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Research Article

Randomized feasibility trial for evaluating the impact of primary nursing on delirium duration during intensive care unit stay

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ABSTRACT

Objective: We tested the feasibility of a randomized controlled trial for comparing primary nursing with standard care.
Research Methodology: Elective cardiac surgical patients were eligible for inclusion. Patients with an intensive care unit stay of ≥ 3 days were followed up until intensive care unit discharge. Recruitment period was one year.
Setting: Two intensive care units at a university hospital specialized in cardiovascular and diabetic diseases.
Main Outcome Measures: Primary outcomes were recruitment and delivery rate. Primary clinical outcome was duration of delirium, as assessed by the Confusion Assessment Method for Intensive Care Units. Secondary outcomes included the incidence of delirium, anxiety (10-point Numeric Rating Scale), and the satisfaction of patient relatives (validated questionnaire).
Results: Of 369 patients screened, 269 could be allocated to primary nursing (n = 134) or standard care (n = 135), of whom 46 patients and 48 patients, respectively, underwent an intensive care unit stay ≥ 3 days. Thus, recruitment and delivery rates were 73 and 26 %, respectively. During primary nursing and standard care, 18 and 24 patients developed a delirium, with a median duration of 32 (IQR: 14–96) and 24 (IQR: 8–44) hours (P = 0.10). The risk difference of delirium for primary nursing versus standard care was 11 % and the relative risk was 0.65 (95 % CI: 0.28–1.46; P = 0.29). The extent of anxiety was similar between groups (P = 0.13). Satisfaction could be assessed in 73.5 % of relatives, without substantial differences between groups.
Conclusion: Data demonstrate that a trial for comparing primary nursing with standard care is generally feasible. However, the incidence of delirium may be a better primary outcome parameter than delirium duration, both in terms of long-term patient outcome and robustness of data quality.
Implications for clinical practice: A randomized clinical trial regarding nursing organization during intensive care unit stay requires detailed planning of patient recruitment, data evaluation, and power calculation.

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Introduction

Background

Nursing organization forms can vary between hospitals, but functional nursing, team nursing or individual nursing, and primary nursing (PN) have been described most frequently (Parreira et al., 2021, Tiedeman and Lookinland, 2004).

In PN, the primary nurse is responsible 24 h and seven days a week for the nursing process of one or more patients during their stay. The primary nurse plans, delivers and evaluates the nursing care in close joint consultation with the patients, their relatives (Tiedeman and Lookinland, 2004), and further staff. PN ideally starts with the day of admission of one or more patients and ends with their discharge (Parreira et al., 2021). During their absence, the primary nurse is represented by an associated nurse, who follows the individualized care plan. The feasibility of PN in an intensive care unit (ICU) has been reported (Cederwall et al., 2023, Chen et al., 2020, Fröhlich et al., 2013).

Positive effects of PN include a reduction of missed nursing care (Moura et al., 2020), improved job satisfaction (Chen et al., 2020), improved nursing documentation (Cocchieri et al., 2023), the development of nursing competencies (Cocchieri, 2023), a better quality of patient care (Chen et al., 2020), and quality of patient life (Wu et al., 2021). However, no positive association between PN and nurse turnover has been reported (Alenazy et al., 2023, Chen et al., 2020).

Recently, first signs of positive effects of PN on non-pharmacological delirium prevention and management have been reported (Eckstein and Burkhardt, 2021). Nevertheless, there is a lack of research concerning PN and patient-related outcomes (Gonçalves et al., 2023). Therefore, we conducted a randomized feasibility trial to determine how many critically ill patients participate in a study on PN and delirium duration. In addition, we wished to assess the incidence of delirium, the anxiety of patients and the satisfaction of their relatives.

Methods

This study was performed according to recommendations of Eldridge et al., (2016b). Study report follows the Consolidated Standards of Reporting Trials (CONSORT) statement to randomized pilot and feasibility trials (Eldridge et al., 2016a).

Study design, setting, and allocation concealment

The study protocol has already been published elsewhere (Krüger et al., 2023a). Briefly, this randomized feasibility trial was performed at a surgical ICU of a university hospital, where PN was already implemented, and at another surgical ICU of this hospital, where standard care (SC) was practiced. We aimed at evaluating the feasibility of a trial comparing PN versus SC on delirium duration. In an embedded pilot study on a smaller scale, we also aimed to calculate statistical power for a definitive RCT. The two ICUs are in different parts of the hospital and both belong to the Clinic for Thoracic and Cardiovascular Surgery. Patients were recruited during elective admission to the hospital. After surgery, randomization to the target ICU was performed in blocks of six patients. Due to the study design, blinding of patients and/or staff was not possible.

Participants

The recommended number for a pilot study is 50 to 75 patients in total (Sim and Lewis, 2012, Totton et al., 2023, Viechtbauer et al., 2015). Based on a data analysis of the destination ICUs over four years, we estimated to screen 400–500 patients and to analyze 50 patients with an ICU stay of at least 3 days in each group during a recruitment period of one year. Between January and December 2023, cardiac surgical patients who attended our clinic were able to participate. Patients were screened by trained nurses during admission to our clinic and considered eligible if they (i) underwent elective cardiac surgery, (ii) were 65 years of age or older, (iii) were familiar with the German language, (iv) gave their written informed consent, and (v) their health insurance company had signed a special quality contract with our clinic. Patients were excluded if (i) the delirium screening with the Confusion Assessment Method for Intensive Care Units (CAM-ICU) was not possible due to neurological illness, such as serious aphasia, (ii) the CAM-ICU was accidently not performed at time of admission to our clinic, (iii) study allocation was not possible because no free bed was available in the destination ICU, or (iv) their stay in the ICU was < 3 days.

Intervention

At our PN ICU, the development and implementation of PN followed the recommendations of the UK Medical Research Council (Skivington et al., 2021). Generally, all primary nurses received comprehensive information and training on the PN role and tasks before the start of PN. In addition, primary nurses, like all nurses, can regularly take part in further training. The process of developing and implementing PN was analyzed in a separate study by using a mixed-methods design as an as-is analysis before development and piloting as well as six and twelve months after implementation. Results are published elsewhere (Krüger et al., 2023b). The modification of PN in our clinic was that it started on the third day of ICU stay (Krüger et al., 2023a; Krüger et al., 2023b) instead of the first day of ICU admission, as described by others (Fernandez et al., 2012, Parreira et al., 2021). Based on the work schedules of the nursing staff in both ICUs, this means that study enrolment started 40 to 55 h after ICU admission. The reason for this was the high effort required to assess and document the patient's social history and to prepare the written care plan as part of PN. PN mainly take over the design and control of the nursing process in connection with a social anamnesis for a maximum of two patients and ideally carry out the planned care independently day by day during their shift. Moreover, the tasks are comparable with the further core elements of PN: responsibility for the nursing process and quality of provided care during the patient's stay in ICU, and direct communication to the patients, relatives and further staff. During their absence, the primary nurse is represented by a nurse without process responsibility, following the digitally documented care plan of the primary nurse (Krüger et al., 2023b). Nurses can become a primary nurse if they have completed basic training within the surgical ICUs. In addition, they must have at least three years of professional experience, a bachelor's degree in nursing, or a German state-approved training course in intensive and anesthesia nursing care (ICU education). Temporarily, specific primary nurse training was offered to registered nurses without a bachelor's degree or ICU education.

SC, comparable with individual nursing (Parreira et al., 2021) or room care, was practiced in the control ICU, where nursing staff allocation to patients is redefined daily at the start of each shift. In SC, the nurses do not write, use or follow a documented nursing care plan. Moreover, the responsibility for the nursing process and quality of provided care during the patients' stay in the ICU is assumed by the ward manager. In both ICUs, the nurse-to-patient ratio was at least 1:2.

Objective and quantitative outcomes

The major goal of this study was to test the feasibility of an RCT with PN versus SC and its impact on delirium duration in an ICU. Baseline characteristics, such as demographic data, surgical procedure, concomitant diagnoses, kidney function, extracorporeal circulatory membrane oxygenation (ECMO) use and European system for cardiac operative risk evaluation (EuroSCORE II) were collected prospectively. In addition, nursing characteristics such as sex, work experience on ICU, and nurse education, as well as perioperative patient data such as operation time, duration of mechanical ventilation, duration of intervention, and duration of ICU stay were assessed. All preoperative,

perioperative, and postoperative data were recorded in a dedicated database on a routine basis.

Primary outcomes were recruitment and delivery rates. In addition, meaningfulness of delirium duration as a clinical outcome measuring the effect of the PN intervention was a primary clinical outcome. Secondary outcomes were the incidence of delirium, pain, anxiety, risk of pressure ulcers, the need for care, and the satisfaction of relatives.

Delirium is a state of acute confusion, belongs to organic-psychic disorders (Wilson et al., 2020), and is one possible nursing-sensitive outcome (Blume et al., 2021). Since 2018, a delirium assessment and management system has been implemented in our clinic (Krüger et al., 2022; Fliegenschmidt et al., 2023) that also follows updated international recommendations of Aldecoa et al. (2024). Occurrence and duration of delirium were recorded in blocks of 8 h by specially trained nurses using the validated CAM-ICU (Guenther et al., 2010). Also, the Richmond Agitation Sedation Scale (RASS) was used (Ely et al., 2003, Sessler et al., 2002). The first data recording was performed at the time of admission to our institution. Delirium was suspected after the first positive CAM-ICU and was considered to be over in case of three consecutive negative data recordings with the CAM-ICU or at ICU discharge. Missed or impracticable measurements were considered as positive results if present after a positive CAM-ICU and non-existent three consecutive negative measurements.

Pain and anxiety were measured using the 10-point Numeric Rating Scale (NRS) (Barnason et al., 1995, Jensen et al., 1986) or, in cases of sedation, the Critical Care Pain Observation Tool (CPOT) (Kiesewetter et al., 2019). Measurements started at the time of admission, continued on ICU and were conducted in blocks of 8 h. The Braden scale and the Barthel Index were used to assess the risk of pressure ulcers (Halfens et al., 2000) and the need for care (Heuschmann et al., 2005), respectively. Both instruments were used on admission and then once a day (Braden scale) or once a week (Barthel Index). The satisfaction of relatives was also examined once during their visit to the ICU by specially trained nurses using ten respective questions of a validated questionnaire (Huber et al., 2008; see Table 2). All nurses in both ICUs and the admission unit received face-to-face training before start of the study and were trained in the same way to assess and document the study-relevant data, including delirium.

Statistical methods

Categorical variables have been summarized as percentages and number of observations. Continuous variables are presented as median with interquartile ranges (IQR) because all variables were non-normally distributed, as indicated by the Kolmogorov-Smirnov test. We used the Mann–Whitney test, Fisher's exact test, and the chi-square test to assess group differences in continuous and categorical variables, where appropriate. Binary logistic regression analysis was used to assess differences between groups in clinical events. For statistical power calculation, a freely available sample size calculator was used (Harvard University, 2024). The P-values < 0.05 were considered statistically significant. We performed all analyses using IBM SPSS Statistics version 27 (IBM Corporation, Armonk, New York, United States).

Ethical approval

Written informed consent was given by all study participants during admission to our clinic. The local ethics committee of the medical faculty of the Ruhr University Bochum, Germany, based in East Westphalia, approved the study (No. 2022–952), which was subsequently registered at ClinicalTrials.gov (NCT05569317).

Results

Baseline characteristics

In total, 3039 patients underwent cardiac surgery at our department, of whom 2670 had to be excluded for different reasons (Fig. 1). Thus, 369 patients were screened and 366 assessed for eligibility. Of the eligible patients, 269 randomized patients could finally be allocated to PN (n = 134) and SC (n = 135). Supplemental Table 1 presents baseline characteristics of these patients by study group. Briefly, the pain score was statistically significantly higher (P = 0.04) and the anxiety score tended to be higher (P = 0.07) in the PN-group than in the SC-group. Other parameters did not differ statistically significant between groups.

In the PN-group and SC-group, 46 and 48 patients respectively were still in the ICU on the third day, including the day of admission. These 94 patients were included in the final data analysis. Thus, the delivery rate of eligible patients was 26 %. Baseline characteristics of these 94 patients, such as demographic data, type of cardiac surgery, concomitant diagnoses, and EuroSCORE II, did not differ clinically or statistically significantly between groups. In addition, the work experience of the nurses was comparable between both ICUs, while the qualification mix was statistically significantly different, which was due to a higher bachelor's degree in the PN-group. All nurses were at least registered nurses (Table 1).

Operation time was comparable between groups. In addition, neither duration of mechanical ventilation, nor duration of intervention, nor duration of ICU stay differed statistically significantly between study groups (Table 1). Likewise, the need for ECMO implants was similar between groups. None of the allocated patients died during ICU stay.

Primary outcomes

Recruitment and delivery rates of eligible study participants were 73 and 26 %, respectively. During PN and SC, 18 and 24 patients developed delirium, respectively. The median duration of delirium was statistically not significantly different between the PN-group (32 h; IQR:14–96 h) than in the SC-group (24 h; IQR:8–44 h; P = 0.10) (Fig. 2).

Likewise, median ICU stay of patients experiencing delirium was statistically not significantly different between the PN-group than in the SC-group (9.0 days, IQR: 4.5–17.5 days and 4.5 days, IQR: 4.0–7.8 days, respectively, P = 0.09), and so was median duration of intervention PN or SC in these patients (7.0 days, IQR: 2.5–15.5 days and 2.5 days, IQR: 2.0–5.8 days, respectively, P = 0.09).

Secondary outcomes

The incidence of delirium in the PN- and SC-groups was 39 % and 50 %, respectively, with a risk difference of 11 % and a relative risk of delirium for PN versus SC of 0.65 (95 % CI: 0.28 to 1.46; P = 0.29). According to these results, a statistical power calculation revealed that 450 patients on PN and 450 patients on SC would have been necessary for a 90 % chance of detecting a statistically significant difference at a two-sided 0.05 significance level.

Regarding secondary outcomes related to the study participants, such as sedation status, pain, anxiety, and pressure ulcer, there were no statistically significant differences between study groups, with the only exceptions being that the lowest value of sedation status and the highest NRS pain value were statistically significantly higher in the PN-group than the SC-group (Table 2). Need for care could not be analyzed in most patients since the median ICU stay was four days, and need for care should be evaluated once a week.

Regarding satisfaction of relatives in the PN- and SC-groups, 74 % and 73 %, respectively, answered the questionnaire. The percentage of missing answers in the PN- and SC-groups varied between 26 % - 57 % and 29 % - 65 %, respectively. Overall, results of the questionnaire did not differ substantially, although the relatives in the PN-group reported

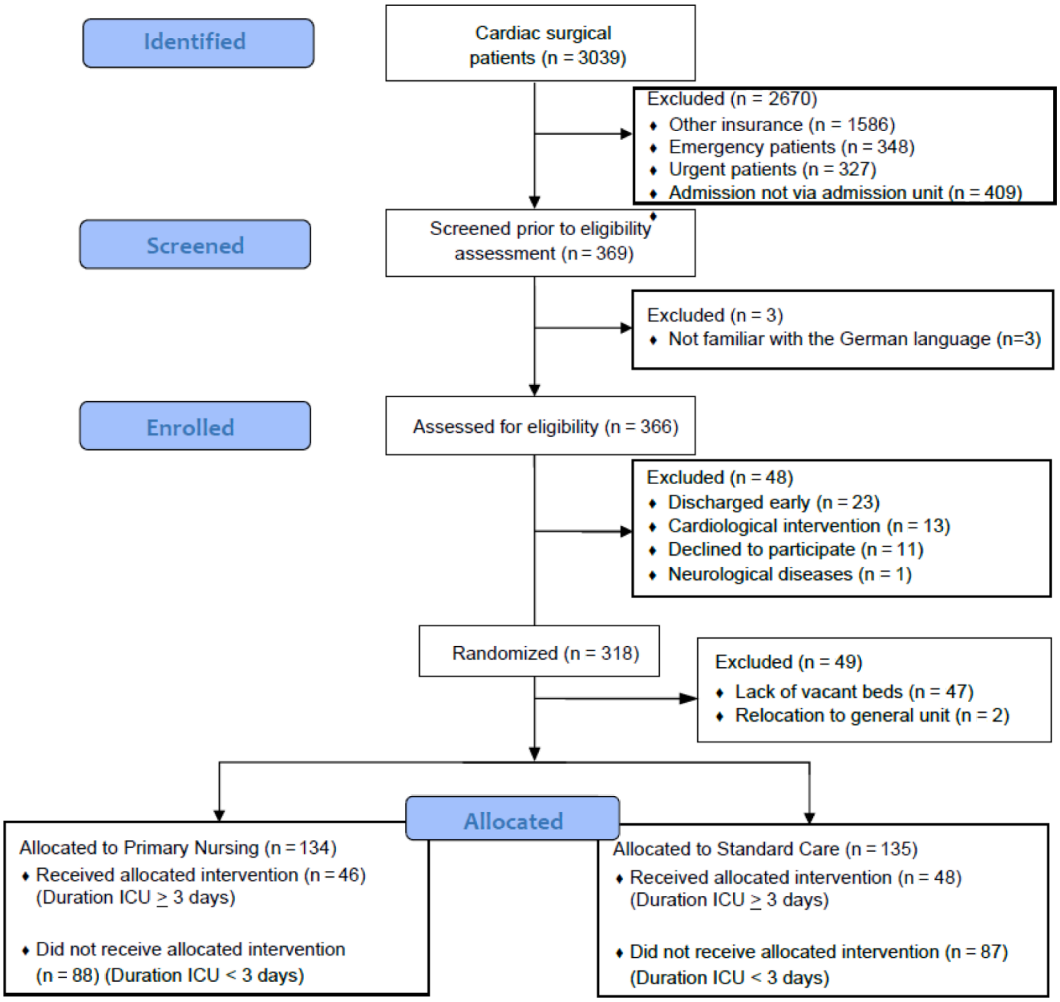

Fig. 1. Flowchart of included and excluded patients, based on the recommendations of Eldridge et al., (2016a). Abbreviations: ICU, Intensive Care Unit.

a lower frequency of visits, a better influence on the patient's care, and more permanent nurse contact than relatives in the SC-group.

Discussion

This trial could demonstrate that an RCT regarding duration or risk of delirium during ICU stay is feasibility, as recruitment and delivery rates were 73 and 26 %, respectively, and a substantial number of study participants developed a delirium.

To the best of our knowledge, this is the first randomized feasibility trial regarding delirium outcome in patients on PN during ICU stay. Only a few patients did not give their informed consent during admission for elective cardiac surgery at our clinic (Fig. 1). However, this was probably a best-case scenario since it was possible to achieve informed written consent from all study participants before surgery. In contrast to our elective cardiac surgical patients, many other patients are admitted to the ICU because of acute serious illness or a serious accident. Therefore, future RCTs should consider the possibility of achieving written informed consent from patients' relatives. This could have the advantage of higher delivery rates since only a minority of our elective cardiac surgical patients were still in the ICU on the third day of admission. In our study, the number of recruited and allocated patients also could have been substantially increased by including all routes of patient admission and patients from all insurance companies (Fig. 1).

Although not statistically significant, our data showed opposite trends regarding delirium duration and delirium incidence in the PN- and SC-groups. This was a surprising finding. Sometimes there were pitfalls and it was not possible to screen positively ranked patients every 8 h with the CAM-ICU, e.g., in case of disease deterioration resulting in the need for mechanical ventilation and an RASS value < -3. This might have, at least in part, influenced duration of delirium (Nydahl et al., 2022). Incidence of delirium may be a stronger and more relevant outcome due to long-term patient related outcome and more robust data quality. Duration of delirium in hours could also be relevant for patients, but in daily practice it is sometimes difficult to assess delirium often enough to ensure data quality. Therefore, it would perhaps be more appropriate to state the duration in days rather than hours. Notably, fewer patients in the PN-group than in the SC-group experienced delirium. Thus, already few unscreenable patients after the delirium diagnosis might have influenced delirium duration substantially. The delirium incidence in the PN- and SC-groups of 39 % and 50 %, respectively, is generally in line with a reported prevalence of 12.5 % to 83.9 % in diagnostic studies using the CAM-ICU tool (Miranda et al., 2023). The large range of reported delirium incidence might be, at least in part, due to the use of different screening intervals. In definitive RCTs, the incidence of delirium may be a better primary outcome parameter than delirium duration. According to our data, the number of study participants to achieve statistically significant results needs to be 450 per group. The 11 % lower incidence of delirium in the PN- versus SC-group is in line with a reported absolute reduction in delirium incidence of 3.4 % and 13.3 %, respectively, by non-pharmacological prevention studies (Brennan et al., 2023, Moon and Lee, 2015).

Both pain and anxiety can cause delirium (Wilson et al., 2020). Although the pain score was statistically significantly higher in the PN-

Table 1
Baseline characteristics by study group.

	Primary Nursing (n = 46)	Standard Care (n = 48)	P-value
Preoperative Data			
Age (years)[1]	73 (69–78)	72 (69–76)	0.14
Female Sex[2]	23 (50)	18 (38)	0.30
Body Mass Index (kg/m^2)[1]	27.6 (24.2–30.5)	26.1 (24.0–29.2)	0.36
Diabetes Mellitus[2]	10 (22)	11 (23)	>0.99
Arterial Hypertension[2]	43 (94)	40 (84)	0.20
Hemodialysis[2]	1 (2)	2 (4)	>0.99
Peripheral Arterial Occlusive Disease[2]	6 (13)	7 (15)	>0.99
Myocardial Infarction[2]	3 (6)	3 (6)	>0.99
ECMO Use[2]	0 (0)	0 (0)	>0.99
Previous Cardiac Surgery[2]	7 (15)	10 (21)	0.16
Stroke[2]	0 (0)	1 (2)	>0.99
Delirium[2]	2 (4)	0 (0)	0.24
eGFR (ml/min/1.73 m^2)[1]	71 (53–87)	69 (48–84)	0.45
EuroSCORE II[1]	4.5 (1.7–12.8)	4.1 (1.5–9.5)	0.72
Pain (NRS 0–10[3])[1]	1.5 (0.0–5.0)	0.0 (0.0–3.0)	0.06
Anxiety (NRS 0–10[3])[1]	4 (1–5)	4 (1–6)	0.78
Braden Scale[1]	23 (22–23)	23 (23–23)	0.30
Need for Care (Barthel Index)[1]	100 (84 to 100)	100 (95 to 100)	0.12
Surgical Procedures			0.40
CABG Surgery[2]	10 (22)	8 (17)	
Valve Surgery[2]	16 (35)	25 (52)	
Combined CABG and Valve Surgery[2]	8 (17)	6 (12)	
Others[2]	12 (26)	9 (19)	
Nursing Characteristics			
Female Sex of Nurses[2]	68 (69)	43 (71)	>0.99
Work Experience on ICU			0.82
< 5 Years[2]	34 (35)	24 (39)	
5–10 Years[2]	22 (22)	12 (20)	
>10 Years[2]	42 (43)	25 (41)	
Nurse Education			0.014
Registered Nurse[2]	28 (29)	31 (55)	
Intensive Care Unit Education[2]	26 (27)	14 (21)	
Bachelor's Degree[2]	16 (16)	4 (6)	
Nurse Educator[2]	11 (11)	7(10)	
Additional Nursing Education[2]	7 (7)	5 (8)	
Primary Nurse[2]	10 (10)	0 (0)	
Perioperative Patient Data			
Operation Time (min)[1]	229 (190–261)	220 (181–301)	0.87
ECMO Use[2]	1 (2)	0 (0)	0.49
Duration of Mechanical Ventilation (h)[1]	11.4 (7.7–16.7)	8.7 (5.6–16.8)	0.24
Duration of Intervention (days)[1]	2.0 (1.0–6.3)	2.0 (1.0–4.0)	0.94
Duration of Intensive Care Unit Stay (days)[1]	4.0 (3.0–8.3)	4.0 (3.0–6.3)	0.94

Abbreviations: CABG, coronary artery bypass grafting; ECMO, extracorporeal circulatory membrane oxygenation; EuroSCORE II, European system for cardiac operative risk evaluation; eGFR, estimated glomerular filtration rate; ICU, intensive care unit; NRS, Numeric Rating Scale.
[1] median with interquartile range.
[2] n with % of patients/nurses.
[3] 0 (min.) to 10 (max.) pain/anxiety.

group than in the SC-group (NRS by 1.5 points), this statistically significant difference already existed at baseline. It is also noteworthy that other secondary outcomes, such as anxiety and pressure ulcers, did not differ statistically significantly between study groups, indicating similar nursing competence at both ICUs.

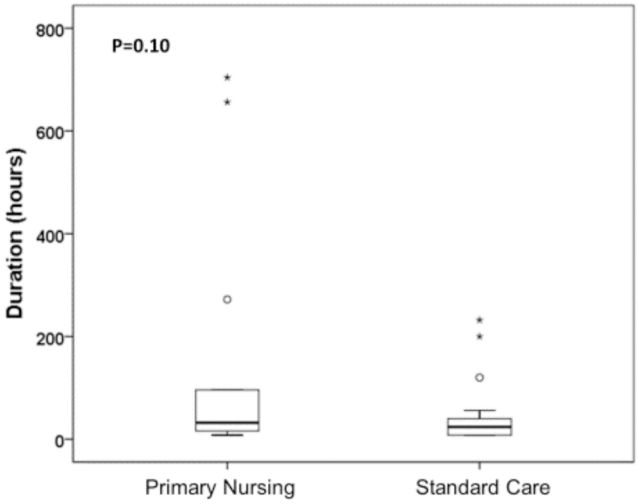

Fig. 2. Boxplot of duration of delirium by study group. The whiskers represent the ranges of the data, the boxes express the upper and lower quartiles, and the central line shows the median. Circles, outliers. Stars, extremes.

Overall, relatives rated the care in both groups as good. Although a statistically significant better influence on the patient's care and on nurse contact was reported in the PN-group than in the SC-group, differences were small and should, thus, not be over-interpreted.

Strengths and Limitations

Our randomized feasibility trial has several strengths. First, it was a study with a well-conducted implementation and evaluation of the intervention prior to the start of this study (Krüger et al., 2023b). Second, all nurses in both ICUs were personally trained before the start of the study. Third, we conducted comprehensive data collection for different parameters and different groups (patients, relatives, nurses). Fourth, with 94 study participants, we were able to exceed the recommended number of 50 to 75 patients in total for a pilot study (Sim and Lewis, 2012, Totton et al., 2023, Viechtbauer et al., 2015).

One limitation is that blinding of patients and nurses was not possible. Another limitation is that inter-observer variability in CAM-ICU use might have influenced study results. However, nurses have rated the CAM-ICU as a well-usable and simple assessment tool (Nielsen et al., 2023). Furthermore, the median intervention duration of two days was probably too short to achieve statistically significant differences in delirium outcomes between PN and SC. Likewise, the evaluation rate of some secondary outcomes, such as need for care, and some of the questions of the relatives' questionnaire, was inadequately low. In addition, the delirium rate was relatively high compared to previous results in our clinic (Hulde et al., 2022), although it should be noted that only patients with a longer ICU stay were analyzed. Finally, we cannot rule out the possibility that exchange of information between the nurses of the two ICUs included in our study may have biased the study results.

Conclusion

This trial demonstrates the feasibility of a definitive RCT regarding PN in the ICU. However, delirium incidence instead of delirium duration may be the better primary outcome. This trial also demonstrates the need for some improvements in the assessment of need for care, such as daily instead of weekly assessment. Altogether, a definitive RCT regarding the improvement of nursing care at the ICU requires detailed planning of the primary clinical outcome, power calculation, patient recruitment, and data evaluation.

Table 2
Secondary outcomes by study group.

	Primary Nursing n = 46	Standard Care n = 48	P-value
Sedation Status			
Richmond Agitation Sedation Scale$_{peak}$[1]	0 (0 to 1)	0 (0 to 1)	0.73
Richmond Agitation Sedation Scale$_{nadir}$[1]	−5 (−5 to −4)	−5 (−5 to −5)	<0.001
Pain			
NRS (0–10)$_{peak}$[1a]	4.5 (3.0 to 6.0)	3.0 (2.0 to 5.0)	0.034
CPOT$_{peak}$[1]	0 (0 to 2.8)	0 (0 to 1.0)	0.99
Anxiety			
NRS (0–10)$_{peak}$[1a]	1 (1 to 4)	0 (0 to 3)	0.13
Pressure Ulcer (n,%)			0.60
Not assessed	7 (15)	8 (17)	
Absent	39 (85)	39 (81)	
Present	0 (0)	1 (2)	
Braden Scale[1]	10.5 (8.0 to 15.0)	12.0 (8.0 to 14.8)	0.41
Satisfaction of Relatives			
Do the nurses respond to your questions and wishes?[b]	1 (1 to 1)	1 (1 to 1)	0.46
Impression of the professional skills of nurses[c]	1 (1 to 1)	1 (1 to 1)	0.92
Information by the nurses about the daily routine [c]	1 (1 to 2)	1 (1 to 2)	0.46
Receiving information material about the ICU stay[d]	1 (1 to 3)	3 (1 to 3)	0.13
Information about care measures[c]	1 (1 to 1)	1 (1 to 2)	0.19
Help to support recovery[c]	1 (1 to 2)	2 (1 to 3)	0.20
Frequency of ICU visits[e]	2 (1 to 2)	1 (1 to 1)	0.009
Discussion of worries and fears with the nurses[b]	1 (1 to 1)	1 (1 to 1)	0.28
Influence of relatives on patient's care[b]	1 (1 to 2)	2 (1 to 2)	0.011
Permanent nurse as contact available[d]	1 (1 to 2)	2 (1 to 3)	0.18

Abbreviations: CPOT, Critical Care Pain Observation Tool; ECMO, extracorporeal circulatory membrane oxygenation; ICU, intensive care unit; NRS, Numeric Rating Scale.
[1] median with interquartile range.
[a] 0 (min.) to 10 (max.).
[b] scale 1–5, 1: yes, completely; 5: no, not at all.
[c] scale 1–5, 1: very good; 5: very bad;
[d] scale 1–3, 1: yes, 2: partly, 3: no.
[e] scale 1–4, 1: ≥ 2x/week; 2: once a week; 3: once a month; 4: < once a month.

CRediT authorship contribution statement

Lars Krüger: Writing – review & editing, Writing – original draft, Visualization, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Armin Zittermann:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Software, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Thomas Mannebach:** Writing – review & editing, Writing – original draft, Investigation, Formal analysis, Data curation, Conceptualization. **Franziska Wefer:** Writing – review & editing, Resources, Data curation, Conceptualization. **Tobias Becker:** Writing – review & editing, Resources, Data curation, Conceptualization. **Sarah Lohmeier:** Writing – review & editing, Resources, Project administration, Investigation, Data curation. **Anna Lüttermann:** Writing – review & editing, Resources, Project administration, Investigation, Data curation. **Vera von Dossow:** Writing – review & editing, Supervision, Resources, Methodology, Conceptualization. **Sebastian V. Rojas:** Writing – review & editing, Supervision, Resources, Methodology, Conceptualization. **Jan Gummert:** Writing – review & editing, Supervision, Resources, Methodology, Conceptualization. **Gero Langer:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Methodology, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Clinical Trial Registration Number

This study is registered at clinicaltrials.gov as NCT05569317.

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Ethical approval

The ethics committee of the medical faculty of the Ruhr University Bochum, Germany, based in East Westphalia, has approved the study (file number 2022-952). All described investigations involving humans were carried out with the approval of the responsible ethics committee, in accordance with national law and the Declaration of Helsinki in 1975 (in the current, revised version).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.iccn.2024.103748.

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