 10 years of work experience. Most of the nurses were Italian (n = 25, 40.4%), French (n = 12, 19.5%), and English (n = 11, 17.7%). More than two thirds of the sample group worked in large (> 500 beds) national and university hospitals (Table 5.1).

Corporate actions taken to address the pandemic

All hospitals opened new wards dedicated to COVID-19 positive patients and limited visits to family members (Table 5.2). A large number of hospitals suspended elective surgical activities (n = 49, 79.0%), closed some wards due to reduced activity (n = 45, 72.6%), identified external areas designated for triage (n = 44, 70.9%), set up dedicated paths for patient transport and isolation (n = 44, 70.9%), and transformed operating theatres into ICUs (n = 43, 69.3%). To a lesser extent, hospital entry and exit routes were reserved for staff caring for COVID-19 positive patients (n = 33, 53.2%) and negative pressure rooms were used for these patients (n = 24, 38.7%).

In ICUs, the number of beds (n = 55; 88.7%) and the number of dedicated nurses (n = 53, 85.5%) were increased; respondents from Poland did not report this increase when compared to the pre- COVID-19 period.

On average, available beds in an ICU before COVID-19 were 28.1 (SD 18.1) and doubled during the pandemic (n = 56.6, SD 36.0; $p <0.01$). The number of nurses per shift increased from 10.2 (SD 7.3) before COVID-19 to 17.9 (SD 13.6) during the emergency ($p <0.01$). Likewise, the number of physicians (n = 4.3, SD 2.9 vs. n = 7.0, SD 5.5; $p <0.01$), health care workers (n = 2.4, SD 2.2 vs. n = 5.6, SD 5.2; $p <0.01$), and other health care professionals (e.g., physiotherapists) (n = 1.8, SD 1.9 vs. n = 3.9, SD 5.3; $p <0.01$) increased. The nurse / patient ratio increased from 0.6 (1 nurse / 1.5 patients, SD 0.3) before COVID-19 to 0.5 (1 nurse / 2 patients, SD 0.2) during the pandemic ($p = 0.05$) (Table 5.3).

Of the three most representative countries (Italy, France, and the United Kingdom), the United Kingdom is the country where there has been the greatest increase in ICU beds (n = 23.9, SD 2.1 before COVID-19 vs. n = 58.3, SD 24.9 during the pandemic; $p <0.001$) and in nurses per shift (n = 20.7, SD 1.4 vs. n = 39.7, SD 4.2; $p <0.001$). The nurse-to-patient ratio, which was 1:1 prior to the COVID-19 pandemic, has dropped to 0.7 (approximately 1 nurse / 1.5 patients). Italy is the country that has increased the number of beds and staff to a lesser extent (Table 5.3).

Changes in ICU nursing

To large extent, patients were admitted to an ICU according to the recommendations (n = 39; 62.9%) issued by national scientific societies to regulate access to intensive care in exceptional conditions of imbalance between needs and available resources. Protocols for

airway management (n = 47, 75.8%) and for transport of infected patients (n = 47, 75.8%) were defined in most ICUs, while out-of-ward diagnostic activities were reduced (n = 48, 77.4%) to avoid relocations and related risks (Table 5.4).

The Venturi mask was the most used device to administer oxygen to spontaneously breathing patients (n = 32, 51.6%); non-invasive ventilation was performed predominantly through a facemask (n = 37, 59.7%), and in most cases, pronation was used (n = 55, 88.7%).

As to most compromised aspects, nurses reported safety (n = 14, 22.6%), such as risk assessment and management; personal hygiene (n = 12, 19.3%) such as oral care; and mobility (n = 12, 19.3%) such as active and passive exercises in bed. With respect to the psychosocial dimension, the most compromised were social involvement, including companionship and support (n = 22, 35.5%), verbal and non-verbal communication (n = 14, 22.6%), and emotional well-being (n = 10, 16.1%). With reference to the relational dimension, it was difficult for the participants to ensure above all the support and involvement of the family member / caregiver (n = 31, 50%), and to be present with the patients (n = 12, 19.3%). Regarding communication with family members, 34 (54.8%) stated that they followed a protocol to ensure daily communication. Information was mostly transmitted once per day (n = 43, 69.4%), predominantly by the physician (n = 32, 51.6%) and over the phone (n = 55, 88.7%).

Major challenges

Forty participants (n = 64.5%) reported a shortage of PPE (Table 5.5): the majority (n = 29, 46.8%) replaced it every four to five hours. The following were used: full protective suit (n = 44, 70.9%), face shield (n = 47, 75.8%), FFP2 mask (n = 38, 71.3%), and two pairs of gloves (n = 40, 64.5%). PPE led to significant physical fatigue in most of the participants (n = 47; 75.8%) and important limitations in the nursing practice (n = 45; 64.5%).

Seven participants (n = 7; 11.3%) turned out to be positive and symptomatic and were placed in quarantine; another 13 (20.9%) reported having at least another positive member in their ICU team. However, less than half of the participants (n = 24; 38.7%) underwent regular surveillance screening with swab testing.

The majority of participants reported psychological distress (n = 41; 66.1%); in 58% (n = 36) of the cases psychological support at ICU level was available but only six nurses (9.8%) reported using it. Participants also reported the availability of briefings and debriefings (n =

14; 22.6%) of clinical and supportive organizational value (for example, discussion sessions between colleagues and in teams, case analyses) and of training courses (n = 11; 17.4%) (for example dressing / undressing courses, execution of nasopharyngeal swabs for the detection of the SARS-CoV-2 virus).

Nursing students continued their clinical learning experience in the UK, France, Germany, and Belgium (n = 24; 38.7%).

5.5 Discussion

All nurses reported the activation of new wards dedicated to the care of COVID-19 patients and policies to restrict family visits; similarly, the majority reported the suspension of elective surgical activities and the closure of some wards due to a reduction in activities. These measures have inevitably led to a redistribution of health personnel and of necessary resources for the care of COVID-19 patients (e.g. oxygen therapy units) (Mari, Crippa, Casciaro, & Maggioni, 2020). This is probably the first time that hospitals re-configure their organization so quickly to deal with an unprecedented health crisis.

Almost 90% of the respondents declared a 50% increase in beds compared to the pre-COVID-19 phase. Although the nursing staff was increased, the overall nurse / patient ratio does not seem to have changed much (from 0.6 pre-COVID-19 to 0.5 during the emergency).

Doubling the beds of an ICU and recruiting trained medical-nursing staff in such a short time is not feasible: a more contained increase (+ 15-30%) of ICU beds combined with a reorganization of territorial medicine could be viable options in the event of a new pandemic (Zangrillo & Gattinoni, 2020).

ICUs had worked hard in recent decades to transform themselves into open structures, overcoming structural and cultural barriers to the point of introducing a more continuous presence of family members at the bedside of patients: the hope is that the COVID-19 emergency will not frustrate these efforts.

5.6 Limits

The main limitations of the study are the dissemination of the link through web channels and the small sample size. The questionnaire was in English, and this may have introduced comprehension problems in non-English native speakers. Finally, the data were analysed in

aggregate form even if the COVID-19 epidemiology and the intensity of the pandemic, and the characteristics of the health systems - including the ICUs - differ in each country.

5.7 Conclusions

The spread of the COVID-19 disease has introduced substantial changes in the critical environments of the ICUs. Common aspects were the increase, up to 50% more, in beds and the introduction of new staff to assist the critically ill patients, although this has not always resulted in a decrease in the nurse / patient ratio. Nursing care for critically ill patients has undergone important changes: some physical needs were inevitably compromised, and the interaction with family members was significantly reduced. Moreover, the constant use of personal protective equipment also contributed to an increase in the physical workload. Psychologically, many nurses have reported having to cope with stressful situations.

Table 5.1 Sample characteristics

Item	Participants (n = 62)
Gender, n (%)	
Female	31 (60.8)
Age, mean (SD), years	37.5 (10.8)
Education, n (%)	
Nursing Diploma	24 (38.7)
Bachelor in Nursing Science	20 (42.3)
Master Degree in Critical Care Nursing or similar	18 (29.0)
Years of ICU experience, mean (SD), years	10.8 (7.5)
Role, n (%)	
Clinical nurse	54 (87.0)
Nurse Manager	8 (13.0)
Country of practice, n (%)	
Italy	25 (40.4)
France	12 (19.5)
U.K.	11 (17.7)
Belgium	3 (4.8)
Poland	3 (4.8)
Switzerland	2 (3.2)
Germany	2 (3.2)
Island	2 (3.2)
Norway	2 (3.2)
Hospital bed size, n (%)	
Small hospital: fewer than 200 beds	5 (8.0)
Medium hospital: 201 to 499 beds	14 (22.6)
Large hospital: 500 or more beds	43 (69.4)
Location and teaching status, n (%)	
Rural	5 (8.0)
Urban, non-teaching	10 (16.2)
Urban, teaching	47 (75.8)

SD, Standard Deviation.

Table 5.2 Corporate actions taken to address the pandemic

Item, n. (%)	Participants (n = 62)
Hospital-level policies enacted during COVID-19 pandemic	
Opening of new COVID-19 wards	62 (100)
Restricting visitor access to hospital	62 (100)
Cessation of elective surgery	49 (79.0)
Closure of hospital wards due to reduced activity	45 (72.6)
Identification of external triage areas	44 (70.9)
Dedicated patient transport and isolation pathways	44 (70.9)
Operating rooms allocated as ICU beds	43 (69.3)
Dedicated entry and exit of staff to/from the immediate COVID-19 clinical area	33 (53.2)
Negative pressure chambers for infected patients	24 (38.7)
ICU-level	
Has been enacted an expansion of ICU beds?	55 (88.7)
Has been enacted an expansion of ICU nurses?	53 (85.5)
How often relatives were given clinical information about their loved ones?	
Once a day	43 (69.4)
Twice a day	12 (19.4)
Three or more	7 (11.2)
Who gave this information?	
Medical Doctor (MD)	32 (51.6)
MD and RN together	21 (33.9)
Nurse (RN)	5 (8.1)
Other health care professionals	4 (6.4)
Mode of communication (predominantly)	
Phone	55 (88.7)
Video call	7 (11.3)

ICU, Intensive Care Unit; SD, Standard Deviation.

Table 5.3 Changes in ICU setting

Item, mean (SD)	Pre-COVID-19	COVID-19	p-value
Number of ICU beds in the hospital	28.1 (18.1)	56.6 (36.0)	<0.001
Number of Nurses per shift	10.2 (7.3)	17.9 (13.6)	<0.001
Number of Medical Doctors per shift	4.3 (2.9)	7.0 (5.5)	<0.001
Number of NAs per shift	2.4 (2.2)	5.6 (5.2)	<0.001
Other health care professionals per shift (e.g., physiotherapists)	1.8 (1.9)	3.9 (5.3)	<0.001
Nurse-to-patient ratio	0.6 (0.3)	0.5 (0.2)	=0.05

SD, Standard Deviation; NAs, Nurse Assistants; ICU, Intensive Care Unit.

Table 5.4 Changes in ICU nursing care

Item, n. (%)	Participants (n = 62)
The Healthcare Professionals (HCPs) had checklists, bundle and explicitly defined airway management strategies	47 (75.8)
Are there local protocols specifically designed for transport COVID-19 patients?	47 (75.8)
The number of outpatient radiological exams was reduced	48 (77.4)
The HCPs had a guideline on how to communicate with families	34 (54.8)
When administering oxygen to a spontaneously breathing COVID-19 patient, you usually used:	
Venturi Mask	32 (51.6)
High-flow nasal cannula	25 (40.3)
Nasal cannula	5 (8.1)
When administering non-invasive ventilation to a COVID-19 patient, you usually used:	
Facemask	37 (59.7)
Oronasal mask	14 (22.6)
Helmet	11 (17.7)
Did you use prone position in management of COVID-19 patients?	55 (88.7)
Was there a clinical recommendation about patient triage before ICU admitting due to rationing of ICU care?	39 (62.9)
Which of these PHYSICAL patient's needs was more compromised when assisting a COVID-19 patient in ICU?	
Safety (risk assessment & management, infection prevention, minimizing complications)	14 (22.6)
Personal hygiene (including oral/mouth care) and dressing	12 (19.3)
Mobility	12 (19.3)
Rest and sleep	8 (12.9)
Comfort (pain management, breathing easily, temperature control)	7 (11.3)
Toileting needs	4 (6.5)
Eating and drinking	4 (6.5)
Medication management	1 (1.6)
Which of these PSYCHOSOCIAL patient's needs was more compromised when assisting a COVID-19 patient in ICU?	
Social engagement, company and support	22 (35.5)
Communication (verbal and non-verbal)	14 (22.6)
Emotional wellbeing	10 (16.1)
Being involved and informed	4 (6.5)
Privacy	4 (6.5)
Choice	2 (3.2)

Dignity	2 (3.2)
Respect	1 (1.6)
Education and information	1 (1.6)
Having interests and priorities considered and accommodated (where	1 (1.6)
possible)	1 (1.6)
Having values and beliefs considered and respected	
Which of these RELATIONAL nursing activities was more compromised when assisting a COVID-19 patient in ICU?	
Supporting and involving families and carers	31 (50.0)
Being present and with patients	12 (19.3)
Helping patients to stay calm	4 (6.5)
Active listening	4 (6.5)
Compassion	4 (6.5)
Engaging with patients	4 (6.5)
Working with patients to set, achieve and evaluate progression of goals	2 (3.2)
Helping patients to cope	1 (1.5)

NIV, Non-invasive ventilation; ICU, Intensive Care Unit.

Table 5.5 Major challenges

Item, n. (%)	Participants (n = 62)
Have you experienced a shortage of PPE?	40 (64.5)
How often have you donned and doffed PPE?	
Every 2-3 hours	20 (32.3)
Every 4-5 hours	29 (46.8)
Every 6-7 hours	7 (11.2)
Every 8 hours or more	6 (9.7)
Have you experienced symptoms and/or infection and thus quarantined?	7 (11.3)
Have been reported COVID-19 infections among doctors, nurses, or other health workers within your ICU?	13 (20.9)
Was there a staff monitoring with a COVID-19 testing swabs?	24 (38.7)
Did you experience physical burdens due to PPE?	47 (75.8)
Did you experience physical restrictions to routine practice due to PPE?	40 (64.5)
Did you experience any psychological burden?	41 (66.1)
There is a dedicated mental health/psychological support helpline for ICU healthcare workers	36 (58.0)
If yes, did you use it?	6 (9.6)
Have you been in briefing and debriefing sessions?	14 (22.6)
Have you been in team training sessions?	11 (17.4)
Nurses' students entered the ICU during the COVID outbreak?	24 (38.7)

SD, Standard Deviation; PPE, Personal Protective Equipment; ICU, Intensive Care Unit.

6. The experiences of relatives

Most of the content of this section has been under review.

> Danielis, M., Terzoni, S., Buttolo, T., Costantini, C., Piani, T., Zanardo, D., Palese, A., Destrebecq, A.L.L. (2021). Relatives caring for a discharged loved one from non-COVID-19 Intensive Care Unit: a qualitative study. International Journal of Environmental Research and Public Health.

6.1 Preamble

Restricted visitations did not allow relatives to be engaged in the care of their loved one during the in-hospital stay; they have also experienced difficulties at home in receiving visits and support, due to restrictions imposed by the COVID-19 pandemic responses. Authors performed the study by deviating from the original quasi-experimental study (Danielis et al., 2020), given that the family engagement intervention under investigation was suspended due to the pandemic. Even if the dramatic research disruption resulting from the pandemic has been largely documented (Palese, Papastavrou, & Sermeus, 2021), authors undertook the challenge to perform the interviews rather than to suspend the study totally, also with the intent to ensure closeness to relatives under the public health restrictions in place. Relative's experiences have been considered to reflect the dramatic changes that have taken place in the last year that have not been investigated do date (Palese et al., 2021): therefore, it was considered a unique occasion to understand their lived experience and to gain insights into the current pandemic.

As a consequence of the deliberate choice made by researchers to deviate from the original study, the aims have been limited by focusing only on qualitative data: therefore, data from SF-12 and FS-ICU were not in depth analyzed and no associations among the quantitative measures collected have been performed.

6.2 Introduction

A large number of ICU patients are ultimately discharged to home with different degrees of functional dependence and cognitive damage requiring continuous care. In a large study performed by Gayat et al. (2018) including a cohort of 2,087 patients in France and Belgium, ICU mortality was 22%, and 333 patients (21%) died in the year after ICU discharge. Similarly,

Detsky et al. (2017) conducted a prospective cohort study in five medical and surgical ICUs in Pennsylvania (US) measuring post-intensive care syndrome at six months after discharge. Of the 303 enrolled patients, 72 (23.8%) died in hospital and 169 (55.8%) were alive at the six-month assessment. Among survivors, 121 (71.3%) were able to mobilise and 138 (81.9%) were able to toilet, while normal functional cognition was reported for 105 (62.4%) (Detsky et al., 2017).

Even though ICU discharge can be considered a positive outcome for the patient, it represents a challenging step for carers. Relatives have a significant role in patient recovery as they are called to provide physical and emotional support. The impact of family care has been investigated in both quantitative (Agard, Lomborg, Tonnesen, & Egerod, 2014) and qualitative research (Auriemma et al., 2021; Choi et al., 2018; van Sleeuwen, van de Laar, Geense, van den Boogaard, & Zegers, 2020). Primarily, after ICU discharge, relatives have been reported to be tired, given that most of the patient's activities in daily living have to be assisted by hands-on care; relatives have been reported to perceive themselves unready because the home environment needs to be rearranged as well as new competences and caring skills that need to be acquired (Choi et al., 2018). At the same time, family carers are optimistic as small patient improvements trigger hope (Choi et al., 2018). However, with the progress of time, relatives have been documented to be negatively affected in terms of their own health status. A review performed by Johnson et al. (2019) summarized all types of burden reported by ICU survivors' carers as anxiety (2–80%), depression (4–94%), and post-traumatic stress disorder (3–62%) within a follow-up ranging from one to 53 months after ICU discharge. In addition, lifestyle interferences (e.g. loss of employment and financial issues), and low health-related quality of life have also been frequently reported among family carers (van Beusekom, Bakhshi-Raiez, de Keizer, Dongelmans, & van der Schaaf, 2016).

In the last 15 years, ICU policies in Italy have been changed by improving visitors' accessibility and by engaging family relatives in the care of patients during hospitalization to increase their awareness of and readiness for the care required after the ICU discharge (Haines, 2018; McAndrew, Schiffman, & Leske, 2020). The presence of relatives at the bedside is the core of family-centered care (FCC) model, which has been threatened during the coronavirus disease 2019 pandemic (Hart, Turnbull, Oppenheim, & Courtright, 2020). Thus, with the intent of ensuring both patient and visitor safety, family hospital visiting has

been suspended (Aziz et al., 2020; Indolfi & Spaccarotella, 2020). The COVID-19 pandemic has brought the ICU back to its past when relatives were used to seeing their loved ones through glass. However, hospitals are not the only care settings to be affected, provision of primary care has also been impacted. Lockdown measures have been reported as impacting patients – especially those with physical disabilities – and their relatives, by reducing family cohesion and preventing the delivery of the required healthcare support (Dalise et al., 2021). It would be anticipated that relatives' documented difficulties and challenges encountered in life after the ICU discharge (Auriemma et al., 2021; Choi et al., 2018; Johnson et al., 2019; van Beusekom et al., 2016; van Sleeuwen et al., 2020), might have increased during the coronavirus pandemic.

To date no research has documented the impact of the coronavirus pandemic on the relatives' experiences after ICU discharge. Thus, the general purpose of this research step was exploring relatives' experiences of everyday life in the first three months after the ICU discharge in times of COVID-19 pandemic.

6.3 Methods

Aim

The research question was: 'What are the experiences of carers caring for a loved one following ICU discharge during the COVID-19 pandemic?'. According to the research question, the study aim was to explore and describe the experiences of a relative who has been facing the day-to-day life during the first three months after non-COVID-19 ICU discharge.

Design

A descriptive qualitative study was conducted from August 2020 to January 2021 with the aim to discover how relatives make sense of their experiences (Sandelowski, 2010). Methods and findings are reported here according to the COnsolidated criteria for REporting Qualitative research principles (Tong, Sainsbury, & Craig, 2007).

The study has been performed as a part of a quasi-experimental study where the objective was to evaluate the effectiveness of a family engagement program during an ICU stay (reference blinded for review) on two expected outcomes: (a) at the family level: a higher

general satisfaction with the care provided in the ICU among the family engagement group, as compared to those relatives belonging to the control group, and (b) at the patient level: a better quality of life after the ICU discharge among those whose relatives have been engaged, as compared to patients in the control group, where relative have been not engaged.

Due to the changes imposed by COVID-19 pandemic on ICU visitation policies, the original study was not conducted (reference blinded for review), thus patients did not receive the intervention; however, in line with the study protocol, data collection regarding relatives' experiences at three months after ICU discharge have been performed.

Setting and participants

Patients and relatives were recruited in two general ICUs of an Academic Hospital in Udine, Italy (> 1,000 beds). The ICUs, each equipped with eight beds, provided care for non-COVID-19 patients admitted from the Emergency Department, operating rooms, or from other hospital wards. At the time of the study, the nurse-to-patient ratio was 1:2. The length of stay (LOS) was, on average, 5 days, and the occupancy bed rate was 80%. Before the COVID-19 pandemic, these ICUs adopted a flexible visiting policy, with an open family presence at the bedside, while during the first wave (Indolfi & Spaccarotella, 2020) visitors have been prohibited from entering facilities. From the end of the first wave of the pandemic (June 2020) to October 21st, 2020, relatives were allowed to visit their loved ones one hour/day, for one visitor/at a time. During the second and third wave, from October 2020 to June 2021, a 'no visitor' policy has been implemented again.

A purposive sampling (Benoot, Hannes, & Bilsen, 2016) was used to include one relative of each adult patient (≥ 18 years) with a LOS ≥ three days cared for in ICU from August 15th to October 20th, 2020. Inclusion criteria were (a) being a wife/husband, or being a blood relation of the patient, or being the identified next of kin; (b) being of age of 18 or above; and (c) willing to visit the patient on a daily basis. Due to the range of relationships possible in these criteria, all those who agreed to participate has been referred to as "relatives". There were excluded those relatives (a) who expressed lack of propensity for participation; (b) of patients diagnosed as terminally ill. Withdrawal criterion for relatives was the unexpected suspension of visiting their loved ones in ICU daily.

Data collection methods and instruments

Relatives meeting inclusion criteria were approached for the study by a member of the research team at the time of admission to the ICU or - in any case - within 24 hours. The informed consent form was written in Italian language, with a vocabulary easily understood by participants; moreover, given the stressful nature of the experience lived by them, the information regarding the study aims and procedures were given by an expert nurse, in a calm environment and all relatives were given 24 hours to consider their participation in the study.

The data collection was carried out in three steps as detailed in Table 6.1. Within 48 hours of ICU admission, baseline quantitative data was collected. At this stage, the patient's quality of life was measured using the 12-item Short-Form Health Survey (SF-12) questionnaire (Apolone & Mosconi, 1998; Gandek et al., 1998) by interviewing the relative. This tool has been validated in several European countries – including Italy – and comprised of the Physical Component Score (PCS) and the Mental Component Score (MCS).

Then, within 48 hours of ICU discharge, data were collected to evaluate families' satisfaction with the Italian version of the Family Satisfaction in the ICU (FS-ICU) questionnaire (Heyland et al., 2001; Pagnamenta et al., 2016).

Lastly, after three months, qualitative data was collected. A researcher (MD, male, PhD student, Nurse Educator expert in ICU care, and not involved in the care of patients at the time of the study) conducted audio-recorded telephone interviews lasting from 10 to 40 minutes with each relative. Participants were encouraged to share as much of their experience as possible. The questions were not provided in advance to the relatives (Table 6.1). In addition, the patient's quality of life was reinvestigated with the SF-12 questionnaire (Apolone & Mosconi, 1998), by re-interviewing the relative, according to the research protocol (reference blinded for review).

Data analysis

Quantitative data were entered into a Microsoft Excel® worksheet. While continuous variables (e.g., age, length of stay) were displayed as mean, standard deviations and median, nominal variables (e.g., gender, reason for admission) were shown as absolute frequencies and percentages.

All interviews were audio-recorded and then transcribed verbatim. Then, the data were thematically analyzed in the following inductive steps (Sundler, Lindberg, Nilsson, & Palmer, 2019; Tie, Birks, & Francis, 2019; Vaismoradi, Turunen, & Bondas, 2013). The first step was *achieving familiarity with the data* through open-minded reading. Three researchers conducted a careful and thorough reading to obtain a comprehensive view of the experiences lived by participants paying attention to the words used by each family member. Researchers also identified and labelled representative quotations. Thereafter, the *search for meanings* was deepened. A preliminary data coding was performed independently by the same three researchers by generating a total of 18 initial codes whereby each quotation extracted was categorized. Lastly, the researchers *reached a meaningful wholeness*. Thus, codes with similar meanings and concepts were grouped into eight categories. Researchers discussed the findings that emerged and labelled three themes through a constructive dialogue. Few disagreements stemmed from unclear definitions or the researchers interpreting quotations differently (e.g., 'searching for support in providing care' instead of 'being supported in providing care'). These differences were solved by consulting a fourth researcher.

Validity and rigor

Credibility, dependability, confirmability and transferability (Maher, Hadfield, Hutchings, & de Eyto, 2018) were ensured. First, credibility in the data and in the findings was ensured by waiting for a period of three months from the ICU discharge before contacting relatives. This was essential to reach an in-depth understanding of the care experience (Choi et al., 2018; van Beusekom et al., 2016; van Sleeuwen et al., 2020). Second, dependability was guaranteed with a rich description of the study method, which allows the qualitative inquiry to be repeatable. Third, confirmability was reached by ensuring agreement among researchers, who independently analyzed the data and agreed upon the findings. Transferability has been established by providing patient and relative profiles, thus allowing the evaluation of the findings in their validity in other contexts, situations, times and populations.

Ethics

The study protocol was approved by the Regional Ethics Committee of the Friuli Venezia Giulia (CEUR-2020-Sper-012) (Appendix 1) and conducted according to the criteria set by the Declaration of Helsinki; moreover, each relative provided a written informed consent after having understood the research goals and steps. Since critically ill patients were under life-threatening conditions, the ICU team was involved aiming at ensuring that the informed consent was collected according to the situation and in appropriate time/manners in the patient's and relatives' best interest. Confidentiality was ensured by the researchers during each data handling process. In reporting findings, relatives' identity was protected: specifically, quotations were indexed as being from a family member interviewed, numbered consecutively (e.g., R1, relative member 1). In addition, they were free to withdraw from the study at any time without the need to provide reasons.

6.4 Findings

Participants

It was enrolled a total of 28 patient–family member pairs from whom baseline data was collected; 21 (75.0%) patients survived and were discharged from the ICU and 14 (50.0%) were alive at the three-month follow-up. The flow of patients' and families' recruitment and follow-up is displayed in Figure 6.1.

As reported in Table 6.2, survivors were predominantly males (n=11; 78.6%), with an average age of 59.4 years (SD 16.0, median 70). They had been admitted in ICU following organ failure, trauma, or cerebrovascular disease (n=6; 42.8%, n=6; 42.8%, and n=2; 14.4%, respectively). The mean APACHE II score was 14.50 (SD 8.5, median 17), the mean RASS score was -2.3 (SD 1.7), and the ICU LOS of 18.0 days (SD 9.0, median 15). At the baseline, the means of SF-12 (PCS) and SF-12 (MCS) were 43.19 (SD 12.44, median 41) and 49.02 (SD 13.29, median 54), respectively. At the three-month follow-up, it was 37.38 (SD 9.22, median 38) and 40.54 (SD 13.44, median 41), respectively.

As reported in Table 6.3, relatives were mainly the partner (e.g., spouses) (n=7; 50.0%), females (n=11; 78.6%), with an average age of 53.9 years (SD 9.5, median 51). Nine of them (64.3%) reported a secondary education, and mostly were employed (n=11; 78.6%). At the time of the interview most were living with the patient (n=8; 57.1%) and some reported previous experience with the ICU (n=4; 28.6%). With regard to the FS-ICU scores, the mean

FS-ICU/total score was 85.2 (SD 8.6, median 82), while the mean FS-ICU/decision-making score was 84.0 (SD 10.0, median 81), and the mean FS-ICU/care was 85.9 (SD 8.5, median 83).

The lived experience

Three main themes emerged, consisting of eight categories (Table 6.4), namely "Being shaken following the ICU discharge", "Returning to our life that is no longer what we are used to", and "Feeling powerless due to the COVID-19 pandemic".

Being shaken following ICU discharge

At the discharge, relatives remembered having lived a complex emotional experience, as 'being shaken', where negative and positive emotions coexisted and have been lived intensively. Relatives reported having felt a sense of astonishment in listening to the unexpected news at the ICU discharge: '*Bad, really bad, no life expectancy...I remember these words, as if they were imprinted with fire*' [R1]. This emotion triggered a widespread sense of despair for what was happening: '*The situation is challenging. As relatives, we all suffer with him, every day*' [R1]. Negative feelings such as anger towards healthcare professionals were also reported when conflicting information was given from one department to another: '*In ICU I was told that the tracheostomy was going to be removed. In the ward, however, I was told that he would never swallow or eat agai*n' [R14]". Relatives also experienced fear of possible complications: '*I just hope the lung infection doesn't come back again...he wouldn't survive another illness*' [R9].

By contrast, relatives reported their positive experiences as trusting in healthcare professionals who they saw as experts and competent in managing the conditions and in giving information regarding the future: '*I have to fully rely on doctors and nurses, also because I'm not an expert and so I have to trust them*' [R1]; moreover, they also reported the gratitude for the care provided to their loved one: '*In my opinion he has always been well looked after. I have nothing to say about the care they gave him, I'm just grateful*' [R2].

Returning to our life that is no longer what we are used to

After the discharge, relatives realized soon that nothing would be as before, a sort of deep interruption in the course of their life, requiring several adjustments. Firstly, participants

become aware regarding the limitations in the activities of daily life of their loved one: '*He does not walk, he does not move by himself, he can't even sign. We're doing the paperwork for the disability pension*' [R2]. As a consequence, relatives rapidly changed the physical environment of their houses, according to the specific limitations and also in the attempt to maximize the patient's functional independence: '*I got a stationary bike to allow her to do some exercise. He cannot climb the stairs anymore*' [R9].

Participants felt supported, having benefited from community-based services: '*At home, we are followed by home care, a nurse visits us. If there are any critical issues, we ask her*' [R13]. However, they focused their priorities on hiring private professionals, as in the case of physiotherapists: '*As to rehabilitation, I opted for a private service. I called a physiotherapist who is now helping us*' [R13] in order to accelerate the healing or the rehabilitation process, but also to compensate the lack of care offered by the community health services available: "*We've arranged a physiotherapist and a caregiver*" [R3].

The complexity of the experience also affected the life of the relatives. They reported changing their routines, as in the case of sleeping habits: '*When we got home, I used to sleep in the living room so as not to stay too close and bring bacteria or viruses near him*' [R8]. In order to protect themselves, relatives reported the need to balance the caring role with the multiple roles lived before: '*I also have to get someone to do grocery shopping so that I don't leave him alone*' [R11].

Feeling powerless due to the COVID-19 pandemic

An additional challenge has been reported by relatives as a consequence of the COVID-19 pandemic. They felt they lacked the power to ensure the full professional care required on the one hand, and also the required emotional support offered by informal carers, such as friends, on the other. In addition, they also perceived themselves as being unprepared to play the complex carer role required.

Some relatives felt that patients have been discharged from the rehabilitation units too early: '*It was a hard blow for him when he was discharged from the rehabilitation hospital – he needed one more month*' [R3]. In contrast, others were unable to receive care in long-term care facilities, which have been converted into COVID-19 units: '*The rehabilitation facility has fewer beds now...neurorehabilitation, which he would need, is now occupied by COVID-19 patients*' [R7]. Moreover, the COVID-19 pandemic has also prevented the regular

check-ups, which are often cancelled or delayed: '*The first visit with the doctor was put off due to COVID-19. In January, the neurological check was cancelled as well*' [R10].

The isolating environment imposed by the COVID-19 pandemic, restricting family and friends' visits, led to patients' loneliness, as reported by relatives: '*If he had any friends, someone who could stimulate him…*' [R7]. In addition, carers' training programs were often missed or reduced in duration: '*We relatives should have had some training, but it was limited*' [R13]. The sense of powerlessness and the lack of available support mean relatives have to start thinking about the future and the important choices required: '*I thought that a facility was going to be the right option for her … she would be looked after by people who are not just company but competent*' [R4].

6.5 Discussion

To the best of our knowledge, this is the first study exploring the experiences of relatives of critically ill patients discharged from non-COVID ICUs during the COVID-19 pandemic.

Participants

Findings from this study summarize the experience of relatives caring for ICU-discharged patients at home, whose quality-of-life scores decreased according to the SF-12, both in physical and mental dimensions, from baseline to the three-month follow-up. These results are not dissimilar to those reported elsewhere (Cuthbertson, Roughton, Jenkinson, MacLennan, & Vale, 2010; Sacanella et al., 2011). Although the long-term quality of life of the ICU-discharged patients at home differ among countries, varying by population and follow-up time, the scores of ICU survivors significantly decreased up to five years from discharge (Rai et al., 2020). As patients' quality of life's deterioration may have a serious impact also on relatives, reflections regarding the implications of treatments and the expected care needs after hospitalization need to be encouraged in ICU units (Douglas, Daly, & Lipson, 2012).

Moreover, findings regarding the experience of relatives reporting an overall satisfaction of >80% according to the FS-ICU tool, suggest that most of them were very satisfied with patient care and the decision-making processes, similarly to previous studies (Jensen et al., 2017; Pagnamenta et al., 2016). This result was achieved despite the lack of the relative's involvement due to the COVID-19 pandemic. However, a more accurate evaluation of family

satisfaction with care in ICU is encouraged to detect the effects of restrictive visitation measures prolonged in time, that might prevent the ability to provide family-centered care.

The lived experience of relatives

Three main themes summarize the experience of relatives in the first three months after ICU discharge: 'Being shaken following ICU discharge'; 'Returning to our life that is no longer what it used to be' and 'Feeling powerless due to the COVID-19 pandemic'.

In the first stage of the experience, when discharging from the ICU, relatives lived a twofold emotional condition. They felt despair and concerns regarding their beloved, findings consistent with those emerged from a two-month follow-up study involving 115 US carers where psychological burden (e.g. sad, distress, anxiety) have been reported (Im, Belle, Schulz, Mendelsohn, & Chelluri, 2004). Negative feelings were also aroused when relatives received conflicting information. As previously documented, the negative psychological impact on relatives is exacerbated when they do not receive sufficient support and consistent information from healthcare professionals (Hetland, McAndrew, Perazzo, & Hickman, 2018). However, while some of these emotions are unavoidable, such as being surprised and conflicted by what has happened, others (e.g., anger, fear) might be prevented and avoided by appropriate support.

On the other hand, relatives reported trusting the ICU staff and expressed gratitude for their work, suggesting that also in hard working conditions and barriers to an effective communication that have been limited to video-calls, healthcare professionals have been perceived as compassionate and effective in the care delivered. Conversely, no concerns for the relatives own physical health emerged at this stage from our findings.

The return to the daily routine implied a sort of invention of a new life: relatives immediately acquired awareness of the limitations of their beloved in the daily activities and the need to rearrange home environment (Choi et al., 2018), in order to adapt the traditional house to the new needs, a process that requires additional expense. Relatives seem to realize these limitations while at home and to find solutions in the lived moment, without being prepared: this unpreparedness might be a consequence of the absence of engagement during the in-hospital length of stay.

Searching for and obtaining support from the community services has also been reported by our relatives. As described in a cross-sectional study on 157 family carers of South Korea,

home care services, such as home-visit nursing or bathing, have been documented as positively impacting on healthy family functioning (Kim & Yeom, 2016). However, as not all these services are available, family carers reported having paid out of their own pocket to obtain such services. Additionally, the care daily required imposed a change of the relative's life and the need to accommodate the different roles and responsibilities played in their life. A systematic review on informal carers of ICU survivors involved in their care reported that up to 50% of them reduced their work hours, quit their job or had been fired (van Beusekom et al., 2016). These effects on jobs should be read in light of the economic crisis triggered by the COVID-19 pandemic and of the additional costs required by care at home, suggesting that relatives of ICU-discharged patients are at risk of acquired poverty that might affect their life and also that of their loved one.

The COVID-19 pandemic has affected ICU accessibility and relatives' engagement, with negative influences also at the time of discharge, making them unable to manage the complex conditions. On the other hand, the priority given to COVID-19 patients and units have affected the availability of healthcare opportunities (e.g. home health assistance, follow-up visits) (Kent, Ornstein, & Dionne-Odom, 2020). In addition, the pandemic has dramatically altered nearly every aspect of their life, including the most basic social interactions, forcing the person to be confined at home (Ambrosi et al., 2020). Therefore, relatives seem to have experienced a bilateral restriction of opportunities, both at the hospital and at the home level, regarding both the formal and informal care. Additionally, the minimization of contacts with healthcare professionals at the hospital and at the community level seems to have impaired the quality of care, suggesting that a strong investment in non-COVID-19 patients discharged from hospital should be considered a priority. The risk of having avoidable admissions in nursing homes is high, as reported by our relatives as a consequence of the care burden, which is also due to the poor support received, as previously documented prior to the COVID-19 pandemic (Kim & Yeom, 2016).

Implications of the findings

The consequences of the COVID-19 pandemic are actually international as lockdowns have increased anxiety and reduced resilience for relatives, while hospital visiting policies have been limited in most ICUs all over the world. To some extent, non-COVID-19 ICUs paid dearly by having the same restrictions as the COVID-19 ICUs. The current study can serve as an

introduction for nurses to (a) developing conditions for family members engagement during the in-hospital length of stay – by observing all COVID-19 preventive measures – and training programmes to overcome the unpreparedness while at home; (b) providing ICU follow-up also for family members, given that collecting carers experiences may be useful to monitor the quality of both hospital and community-based care; and (c) assessing over time the carers wellbeing, given that their health and quality of life are essential for the outcomes of the loved one, in order to avoid further readmissions to hospital or, worse, in long term facilities.

6.6 Limitations

The study has several limitations. First, sample recruitment was imposed by the second wave of the COVID-19 pandemic that began in Autumn 2020, thus introducing a potential selection bias. However, no additional codes and insights have emerged during the data analysis process, suggesting that data saturation (Vasileiou, Barnett, Thorpe, & Young, 2018) was reached. Second, a three-month follow-up was established by researchers. It would be of interest to also investigate relatives' long-term experiences, which could change over time. Third, as both the baseline and the three-month follow-up, the quality-of-life evaluation has been measured by interviewing relatives as a proxy – in line with earlier studies (Sacanella et al., 2011) – and this evaluation might have produced under or over estimations, suggesting the need to investigated the validity of these measures in a context where the proximity of relatives is limited by the restrictions imposed.

6.7 Conclusions

Relatives of critically ill patients discharged from a non-COVID-19 ICU experienced a mix of negative and positive feelings in the early stages. In terms of the return to their daily life, the need to change their life has been faced; the limitations of the community services available has triggered the search for additional support by private healthcare providers. Moreover, due to the COVID-19 pandemic, some issues of care have been exacerbated by altering the clinical pathway of the patient and forcing the dyad – the patient and his/her relative, toward loneliness. Relatives seem to have experienced a bilateral restriction of opportunities, both at the hospital, without any engagement and with limited possibility to

access the ICU, and at the home level in terms of formal and informal care. These individual experiences trigger urgent public health considerations in order to prevent patient and relative's mental and physical health issues.

Figure 6.1 Flowchart of patient recruitment and follow-up
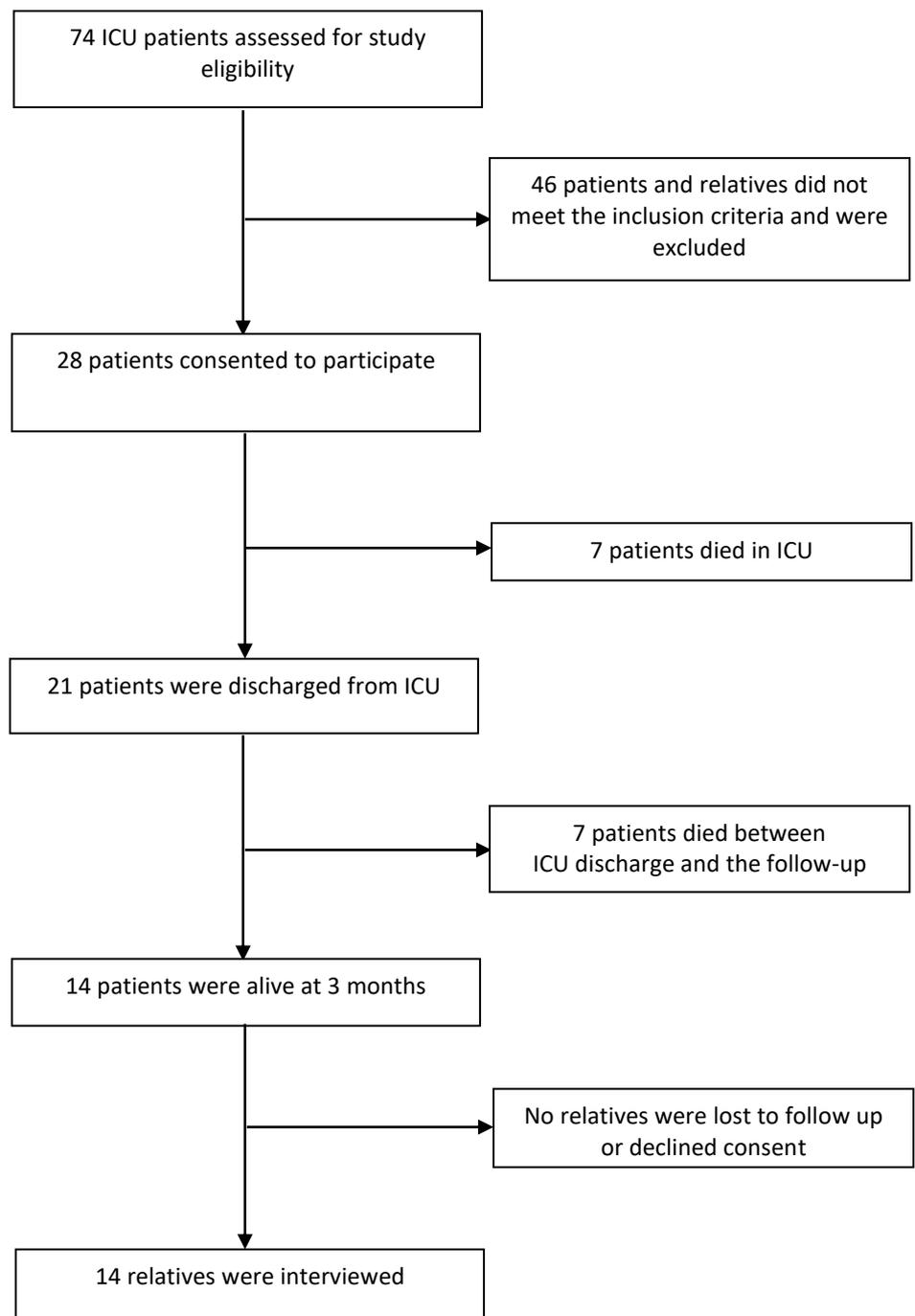
Legend: ICU = Intensive Care Unit.

Table 6.1 Data collection phases, time, and instruments

Timeline	Instrument and data collection process
From August to October 2020	
Within 48 hours of ICU admission	At the patient level, socio-demographic (e.g. age) and clinical (e.g. reasons for admission in ICU, comorbidities, RASS and APACHE II scores) data have been gathered by accessing clinical records. In addition, patient's quality of life with the SF-12 tool[a] was collected. This instrument demonstrated good psychometric properties (e.g., Cronbach's alpha median 0.83) and encompassed two domains summarised into a Physical Component Score (PCS; e.g., moderate activities) and Mental Component Score (MCS; e.g., calm and peaceful). At the relative level, in the same day, some demographic data were gathered by face-to-face interview (e.g., age, relationship to patient, education level).
Within 48 hours of ICU discharge	Relatives' satisfaction was investigated with the FS-ICU questionnaire[b], composed by two factors regarding the satisfaction with the care received (14 items; e.g., management of pain) and with the decision-making (10 items; e.g., feel control over the care of the patient). This instrument has been validated in the Italian ICU context and reported an internal consistency of Cronbach's alpha of between 0.944 and 0.962. A copy of the questionnaire was given to relatives by asking them to complete the survey and return it in an envelope at the time of the patient's ICU discharge.
From November 2020 to January 2021	
After three months following ICU discharge	Relatives' experience was collected through telephone interviews, as participants were not authorised to travel to the hospital or researchers were limited in conducting face-to-face interviews due to the pandemic restrictions. Each interview started with an open-ended question to introduce the discussion: "*Please, tell me about your experience just after the ICU discharge up to now*". Then, the following main question was introduced: '*Can you please share your experience about caring for your beloved and challenges you have encountered in daily life since the ICU discharge?*' Moreover, probing questions were asked during the call (e.g., '*What do you mean*?' and '*Can you explain this concept a little further?*') to clarify the experiences or turn the attention back to the main topic. In addition, the patient's quality of life with the SF-12 tool was collected as a proxy assessment by interviewing relatives.

Legend: ICU = intensive care unit; APACHE = Acute Physiology and Chronic Health Evaluation; RASS = Richmond Agitation-Sedation Scale; SF-12 = Short Form Health Survey-12; FS-ICU = Family Satisfaction in the ICU questionnaire.
[a] The SF-12 tool provides a score ranging from 0 (indicating the worse health status) to 100 (the best health status).
[b] The FS-ICU returns a score of 0–100 as recommended, with 0 representing the lowest satisfaction and 100 representing the highest satisfaction.

Table 6.2   Baseline and three-month follow-up socio-demographic characteristics of included patients

	Baseline n = 28	Three-month follow-up n = 14
Age (years), mean (SD; median)	67.3 (15.0; 72)	59.4 (16.0; 70)
Gender, n (%)		
Female	7 (25.0)	3 (21.4)
Male	21 (75.0)	11 (78.6)
BMI (kg/m^2), mean (SD; median)	25.2 (6.1; 24)	24.8 (6.0; 24)
Reason for ICU admission, n (%)		
Organ failure	17 (60.7)	6 (42.8)
Trauma	7 (25.0)	6 (42.8)
Cerebrovascular disease	3 (10.7)	2 (14.4)
Post-operative	1 (3.6)	-
At least one comorbidity, n (%)	17 (60.7)	8 (57.1)
APACHE 2 score, mean (SD; median)	17.00 (9.5; 18)	14.50 (8.5; 17)
RASS score, mean (SD; median)	-2.4 (1.7; -3)	-2.3 (1.7; -3)
Length of stay in ICU (days), mean (SD; median)	15.0 (8.0; 15)	18.0 (9.0; 15)
SF-12[a], mean (SD; median)		
PCS score	43.19 (12.44; 41)	37.38 (9.22; 38)
MCS score	49.02 (13.29; 54)	40.54 (13.44; 41)

Legend: SD = standard deviation; BMI = body mass index; ICU = intensive care unit; APACHE = Acute Physiology and Chronic Health Evaluation; RASS = Richmond Agitation-Sedation Scale; SF-12 = Short Form Health Survey-12; PCS = Physical Component Summary; MCS = Mental Component Summary.
[a] Data collected within 48 hours from patient's ICU admission and at three-month follow-up.

Table 6.3 Baseline and three-month follow-up socio-demographic characteristics of relatives

	Baseline n = 28	Three-month follow-up n = 14
Age (years), mean (SD; median)	55.4 (10.9; 50)	53.9 (9.5; 51)
Gender, n (%)		
Female	23 (82.1)	11 (78.6)
Male	5 (17.9)	3 (21.4)
Relationship to patient, n (%)		
Spouse/husband or significant partner	13 (46.5)	7 (50.0)
Daughter/son	10 (35.7)	3 (21.4)
Mother/father	2 (7.1)	2 (14.4)
Sister/brother	1 (3.6)	1 (7.1)
Other degree of relatedness	2 (7.1)	1 (7.1)
Education, n (%)		
Primary school	7 (25.0)	4 (28.6)
Secondary school	15 (53.6)	9 (64.3)
Degree or above	6 (21.4)	1 (7.1)
Employment, n (%)		
None	4 (14.3)	2 (14.4)
Public employee	8 (28.6)	5 (35.7)
Private employee	10 (35.7)	6 (42.8)
Retired	6 (21.4)	1 (7.1)
Prior experience with ICU, n (%)	8 (28.6)	4 (28.6)
Cohabitation with the patient, n (%)	13 (46.4)	8 (57.1)
How often the relative sees the patient, n (%)		
More than weekly	20 (71.4)	12 (85.6)
Weekly	7 (25.0)	2 (14.4)
Monthly	1 (3.6)	-
FS-ICU[a], mean (SD; median)		
FS-ICU/care	83.1 (10.3; 83)	-
FS-ICU/decision-making	81.2 (11.6; 81)	-
FS-ICU/total	82.4 (10.3; 82)	-

Legend: SD = standard deviation; ICU = intensive care unit; FS-ICU = Family Satisfaction in the ICU questionnaire.

[a] Data collected within 48 hours from patient's ICU discharge.

Table 6.4 Data synthesis by extracting and abstracting findings in common categories and themes

Abstraction: Themes	Abstraction: Categories	Codes as defined by researchers	Example of quotations extracted from interviews
Being shaken following ICU discharge	Experiencing negative feelings	Astonishment at unexpected news	*'Bad, really bad, no life expectancy... I remember these words, as if they were imprinted with fire'* [R1]
		Despair for what has happened	*'The situation is challenging. As relatives, we all suffer with him, every day'* [R1]
		Anger regarding conflicting information	*'In ICU I was told that the tracheostomy was going to be removed. In the ward, however, I was told that he would never swallow or eat again'* [R14]
		Fear of complications arising	*'I just hope the lung infection doesn't come back again…he wouldn't survive another illness'* [R9]
	Experiencing positive feelings	Trust in healthcare professionals	*'I have to fully rely on doctors and nurses, also because I'm not an expert and so I have to trust them'* [R1]
		Gratitude for the care provided	*'In my opinion he has always been well looked after. I have nothing to say about the care they gave him, I'm just grateful'* [R2]
Returning to our life that is no longer what we are used to	Realising that nothing can be as before	Awareness of the limitations	*"I haven't seen him for two months; I can only bring him his clothes once a week and leave them outside the ward"* [R9] *"He doesn't walk, he doesn't move by himself, he can't even sign. We're doing the paperwork for the disability pension"* [R2] *"For him to eat, everything has to be blended now, there is little to do, that's it"* [R14] *"An example: he is no longer able to cook pasta"* [R4]
		Rearrange the home environment	*"I got a stationary bike to allow her to do some exercise. He cannot still climb the stairs"* [R9]
	Searching for support in providing care	Benefit from community-based services	*"At home, we are followed by home care, a nurse visits us. If there are any critical issues, we ask her"* [R13]
		Enlist privately hired professionals	*"As to rehabilitation, I opted for a private service. I called a physiotherapist who is now helping us"* [R13] *"We've arranged a physiotherapist and a caregiver"* [R3] *"A private nurse comes twice a day"* [R13]
	Changing my life	Change my routine	*"At first I ate what he ate, so as not to give him cravings"* [R14] *'When we got home, I used to sleep in the living room so as not to stay too close and bring bacteria or viruses near him'* [R8]
		Balance caring with other activities	*'I had to take time off work to assist him'* [R10] *'I also have to get someone to do grocery shopping so that I don't leave him alone'* [R11]

		Early discharge from rehabilitation structure	'*It was a hard blow for him when he was discharged from the rehabilitation hospital – he needed one more month*' [R3]
Feeling powerless due to the COVID-19 pandemic	Altering the clinical pathway	Access denied to long-term care	'*She is still hospitalized due to COVID-19, she is not accepted in any other facility. I applied but we are still on hold*' [R4] '*The rehabilitation facility has fewer beds now ... neurorehabilitation, which he would need, is now occupied by COVID-19 patients*' [R7]
		Regular check-ups cancelled	'*The first visit with the doctor was put off due to COVID-19. In January, the neurological check was cancelled as well*'" [R10]
	Restricting family and friends visiting	Patients' loneliness	'*If he had any friends, someone who could stimulate him…*' [R7] '*Some colleagues and friends of hers came to the house, but only to the door, no further than that*' [R8]
		Missed carer training programme	'*We relatives should have had some training, but it was limited*' [R13]
	Thinking about the future	Make important choices	'*Where to place him is going to be a problem because he used to live on the second floor ... a more equipped facility is needed ... I think I will opt for a nursing home*' [R2] '*I thought that a facility was going to be the right option for her ... she would be looked after by people who are not just company but competent*' [R4]

Legend: R1 = Relative n.1; ICU = Intensive Care Unit; COVID = Coronavirus Disease.

7. Intensive Care Units as learning environment

Most of the content of this section has been published.

Danielis, M., Destrebecq, A. L. L., Terzoni, S., & Palese, A. (2021). Are intensive care units good places for nursing students' learning compared to other settings? Findings from an Italian national study. Intensive & Critical Care Nursing, 103074.

7.1 Introduction

In the context of nursing education, clinical rotations allow students to apply knowledge in a real environment, developing technical, relational and reasoning skills (Papastavrou, Dimitriadou, Tsangari, & Andreou, 2016). Students are required to attend different rotations that, across Europe, should account for 50% of the total duration of the undergraduate nursing education and must be offered in different settings (European Directive 2013/55/EU, (European Parliament, 2013). Areas of clinical training recommended by the European Directives do not include ICUs, but several nursing programmes also provide students to this clinical rotation because of its positive influence on learning (Williams & Palmer, 2014); moreover, even though the role of advanced educated nurses is recognised in critical care (Endacott et al., 2015), several countries still have only pre-registration clinical rotations in ICUs.

The ICU is a particular physical space in which critically ill patients, suffering from life-threatening conditions, are supported by advanced technology and continuous monitoring, and cared for by a multidisciplinary team (Marshall et al., 2017). To date, Swinny and Brady were among the first authors to answer the question of whether the ICU setting could be an effective clinical rotation (Swinny & Brady, 2010). The ICU environment has been recognised as providing students with the opportunity to perform a variety of technical skills (e.g., endotracheal tube suctioning, central line management), to learn through an interdisciplinary approach and to develop communication skills in stressful situations (e.g., end-of-life decision making) (Sanchez Exposito, Leal Costa, Diaz Agea, Carrillo Izquierdo, & Jimenez Rodriguez, 2018; Swinny & Brady, 2010).

From their perspective, nursing students have reported experiencing both positive and negative feelings during their ICU clinical training (Gonzalez-Garcia, Lana, Zurron-Madera, Valcarcel-Alvarez, & Fernandez-Feito, 2020), specifically, satisfaction for patient's favourable

evolution, personal enrichment, as well as expanded knowledge, have been described. On the other hand, some students acknowledged their difficulty in caring for patients who were in very serious conditions and dying (Gonzalez-Garcia et al., 2020). They have reported fear and anxiety before and during a shift, and that might potentially meddle with educational goals (Williams & Palmer, 2014). When students are not adequately prepared for ICU clinical rotation, learning and safety issues have been reported (Swinny & Brady, 2010).

Critically evaluating the value of the ICU clinical rotation is of great interest to contemporary nursing education (Ekstedt, Lindblad, & Lofmark, 2019; Woo & Li, 2020) and also with regards to the recent COVID-19 outbreak, which has called for a huge recruitment of nurses in ICUs around the world (Rosa et al., 2020). Positive learning experiences have been reported to increase learning outcomes, as well as increasing the likelihood of choosing the setting in a future career (Carlson & Idvall, 2014). However, the way to measure the effectiveness of a clinical rotation is still debated: several qualitative (Baraz, Memarian, & Vanaki, 2015; Jamshidi, Molazem, Sharif, Torabizadeh, & Najafi Kalyani, 2016; Kalyani, Jamshidi, Molazem, Torabizadeh, & Sharif, 2019) and quantitative (Nicotera, Altini, & Dimonte, 2017) studies have been conducted suggesting that the perception of students, as measured by validated tools, can be considered the gold standard (Mansutti, Saiani, Grassetti, & Palese, 2017). Employing a validated tool also allows comparison across units; different clinical learning environments have been investigated to date in their perceived effectiveness, from acute care hospitals – as in medical and surgical (Bisholt, Ohlsson, Engstrom, Johansson, & Gustafsson, 2014; Ekstedt et al., 2019; Pitkanen et al., 2018) – to long-term care facilities, such as nursing homes (Carlson & Idvall, 2014; Gonella et al., 2019). However, to our best knowledge, no studies exploring nursing students' experience of an ICU clinical learning environment are available to date. Having evidence on students' learning experiences in this context, as well as comparing this evidence with other settings, might help nurse educators to understand the value of this rotation, and clinical nurses and managers to implement strategies to increase its effectiveness. Therefore, the main aims of this study were to: (a) explore students' perceived quality of the ICU environment during their clinical rotations, (b) compare these perceptions with those reported by students attending other settings, and (c) assess correlations, if any, between the perceived quality of the environment attended and the competences gained.

7.2 Methods

Design

The researchers performed a secondary analysis of a previous cross-sectional national research conducted between 2015 and 2016 (Palese et al., 2016). The 'Strengthening the Reporting of Observational Studies in Epidemiology' (STROBE) guidelines for cross-sectional studies were followed to improve accuracy and transparency (von Elm et al., 2014).

Setting and participants

In Italy, since 2003, all nurses have been educated at the university level with a Bachelor of Nursing Science (BNS) degree lasting 3 years, for a total of 5,400 hours (180 credits) (Palese et al., 2014). Theoretical education regarding patients in need of intensive care is offered in the final year, composed of different clinical modules (e.g., anaesthesiology, emergency surgery, orthopaedics and traumatology, intensive and critical care nursing). Clinical rotations are then offered in National Health Service units in an agreed pattern – with some local variations (Di Giulio, Palese, Saiani, & Tognoni, 2020) – that is reflected as follows: first-year students usually attend two rotations (e.g., medical and surgical units); second-year students attend around three rotations (e.g., oncology, cardiac and vascular surgery); and third-year students are exposed to different units (e.g., mental health, maternal and child, intensive care settings).

In this context, a network of BNS degrees was established by promoting the participation of all nursing programmes (n = 208) of available universities (n = 43) in Italy (Palese et al., 2016). Initially, all were invited, and three recalls at two-week intervals were then performed. A network of 27 universities with their 95 BNS degrees participated, spread in 15 Italian regions. Those students who a) were attending the nursing education in one of the programmes composing the network, b) attended the same unit for at least a couple of weeks, and c) desired to take part in the research, were all eligible.

Data collection and instruments

Each nursing programme identified a researcher responsible for the recruitment; the researcher shared the study aims with the potential participants and verified the inclusion criteria before data collection. Depending upon the resources available at the local level, data was collected via a questionnaire administered through two methods: web-based

(Google Drive) and paper-and-pencil. As a preliminary measure, the comprehension and feasibility of the questionnaire were ensured through a pilot involving 100 students. At the end of the process, no changes were required. The final tool concerned three dimensions of variables:

(1) socio-demographic (e.g., age, previous education);

(2) previous clinical learning experiences (e.g., number, settings); and

(3) current clinical learning experience (e.g., unit attended, duration in weeks).

To assess the quality of the learning environment, the Clinical Learning Quality Evaluation Index (CLEQI) was used (Palese et al., 2017). This tool is formed by a total of 22 items, categorised in 5 factors measuring (a) the quality of tutorial strategies, (b) the perceived opportunities of learning, and that of (c) self-directed learning, as well as the (d) quality and safety of care delivered, and (e) the overall quality of the learning environment. Participants were asked to rate each item (Likert scale; from 0 = nothing, to 3 = very much). The higher the score, the higher was the quality of the environment for learning. The original tool was found to be reliable, valid and appropriate in its internal structure and construct (Palese et al., 2017). Moreover, participants were asked to rank the overall perceived level of competences (Likert scale; from 0 = none, to 3 = very much).

Data analysis

Data were analysed using SPSS Software (version 26.00, IBM Corporation, 2020), setting the significance at $p < 0.05$, two tailed. Evaluation of the perceived quality of the learning environment was made between the stratified group of ICU students and non-ICU students (= attending their rotations in other units). Descriptive statistics were performed by calculating averages (with 95% confidence interval [CI]), absolute values and percentages. Differences in data distribution, if any, between the ICU and non-ICU students were explored through the chi-squared test and the t-test. Correlations (Spearman's test, ρ) between the overall competences learned and the CLEQI factors/item scores were also performed. Correlations were considered as weak when ρ coefficient was < 0.50, moderate from 0.50 to 0.70, and strong when > 0.70 (Mukaka, 2012).

Bias control

In order to ensure the process was trustworthy (Yang, Chang, & Chung, 2012), the researchers followed some strategies to control biases.

(a) Selection: Invited all active undergraduate nursing programmes in Italy by engaging as many Bachelors' degrees as possible.

(b) Information: Involved experienced researchers' experts in nursing education and research, both at the national and local levels; Standardised informed participants, by giving them truthful information about the study procedures and aims; Implied a standardized – validated questionnaire to collect data.

(c) Recall: Asked students filling out the questionnaire mandatorily on their last week of the clinical experience in ICU or within a period of two weeks from the end of it.

Ethical considerations

The research protocol was first developed and approved by the national network (Palese et al., 2016). Then, appropriate permissions were obtained from the Milano Statale University (number 40/15). The privacy, rights and confidentiality of participants were ensured throughout each phase of the study. Students were free to participate or not, and no incentives were offered. Before data collection, the students' written consent was collected.

7.3 Results

Participants

There were 9,607 (91.6%) undergraduate nursing students engaged, out of the 10,480 eligible. Among them, 324 (3.5%) attended their clinical rotation in an ICU. As described in Table 7.1, no difference emerged from ICU and non-ICU students in terms of age, gender, civil status, children and secondary education. ICU students were more often attending the third academic year compared with non-ICU students (77.1% vs. 33.9%; $p < 0.001$). Additionally, ICU students reported more previous clinical experiences compared to non-ICU students (mean 7.66 vs. 4.81; $p < 0.001$). Moreover, these experiences were attended largely at the hospital and community levels by ICU students as compared to non-ICU students (44.7% vs. 29.8%; $p < 0.001$).

The quality of the clinical environment

ICU students were supervised significantly more frequently by a clinical nurse (63.5% vs. 52.9%, p < 0.001) and far less by the staff (31.3% vs. 40.1%) compared to non-ICU students (Table 7.2).

At the overall level, ICU students scored the quality of the learning environment significantly higher (n = 2.11 out of 3; 95% CI = 2.05, 2.17) than the non-ICU students (n = 1.91, 95% CI = 1.89, 1.92; p = < 0.001). Moreover, the highest scores were perceived by ICU-students in the "Safety and nursing care quality" factor (n = 2.35; 95% CI = 2.29, 2.40) compared to those attending their rotation elsewhere (n = 2.07; 95% CI = 2.05, 2.08; p < 0.001), followed by the "Quality of the learning environment" factor (n = 2.25; 95% CI = 2.18, 2.33 vs. 2.02; 95% CI = 2.01, 2.04; p < 0.001, respectively). The "Quality of the tutorial strategies" were also perceived to be significantly higher by students attending their clinical rotation in ICU (n = 2.13; 95% CI = 2.05, 2.20) compared to their non-ICU colleagues (n = 1.97; 95% CI = 1.95, 1.98; p < 0.001). Furthermore, as reported in Table 7.2, ICU students reported more appreciation in both "Learning opportunities" (n = 2.11; 95% CI = 2.04, 2.18 vs. 1.96; 95% CI = 1.95, 1.98; p < 0.001) and "Self-directed learning" (n = 1.68; 95% CI = 1.59, 1.77 vs. 1.50; 95% CI = 1.48, 1.51; p < 0.001) compared to their colleagues.

Degree of competences achieved

ICU students reported higher competences learned compared to non-ICU students (n = 2.31 out of 3; 95% CI = 2.23, 2.39 vs. n = 2.06, 95% CI = 2.05, 2.08; p < 0.001). The proportion of students who reported to have learnt "very much" was significantly greater in the ICU group compared to non-ICU students (44.3% vs. 30.0%; p < 0.001).

The overall CLEQI score significantly correlated to the competencies learned both by ICU (ρ = 0.652; p < 0.01) and non-ICU students (ρ = 0.630; p < 0.01) (Table 7.3). Similarly, the relationship between the CLEQI factor and item scores and the perceived level of competence achieved was significantly positively correlated for both ICU and non-ICU students (ρ ranged from 0.357 to 0.638 and from 0.358 to 0.615, respectively).

7.4 Discussion

The study assessed the quality of ICU environments and the level of competences learned by students compared to the perceptions reported by students attending other units. As far as we know, this is the largest national study performed to date in a research field that has produced a limited evidence regarding undergraduate students (Gonzalez-Garcia et al., 2020), also because clinical learning in this context is expected during the advanced education.

Most of our respondents attending ICU clinical rotation were third-year nursing students. This can be explained by the fact that the Italian undergraduate curriculum incorporates critical care teaching in the last year of the bachelor's degree. This may also explain why these students attended more previous clinical experiences in both hospital and community settings compared to those experiencing clinical rotations in other contexts. Particularly during the final year, nursing students are expected to have knowledge and skills and to function in a more independent manner (Kobe, Downing, & Poggenpoel, 2020), and nurse educators might expose them to the complex ICU environment (Gonzalez-Garcia et al., 2020). However, a shortage of nurses has also been reported to affect nursing education by reducing clinical placements (Rauch & Malloy, 2020). As a result, nurse educators might have also been forced to place some first- or second-year students in ICU, albeit to a lesser extent. In total, only 3.5% of nursing students have been reported to have attended an ICU. This result can be explained by the fact that the student's independence is limited in a complex context such as an ICU, thus requiring more nurse preceptors (Gonzalez-Garcia et al., 2020), which are often not available due to the nursing shortage. On the other hand, nursing programmes located in rural areas or those ensuring their clinical placements in rural hospitals might have less opportunity to ensure rotations in ICUs. Furthermore, some nursing programmes might offer only those settings recommended by the EU directives (European Parliament, 2013), where ICU settings are not mentioned; the same programmes might also be hesitant to offer clinical rotations in ICU due to the limited evidence available on its effectiveness.

According to the findings, ICU students were more likely supervised by a clinical nurse compared to students in other settings, and this seems to be consistent with the nurse-to-patient ratio in ICU. Being supervised individually by an expert nurse in caring for such complex and challenging patients is a great opportunity for students (Omer, Suliman,

Thomas, & Joseph, 2013). However, around one third of students have been supervised by the entire staff, and this might increase their uncertainty, given the variability of caring approaches across nurses.

With regards to the quality of the learning environment, higher mean scores in all factors have emerged among students who attended the ICU as compared to those attending their rotation in other care settings. Few studies have been documented in critical care settings to date, all of which are qualitative in design (Alteren, 2019; Gonzalez-Garcia et al., 2020). The findings that emerged are in line with that documented in Spain, where students attending ICU rotations felt supported by nursing preceptors, who thus provided good role models (Gonzalez-Garcia et al., 2020).

Moreover, a higher percentage of ICU students reported having learned 'very much' compared to non-ICU students, also suggesting that nursing students might have a great opportunity to learn in the complexity of the ICU. Firstly, students can gain experience of learning in multidisciplinary teams in ICU environments, breaking down barriers – with medical staff in particular – and developing communication skills (Williams & Palmer, 2014). Secondly, students might have the opportunity to learn under the primary nursing model in the ICU by assuming the responsibility of the whole care process, from performing technical procedures (e.g., vascular access placement, airway management) to addressing the fundamental care needs (e.g., patient' comfort, family involvement) (Minton et al., 2018). Moreover, nursing students in ICU might also develop skills which are essential for any nurse in every context, such as promptly recognizing and responding to a deteriorating patient (Cooper et al., 2010). The quality of the education experience might influence the desire to work in a specific area (Wareing, Taylor, Wilson, & Sharples, 2018); therefore, as third-year nursing students will soon graduate and begin looking for employment, perceived satisfaction could lead to the identification of the ICU as a working option.

The perceived competences learned and the CLEQI scores among ICU and non-ICU students reported a moderate strength (Mukaka, 2012), as in other settings. This suggests that, as for other traditional clinical placements settings, the ICU might be a useful experience for students when the quality of the clinical environment is good. Therefore, in promoting the inclusion of ICU in nursing education, the quality of the learning environment should be considered with care in order to increase the likelihood that it will contribute to achieving the degree of competence expected.

7.5 Limitations

The study has several limitations. First of all, the nursing students' perceptions were assessed: their different self-directed learning skills, which were not assessed, might have influenced their evaluations. Secondly, local adaptations of curricula at the BNS degree level (e.g., organization of the theoretical critical care nursing course, number of hours of training in ICU) might have shaped nursing students' expectations and skills regarding the critical care context, thus affecting results. Thirdly, different patients might have been cared for in the ICU, as general or specialist ICUs: this data has not been collected and might have affected the findings. Moreover, we compared unbalanced groups of students, with a few of them attending their clinical learning rotations in ICU and most attending other settings.

7.6 Conclusions

This study adds a direct viewpoint of the nursing students' education in the ICU setting, on a large scale, by reporting their perceptions about the quality of the clinical learning environment and the competences learned.

According to the findings, ICU students reported a higher appreciation of the quality of the learning environment in all dimensions compared to non-ICU students, in terms of the quality of the tutorial strategies, the perceived opportunities of learning and that of self-directed learning, as well as the quality and the safety of care delivered. Moreover, students perceived a high degree of competencies achieved in this setting compared to their colleagues. Therefore, ICU should be considered by nurse educators as a place for clinical rotation, according to the learning opportunities available, only in high acuity areas that can promote positive attitudes regarding the prompt detection of clinical deterioration.

Alongside the possible influence of being exposed to positive learning experiences during undergraduate education with regards to future career choices, newly graduated nurses should be equipped with the knowledge and skills needed to face the high level of care required by patients, regardless of the location within the health care setting. Therefore, anticipating and responding to these challenges by ensuring appropriate ICU rotations might increase the readiness of future nurses. However, establishing an appropriate balance between the critical care competences that should be achieved during the undergraduate education and those that should be achieved in the postgraduate programmes are at merit of discussion, especially in countries such as Italy where no requirements are established for

nurses who are recruited into ICUs.

Table 7.1   Participants (n = 9607)

	ICU setting N = 324 (3.5%)	Other settings N = 9283 (96.5%)	p-value[§]
Participant profile			
Age, years, mean (95% CI)	23.46 (23.05-23.88)	22.87 (22.79-22.96)	0.078
Female gender (n = 9596), n (%)	237 (73.1)	7066 (76.2)	0.208
Civil status, (n=9524) n (%)			
Unmarried	301 (94.4)	8744 (94.9)	0.137
Married/cohabitant	14 (4.4)	421 (4.6)	
Divorced	3 (0.9)	34 (0.4)	
Widowed	1 (0.3)	6 (0.1)	
With children, n (%)	15 (4.6)	413 (4.5)	0.890
Secondary education (n=9442), n (%)			
High school	248 (76.8)	6382 (69.9)	0.135
Technical school	10 (3.1)	400 (4.4)	
Professional school	42 (13.0)	1476 (16.2)	
Teacher school	20 (6.2)	748 (8.2)	
Secondary school abroad	3 (0.9)	113 (1.3)	
Academic year attended (n=9579), n (%)			
First	14 (4.3)	2895 (31.3)	<0.001
Second	60 (18.6)	3222 (34.8)	
Third	249 (77.1)	3139 (33.9)	
Previous academic experience (n=9515), n (%)			
None	207 (64.5)	6380 (69.4)	0.147
Graduated in other fields	17 (5.3)	403 (4.4)	
Incomplete degree	96 (29.9)	2330 (25.3)	
Other	1 (0.3)	81 (0.9)	
Secondary education grade score (n=9312), mean (95% CI)	76.58 (75.38-77.78)	76.88 (76-66-77.09)	0.615
On a 100-point scale (n=9108, 97.8%)	45.77 (41.12-50.43)	45.41 (44.26-46.55)	0.884
On a 60-point scale (n=172, 1.4%)	8.90 (7.63-10.17)	7.77 (7.29-8.24)	0.228
On a 10-point scale (n=32, 0.8%)			
Previous work experience (n=9553), n (%)	105 (32.5)	3196 (34.6)	0.475
Work experience during the degree (n=9526), n (%)	76 (23.5)	1866 (20.3)	0.160
Previous clinical experiences (n=9498)			
Experiences, n, mean (95% CI)	7.66 (7.28-8.04)	4.81 (4.75-4.88)	<0.001
Setting (n=9551), n (%)			
Only hospital	175 (54.7)	6331 (68.6)	<0.001
Only community setting	2 (0.6)	151 (1.6)	
Hospital and community setting	143 (44.7)	2749 (29.8)	

Legend: ICU, Intensive Care Unit; SD, Standard Deviation; CI, Confidence Interval; N, Number.
[§] Chi-squared for dichotomous variables, T test or Mann-Whitney U test.

Table 7.2 The last clinical experience

	ICU setting N = 324 (3.5%)	Other setting N = 9283 (96.5%)	p-value[§]
Duration, weeks, mean (95% CI)	5.48 (5.22-5.77)	5.82 (5.77-5.87)	0.090
Tutorial model of the last clinical experience (n=9563), n (%)			
I was supervised by a clinical nurse	205 (63.5)	4891 (52.9)	0.001
I was supervised by the nursing staff	101 (31.3)	3703 (40.1)	
I was supervised by nurse identified on a daily basis by the head nurse	1 (0.3)	92 (0.9)	
I was supervised by the nurse teacher	15 (4.6)	390 (4.3)	
I was supervised by the head nurse	1 (0.3)	164 (1.8)	
CLEQI factor scores, mean (95% CI)[a,b]			
Quality of the tutorial strategies	2.13 (2.05-2.20)	1.97 (1.95-1.98)	<0.001
The preceptor[c] explained me the clinical thinking underlying clinical decisions	2.16 (2.08-2.25)	1.97 (1.95-1.99)	<0.001
The preceptor[c] asked me questions to help me in clinical thinking	2.26 (2.17-2.34)	1.98 (1.96-2.00)	<0.001
I had the opportunity to share with the preceptor[c] the emotions experienced during the clinical experience	2.03 (1.93-2.13)	1.97 (1.95-1.99)	0.227
The preceptor[c] mediated my relationship with patients/ family members in difficult situations	1.97 (1.88-2.07)	1.82 (1.80-1.83)	0.002
The preceptor[c] mediated my relationship with patients/ family members in difficult situations	2.13 (2.04-2.21)	2.01 (1.99-2.02)	0.014
The preceptor[c]'s final evaluation was consistent with the feedback I received during the clinical experience	2.22 (2.13-2.30)	2.05 (2.03-2.07)	0.001
Learning opportunities	2.11 (2.04-2.18)	1.96 (1.95-1.98)	<0.001
I felt trust	2.14 (2.06-2.23)	2.03 (2.01-2.05)	0.014
I was given the opportunity to experience activities independently	2.16 (2.07-2.25)	2.03 (2.01-2.04)	0.004
I was given an adequate amount of responsibilities	2.10 (2.02-2.18)	1.91 (1.90-1.93)	<0.001
I was given the opportunity to express my opinions and critical reflections	2.03 (1.95-2.12)	1.90 (1.88-1.92)	0.004
I felt respected as a student	2.15 (2.05-2.24)	1.98 (1.96-1.99)	<0.001
I felt encouraged during difficult situations	2.31 (2.23-2.39)	2.15 (2.14-2.17)	<0.001
Self-directed learning opportunities	1.68 (1.59-1.77)	1.50 (1.48-1.51)	<0.001
I was offered meetings about my learning needs	1.54 (1.42-1.65)	1.33 (1.31-1.35)	<0.001
I was invited to develop my self-learning plan	1.72 (1.61-1.81)	1.55 (1.54-1.57)	0.001
I was invited to do a self-evaluation	1.80 (1.70-1.89)	1.61 (1.59-1.63)	<0.001
Safety and nursing care quality	2.35 (2.29-2.40)	2.07 (2.05-2.08)	<0.001
Nurses fulfilled good standard of professional practice	2.35 (2.28-2.42)	2.05 (2.04-2.07)	<0.001
Patient's safety was guaranteed	2.47 (2.40-2.54)	2.16 (2.14-2.17)	<0.001
Individual and safety devices were accessible	2.46 (2.39-2.55)	2.18 (2.16-2.19)	<0.001
Nurses showed passion for the profession	2.10 (2.02-2.18)	1.87 (1.86-1.89)	<0.001
Quality of the learning environment	2.25 (2.18-2.33)	2.02 (2.01-2.04)	<0.001
This setting has been a good learning environment	2.34 (2.25-2.42)	2.12 (2.10-2.14)	<0.001
Overall, I am satisfied with my clinical learning experience	2.37 (2.29-2.46)	2.17 (2.16-2.20)	<0.001
I would like to come back to this setting to work	2.16 (2.06-2.28)	1.95 (1.93-1.98)	<0.001
Overall CLEQI score[a,b]	2.11 (2.05-2.17)	1.91 (1.89-1.92)	<0.001
Competence learned in the last clinical experience (n=9577), mean (95% CI) [a,b]	2.31 (2.23-2.39)	2.06 (2.05-2.08)	<0.001
None	3 (0.9)	89 (0.9)	<0.001
Little	35 (10.9)	1951 (21.2)	
Some	142 (43.9)	4438 (47.9)	
Very much	143 (44.3)	2776 (30.0)	

Legend: ICU, Intensive Care Unit; SD, Standard Deviation; CI, Confidence Interval; CLEQI, Clinical Learning Quality Evaluation Index.

[§] Chi-squared for dichotomous variables, T test or Mann-Whitney U test.

[a] The last clinical experience was that under evaluation.

[b] On a 4-point Likert scale (0 = none; 3 = very much).

[c] Preceptor/clinical nurse, nursing staff, nurse identified on a daily basis by the head nurse, or nurse teacher according to the tutorial model adopted.

Table 7.3 Correlations between perceived degree of competence learned and the CLEQI factors and item scores

CLEQI factors and item scores [a,b]	ρ in ICU setting	ρ in other setting
Quality of the tutorial strategies	0.589[*]	0.546[*]
The preceptor[c] explained me the clinical thinking underlying clinical decisions	0.564[*]	0.478[*]
The preceptor[c] asked me questions to help me in clinical thinking	0.569[*]	0.470[*]
I had the opportunity to share with the preceptor[c] the emotions experienced during the clinical experience	0.469[*]	0.457[*]
The preceptor[c] mediated my relationship with patients/ family members in difficult situations	0.403[*]	0.415[*]
The preceptor[c] mediated my relationship with patients/ family members in difficult situations	0.504[*]	0.497[*]
The preceptor[c]'s final evaluation was consistent with the feedback I received during the clinical experience	0.460[*]	0.439[*]
Learning opportunities	0.591[*]	0.557[*]
I felt trust	0.544[*]	0.465[*]
I was given the opportunity to experience activities independently	0.507[*]	0.440[*]
I was given an adequate amount of responsibilities	0.498[*]	0.465[*]
I was given the opportunity to express my opinions and critical reflections	0.502[*]	0.453[*]
I felt respected as a student	0.417[*]	0.455[*]
I felt encouraged during difficult situations	0.426[*]	0.439[*]
Self-directed learning	0.462[*]	0.446[*]
I was offered meetings about my learning needs	0.450[*]	0.395[*]
I was invited to develop my self-learning plan	0.365[*]	0.388[*]
I was invited to do a self-evaluation	0.357[*]	0.361[*]
Safety and nursing care quality	0.498[*]	0.514[*]
Nurses fulfilled good standard of professional practice	0.398[*]	0.462[*]
Patient's safety was guaranteed	0.364[*]	0.368[*]
Individual and safety devices were accessible	0.377[*]	0.358[*]
Nurses showed passion for the profession	0.411[*]	0.441[*]
Quality of the learning environment	0.638[*]	0.615[*]
This setting has been a good learning environment	0.617[*]	0.590[*]
Overall, I am satisfied with my clinical learning experience	0.601[*]	0.592[*]
I would like to come back to this setting to work	0.462[*]	0.495[*]
Overall CLEQI score	0.652[*]	0.630[*]

Legend: ICU, Intensive Care Unit; SD, Standard Deviation; CI, Confidence Interval; CLEQI, Clinical Learning Quality Evaluation Index; ρ, Spearman's test coefficient.
[a] The last clinical experience was that under evaluation.
[b] On a 4-point Likert scale (0 = nothing; 3 = very much).
[c] Preceptor/clinical nurse, nursing staff, nurse identified on a daily basis by the head nurse, or nurse teacher according to the tutorial model adopted.
[*] $p \leq 0.01$.

8. Thesis conclusions

Overview of the results obtained

The aims of this PhD thesis were to dissect published literature to recognize the contribution of nursing care in intensive care environments and to advance knowledge by planning and conducting a nursing intervention to achieve specific outcomes in critically ill patients.

To date, 35 NSOs were reported and grouped in seven sub-domains (healthcare-associated infections, critical incidents, goal assessment and monitoring, general health, psychosocial dimension, physical dimension, experience of being in intensive care) and four domains according to Doran's classification (safety, clinical, functional and perceptual). The most commonly reported outcome was pressure ulcers.

Additionally, a total of 21 nursing care factors have been linked with those NSOs. As to structural dimension, nursing factors have been investigated both at organisational level (work environment, magnet hospital proprieties, nurse-physician communication and material availability), and at personnel level (nurse staffing, nurse specialist role and nurses' experience). As to process dimension, nurse-led programmes (early mobility programmes, checklists, algorithms and specific assessment tools, family participation in patient care, educational and reality orientation programmes), nurse's independent interventions (music therapy, massage interventions, relaxation and guided imagery, body positioning, therapeutic touch, aromatherapy, cold application), and nurse behaviours (care bundle compliance and night-time care routine interactions) have been reported.

Due to the scarce research which investigates family member's contributions to care in ICU, including its outcomes on family itself and on patient care, a research project aiming at assessing the effects of a family engagement program on family members' satisfaction and on patients' well-being and quality of life has been developed. Unfortunately, data collection deviated from the original quasi-experimental study because the family engagement intervention under investigation was suspended due to the COVID-19 pandemic. A purposeful sampling of 14 relatives of adult patients who had been cared for in non-COVID-19 ICU were selected and interviewed after a three-month period following the ICU discharge. The relatives' caring of a discharged beloved is summarized in three themes: "Being shaken following the ICU discharge", as experiencing negative and positive feelings; "Returning to our life that is no longer what we were used to", as realizing that nothing

could be as before; and "Feeling powerless due to the COVID-19 pandemic", given the missed care from community services and the restrictions imposed by the public health measures regarding home visiting.

With regard to the COVID-19 pandemic, a European survey revealed the increase, up to more than 50%, in ICU beds and the introduction of new staff to assist the critically ill patients. Nursing care for critically ill patients has undergone important changes: some physical needs were inevitably compromised, and the interaction with family members was significantly reduced. Moreover, the constant use of personal protective equipment contributed to an increase in nurses' physical workload. Psychologically, many nurses have reported having to cope with stressful situations.

Nevertheless, non-COVID-19 ICUs are highly appreciated by students, both in terms of the quality of the learning environment and their capacity to promote learning as compared to other settings. 323 students perceived the quality of the environment to be significantly higher (n = 2.11 out of 3) than those rotating in non-ICU wards (n = 1.91; p < 0.001). The competences learned by ICU students were significantly higher than those reported by students attending non-ICU wards (n = 2.31 out of 3 vs. 2.06 out of 3; p < 0.001).

Implications

This thesis tried to answer the question pinpointed in the Preface: what does the nurse actually produce? Referring in particular to the ICU context, a large heterogeneity of outcomes that measure the effects of nursing care emerged from the scoping review. Future efforts to establish homogeneous conceptual and operative definitions are required. Furthermore, additional endeavours in establishing perceptual outcomes, or those close to the fundamentals of nursing care, were suggested in this thesis.

The set of nursing factors that emerged from the rapid review can be considered as a basis for further research, especially regarding least developed areas. Therefore, emergent nursing care factors can be used as a blueprint to design and develop educational programmes both at under- and postgraduate levels. In addition, at managerial levels, both structural and procedural dimensions of nursing care, which are capable of affecting outcomes, could be used to inform decision making. The reviews highlight the need for further research that produces more causal relationship between the NSOs that are found to be less explored and nursing activities in ICUs.

The FENICE protocol presented in this thesis constitutes a significant step in a research agenda aimed at deepening the NSOs' reliability across ICUs and a useful tool to proxy monitoring the quality of hospital care. Its results may have the potential, on one hand, to provide additional evidence to family participation in bedside care in the ICU, and on the other hand, to better understand how family members and critically ill patients benefit from this engagement. As confirmation, relatives of critically ill patients discharged from an ICU reported the need to receive appropriate hands-on training or education. Routine family visiting policies should be resumed in ICUs as soon as possible by promoting active engagement with care activities; likewise, healthcare services should give priority to discharged patients in an attempt to compensate for the missed care. In times of the COVID-19 pandemic, patients and families need to be supported with alternative solutions, such as telephone consultations with nurses and physicians and the professional online support and follow-up.

From an educational point of view and according to the available learning opportunities, ICUs should be considered by nurse educators as a place for clinical rotation that can promote positive attitudes regarding the prompt detection of clinical deterioration. Establishing an appropriate balance between the critical care competences that should be achieved during the undergraduate education (e.g., patient outcomes) and those skills that should be achieved in postgraduate programs (e.g., the specific interventions to achieve those outcomes) is worthy of discussion.

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Appendix 1

The Regional Ethics Committee of the Friuli Venezia Giulia approval (CEUR-2020-Sper-012).

ARCS
Azienda Regionale
di Coordinamento
per la Salute

REGIONE AUTONOMA FRIULI VENEZIA GIULIA

Egr. Dott. Matteo Danielis
Corso di Laurea in infermieristica
Dip. di Area Medica – Università degli studi di
Udine
E,mail: matteo.danielis.@uniud.it

e p.c.
Egr. dr. De Monte Amato
Dipartimento di Anestesia e Rianimazione
ASUFC di Udine

Gent.ma Sig.ra Elda Cameranesi
Direttore SOC Affari Generali Azienda
Sanitaria Universitaria
Friuli Centrale (ASU FC)

OGGETTO: Trasmissione parere CEUR (seduta dd.11/02/2020 - odg 4.1)

ID studio	3070
Codice interno al centro	NON APPLICABILE
Tipologia studio	Interventistico senza farmaco e dispositivo
Tipo studio	No Profit
Codice studio	FENICE
Titolo studio	"Family ENgagement in Intensive Care Environments (FENICE): a quasi-experimental study protocol"
EudraCT	//
Promotore	Università degli studi di Udine
CRO	NA
Centro - UO	Azienda Sanitaria Universitaria Friuli Centrale (ASU FC)- Dipartimento di Anestesia e Rianimazione
Centro coordinatore	Dipartimento di Anestesia e Rianimazione ASU FC Udine
Sperimentatore	De Monte Amato
Documentazione	• Protocollo di studio v. 2 del 19.01.2020 • Lettera di chiarimenti a seguito di parere sospensivo

struttura competente: Comitato Etico Unico Regionale FVG- sede operativa: C.R.O. via F. Gallini 2-33081 Aviano; sede legale: c/o ARCS
responsabile del procedimento: Alessandra Bearz, telefono 0432 1438091, mail: comitato.etico@arcs.sanita.fvg.it
responsabile dell'istruttoria: Caterina Comand, telefono 0432 1438092, mail: caterina.comand@arcs.sanita.fvg.it
Sede legale di ARCS: Udine – Via Pozzuolo 330 Tel.: + 39 0432/1438010 C.F./P.IVA 02948180308, PEC: arcs@certsanita.fvg.it

Documento informatico redatto e sottoscritto digitalmente ai sensi degli artt. 20 e 21 del D.Lgs 82/2005 (codice dell'amministrazione digitale); originale
disponibile presso gli Uffici dell'Azienda Regionale di Coordinamento per la Salute - ARCS

Lo studio valutato nella seduta del 17.12.2019, con parere sospensivo, viene riportato in seduta per una rivalutazione in relazione agli aspetti statistici. Il Comitato esaminata la documentazione ripresentata esprime **parere FAVOREVOLE** all'unanimità.

Parere-CEUR-2020-Sper-012

Le decisioni sono assunte a maggioranza assoluta dei presenti aventi diritto al voto. I componenti del Comitato si sono astenuti dal pronunciarsi su quelle sperimentazioni per le quali possa sussistere un conflitto di interesse di tipo diretto o indiretto.

Questo Comitato Etico dovrà essere informato della data di inizio e di conclusione della sperimentazione, dell'eventuale sospensione od interruzione della stessa, per qualsiasi causa.

Si rammenta che la presente lettera non costituisce autorizzazione all'avvio dello Studio, presso la Struttura Operativa in indirizzo, e che detta autorizzazione dovrà essere formalizzata con successivo decreto della Direzione aziendale.

Distinti saluti

il Presidente del Comitato Etico Unico Regionale
Claudio Fresco
Firmato digitalmente

All.: Foglio firme dd 11.02.2020

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Il Comitato Etico Unico Regionale, istituito ai sensi del Decreto 8 febbraio 2013 e Legge Regionale n. 33 del 29.12.2015, con DGR 22 gennaio 2016 n. 73, Decreto n. 414/SPS del 31.03.2016, e Decreto 694/SPS del 31.05.2016, opera in osservanza a quanto previsto dal DM 15 luglio 1997, dalla Circolare n. 15 del 15 ottobre 2000, dal D. Lgs n. 211 del 24 giugno 2003, e nel rispetto delle norme di Buona Pratica Clinica (GCP-ICP).

Sistema Sanitario Regionale

ARCS
Azienda Regionale
di Coordinamento
per la Salute

REGIONE AUTONOMA FRIULI VENEZIA GIULIA

COMITATO ETICO UNICO REGIONALE

(Decreto del Ministero della Salute 08.02.2013; Legge Regionale n. 33 del 29.12.2015, DGR 22 gennaio 2016 n. 73; Decreto del Direttore centrale salute e integrazione sociosanitaria politiche sociali e famiglia n. 414/SPS del 31.03.2016; Decreto n. 31/Egas dd. 26.04.2016; Decreto del Direttore centrale salute e integrazione sociosanitaria politiche sociali e famiglia n. 694/SPS del 31.05.2016; Decreto Egas n. 48 del 06.06.2016; Decreto del Direttore centrale salute e integrazione sociosanitaria politiche sociali e famiglia n. 425/SPS del 15.03.2017; Decreto Egas n. 40/Egas 10.05.2017; Decreto n. 1150/SPS del 10.08.2018; Decreto n. 1464/SPS del 05.10.2018; Decreto n. 90/Egas del 16.10.2018; Legge Regionale n. 27 del 17 dicembre 2018; Nota prot. n. 1323/ARCS dd. 15.01.2019; Decreto del Direttore centrale salute, politiche sociali e disabilità n. 538/SPS del 21.03.2019; Delibera ARCS n. 36 del 28.03.2019, Decreto n. 1799/SPS, Decreto n. 1799/SPS del 30.09.2019, Decreto n. 2162/Sps del 30/10/2019; Delibera ARCS n.190 del 20/12/2019).

Seduta del 11.02.2020   _firma PRESENTI

COMPONENTI PERMANENTI	
Clinico 1: **dott. Claudio FRESCO**	
Clinico 2: **prof. Francesco ZAJA**	ASSENTE
Clinico 3: **prof. Gianluigi GIGLI**	ASSENTE
Clinico 4: **prof. Paolo MANGANOTTI**	
Clinico 5: **dott.ssa Alessandra BEARZ**	
Clinico 6: **dott. Cosimo Stanislao SACCO**	ASSENTE
Clinico 7: **dott. Fabio FISCHETTI**	
Pediatra 1: **dott.ssa Grazia DI LEO**	ASSENTE
Pediatra 2: **prof. Tarcisio NOT**	
Statistico 1: **dott. Jerry POLESEL**	
Statistico 2: **prof.ssa Miriam ISOLA**	ASSENTE
Farmacologo: **prof. Massimo BARALDO**	ASSENTE
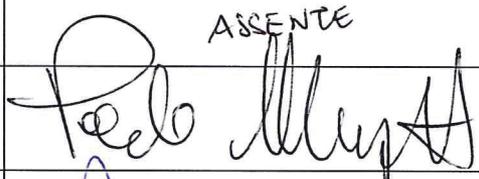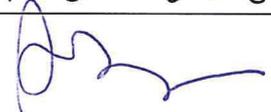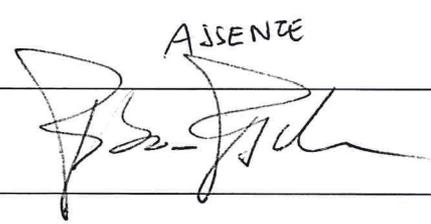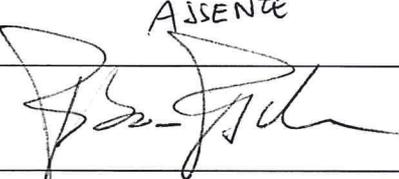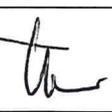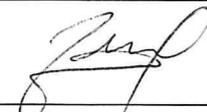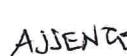
* Assente (ha inoltrato relazione scritta)

Seduta del 11.02.2020   firma PRESENTI

Bioeticista: **don Luis German Ramon OKULIK**	*Luis Okulik*
Genetista: **dott.ssa Serena ZACCHIGNA**	
Farmacista pubblico 1: **dott.ssa Germana MODESTI**	
Farmacista pubblico 2: **dott. Paolo SCHINCARIOL**	
Medico di medicina generale: **dott. Gianni TUBARO**	
Pediatra di Libera Scelta: **dott. Paolo PECILE**	ASSENTE
Rappresentante delle Professioni Sanitarie: **dott. Ilario GUARDINI**	
Medico legale: **dott.ssa Barbara POLO GRILLO**	ASSENTE
Esperto in dispositivi medici: **dott. Erica CERESOLA**	
Rappresentante del volontariato 1: **dott. Giuseppe GIOFFRE'**	
Rappresentante del volontariato 2: **dott.ssa Manuela QUARANTA**	
Rappresentante del volontariato 3: **ing. Giorgio ARPINO**	
COMPONENTI di SEDE	
Azienda per l'assistenza sanitaria n. 2: **dott.ssa Claudia GIULIANI** sostituto	ASSENTE
Azienda per l'assistenza sanitaria n.3: **dott.ssa Paola ZULIANI** sostituto	ASSENTE
Azienda per l'assistenza sanitaria n 5: **dott.ssa Paola TOSCANI** sostituto	ASSENTE

* Assente (ha inoltrato relazione scritta)
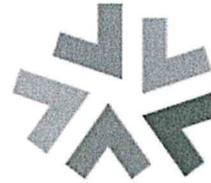
Seduta del 11.02.2020	firma PRESENTI
Azienda sanitario universitaria integrata di Trieste: **dott.ssa Lucia PELUSI** sostituto	ASSENTE
Azienda sanitario universitaria integrata di Udine: **dott.ssa Rosanna QUATTRIN** sostituto	ASSENTE
IRCCS CRO di Aviano: **dott. Valter GATTEI** sostituto	
IRCCS BURLO di Trieste: **prof. Fabio BARBONE** direttore scientifico	ASSENTE
COMPONENTI IN RELAZIONE ALLO STUDIO CLINICO	
Nutrizionista esperto in nutrizione umana: **prof. Gianni BIOLO**	ASSENTE
Specialista in terapia intensiva: **dott.ssa Adriana DI SILVESTRE**	
Ingegnere Clinico: **ing. Massimo D'ANTONI**	
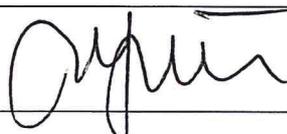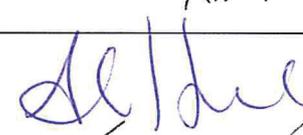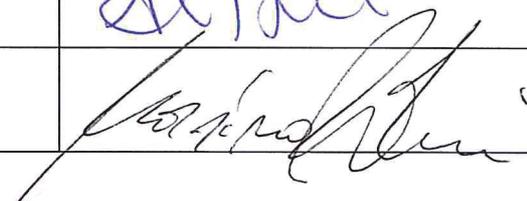
I sopra elencati componenti del Comitato Etico Unico Regionale dichiarano che si asterranno dal pronunciarsi su quelle sperimentazioni per le quali possa sussistere un conflitto di interessi di tipo diretto o indiretto.

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I numero legale per la validità della seduta viene raggiunto in presenza della metà più uno dei componenti permanenti del Comitato.

* Assente (ha inoltrato relazione scritta)