Received: 19 April 2023 | Revised: 1 August 2023 | Accepted: 7 August 2023

DOI: 10.1111/apa.16944

ACTA PÆDIATRICA NURTURING THE CHILD WILEY

ORIGINAL ARTICLE

Impact of a family-centred clinical care programme on short-term outcomes of very low-birth weight infants

Rafael Pricoco[1] | Sandra Mayer-Huber[2] | Johannes Paulick[1] | Franz Benstetter[2] | Michael Zeller[1,3] | Matthias Keller[1,3]

[1]Department of Pediatrics, Technical University of Munich, School of Medicine, Munich, Germany

[2]Technische Hochschule Rosenheim, Rosenheim, Germany

[3]Kinderklinik Dritter Orden, Passau, Germany

Correspondence
Matthias Keller, Kinderklinik Dritter Orden, Munich Technical University, Bischof Altmann-Strasse 9, Passau 94032, Germany.
Email: matthias.keller@kinderklinik-passau.de

Abstract

Aim: We evaluated the effects of a family-centred clinical care pathway and case management programme on short-term clinical outcome in a cohort of very low-birth weight (VLBW) infants.

Methods: The programme, named NeoPAss, was developed at the Department of Neonatology Children's hospital Passau in 2013. Short-term outcomes of infants were compared to matched controls from the Bavarian neonatology surveillance database before ($n=111$; 2008–2012) and after implementation ($n=170$; 2014–2017).

Results: After implementation the rate of late-onset sepsis was significantly lower (2.5% vs. 10.7%, $p=0.005$) and the length of stay was significantly shorter (VLBW 28 to 31 weeks' gestational age (GA) 47.5 vs. 53.1 days, $p=0.047$; <28 weeks' GA 79.4 vs. 91.9 days, $p=0.007$) in the intervention group compared to controls. Infants were discharged with significantly lower weight (mean 2351 vs. 2539 g, $p=0.013$). There was no statistically significant difference in the rate of intraventricular haemorrhage (3.7% vs. 8.2%), necrotizing enterocolitis (0.6% vs. 1.9%) and bronchopulmonary dysplasia (0% vs. 6.9%).

Conclusion: Our data confirm that of other studies demonstrating a beneficial effect of family-centred care programmes and provides evidence that structured parental involvement is not associated with increased risk of infection in a VLBW cohort.

KEYWORDS
family integrated care, family-centred care, matched-pairs, preterm infant, very low birth weight

1 | INTRODUCTION

Every year, approximately 15 million preterm infants are born globally[1] and require postnatal support. In particular infants born with a birth weight ≤1500 g (VLBW) frequently experience significant short- and long-term morbidity such as neurodevelopmental delay and poor growth.[2] The highly technical setting of a modern neonatal intensive care unit (NICU) is a stressful environment and leads to physical and emotional separation between infants and their parents.[3] Parents of admitted infants frequently express feelings of anxiety, distress and helplessness.[4]

A growing body of evidence suggests that the presence of parents, the promotion of their competence and self-efficacy, and the facilitation of infant-parent bonding may improve infant outcomes, reduce stress for parents and lower costs for the health care system.[3,5–9]

Abbreviations: BPD, Bronchopulmonary Dysplasia; EOS, Early-onset Sepsis; FCC, Family Centred Care; FIC, Family Integrated Care; IVH, Intraventricular Haemorrhage; KMC, Kangaroo Mother Care; LOS, Late-onset Sepsis; NEC, Necrotizing Enterocolitis; NICU, Neonatal Intensive Care Unit; PVL, Periventricular Leukomalacia; VLBW, very low birth weight.

Family-centred care (FCC) is a philosophical concept of care based on principles to guide healthcare delivery, such as respect, recognition of the strengths of the individual patient and their families, information sharing and informed decision making as well as collaboration and empowerment.[3,8] FCC aims to improve the quality of care including clinical outcomes and the psychological well-being of patients and their families. Another objective of FCC in the NICU setting is to reduce the physical and emotional separation of infants and their parents and to alleviate the impact of prematurity for the whole family. This approach to care delivery has shaped several parent-focused interventions and parent-partnered care models in the NICU with varying and often overlapping specific components and strategies for implementation.[8,10–12]

Overall, FCC models and interventions have been associated with positive effects on weight gain, breastfeeding rates as well as a reduction in length of stay.[7,9] Furthermore, lower rates of bronchopulmonary dysplasia (BPD), retinopathy of prematurity (ROP) and necrotizing enterocolitis (NEC) have been reported, but the evidence on positive effects on short-term morbidities is conflicting, as different outcomes are likely due to heterogeneity of the specific care models and study populations.[13,14]

In German neonatology, there is a particular lack of structured and comprehensive multicentre FCC models that integrate evidence-based measures in a cohesive manner. We established a multi-component FCC clinical care pathway and case management programme named NeoPAss in the department of neonatology in the children's hospital Passau. Key elements of the programme include a FCC clinical care pathway and case management. The programme is described in detail in the methods section. In short, case managers were appointed to be responsible for each individual family already before preterm birth as soon as a pregnancy at risk was detected. The programme was implemented by a structured change management, staff training and mandatory participation of all staff members involved in neonatal care. Additionally, infrastructural interventions were implemented to tend to parental needs such as unlimited access for parents to their newborns at the NICU and rooming-in facilities.

In these analyses, we evaluated the effects of this programme on short-term clinical outcome in a cohort of very low-birth weight (VLBW) infants. We hypothesised that this structured programme improves short-term outcome and facilitates earlier discharge.

Key notes

- This study evaluated the effect of the family-centred clinical care pathway and case management programme on short-term outcomes of very low-birth weight (VLBW) infants.
- The implementation of this programme was associated with a significant and persistent reduction in the rate of late-onset sepsis, hospital stay and weight at discharge.
- Family-centred care and parental involvement have short-term beneficial effects and are not associated with increased risk of infection in a VLBWs.

2 | METHODS

2.1 | Study design

This study employed a quasi-experimental design, utilising a convenience sample and a matched control group based on secondary data obtained from the Bayerische Arbeitsgemeinschaft für Qualitätssicherung (BAQ), a neonatal surveillance database in Bavaria. Data from patients and controls were collected before (2008–2012, baseline period) and after (2014–2017, intervention period) the implementation of the family-centred care pathway and case management programme termed "NeoPAss" at the department of neonatology of the children's hospital Kinderklinik Dritter Orden Passau.

2.2 | Participants and recruitment

As NeoPAss was implemented throughout the entire department of neonatology, all infants admitted to the NICU during both the baseline and intervention period were assessed for eligibility. The inclusion criteria were: preterm infants with a birth weight between 500 and 1500 g; gestational age >24 weeks; birth in the Passau maternity clinic. Exclusion criteria were: transfer to or from another hospital, obvious malformations or known chromosomal aberrations, maternal substance abuse, death during the observation period.

2.3 | Intervention

In 2013, the clinical multi-professional, interdisciplinary clinical care pathway for family-centred care and case management NeoPAss was implemented in our department of neonatology. Key elements of the programme include a FCC clinical care pathway and a case management routine.

The clinical care pathway programme comprises a broad range of measures from the prenatal period to aftercare with the aim of involving the family in the care of the infant as well as structuring and optimising care for infants and their families.

The pathway includes the implementation of central guiding principles and standard operating procedures on, for example, prenatal consultations, promotion of early and continuous KMC, breastmilk feeding and a parental empowerment programme, that allows parents to perform daily routines with their newborns and gradually become the primary caregiver of their infant, for example, handling, bathing and feeding their newborn.

A management team was established, consisting of neonatologists, psychologists and case managers, which was responsible

for training, implementation and improvement of the treatment pathway.

Central guiding principles, standard operating procedures (SOPs) and process descriptions were defined and regularly adapted for all professional groups and for each component of the treatment pathway. In addition, information material for parents was developed. In obligatory modules, all employees, including staff from housekeeping and cleaning, were instructed in the concept and the basic principles, and the tasks of the individual occupational groups were communicated. New members of the team are also repetitively trained. The training consisted of five modules that encompassed information on preterm birth, principles of family-centred care and the structure of NeoPAss. Furthermore, it included the necessary content for prenatal consultations, assessment, case management, weekly re-assessments, information material for parents, breast feeding, psychological support, milestones of transitioning home and aftercare.

Former neonatal intensive care registered nurses underwent training as case managers to coordinate all elements of the pathway, monitor the consistency of processes and serve as continuous contact persons for each family. They were appointed to be responsible for each individual family already before preterm birth as soon as a pregnancy at risk was detected. They assess and re-evaluate the individual family's needs and coordinate the interdisciplinary team as foreseen in the pathway and according to the family's needs. For the assessment, we developed an assessment tool based on the international classification of functioning, disability and health for children and youth, with overarching objectives and specific goals.[15] With this tool, the respective child's needs, the parents' resources and competencies and their current need were assessed. Based on a classic Deming cycle continuous assessments and reassessments were conducted by the interdisciplinary NeoPAss team. Prenatally, reassessments occurred at least every 2 weeks. After birth, the scheduled times were the 1st, 4th, 14th and 28th day of life as well as 4 and 2 weeks before discharge.

The case managers also carried out the admission planning, accompanied the family from prenatal consultation through inpatient stay, supported the transition from NICU to intermediate care, were involved in the discharge management, and organised post-discharge care by the children's hospital aftercare team. Case managers also facilitated connections to paediatricians and the Social Paediatric Centre if needed.

Psychologists conducted therapeutic sessions, addressing concerns and providing support before and after birth. They collaborated with nursing staff to evaluate parental competence and provided psychoeducation and stress management techniques to equip parents in navigating challenges. They also facilitated sensitivity training and actively participated in team meetings and medical consultations.

Lactation consultants offered breastfeeding counselling. Additionally, registered nurses participated in handling courses and contributed to parental competence training.

The infrastructural conditions of the NICU were designed to foster a soothing and welcoming environment. We minimised noise and light levels, while also providing spaces for families to have privacy. Our aim was to reduce stress and discomfort resulting from invasive procedures, while promoting early sensory stimulation for newborns and catering to their unique requirements.

We recognise the importance of treating parents and their child as a unit. Parents gradually become primary caregivers and are actively encouraged to participate in their infant's care at any time, including involvement in treatment decisions. Throughout their NICU stay, parents received comprehensive instruction, both in theory and at the bedside, on essential infant care procedures. We encouraged early (within 2 h after birth) and daily KMC practice to enhance parental competence, nurture parent–child bonding and prepare them for the transition home. Our qualified professionals guided parents through a structured catalogue, teaching them various nursing procedures such as meal preparation, feeding, handling, hygiene, bathing, skincare or stimulating their newborns in case of apnoea. As part of discharge management, we assessed parents' skills for accuracy and completeness in executing these procedures. Recognising the importance of breast milk as the optimal source of nutrition for newborns' we provided dedicated support from lactation consultants within the inpatient setting. In cases where sufficient breast milk was not immediately available, we bridged the gap with donor milk from our human milk bank.

As part of rooming-in, at least one parent is accommodated in the hospital while the other has 24 h-access to the NICU and the opportunity to monitor their infant from at home through encrypted video transmission. Parents are involved in daily visitations and decision making and receive psychological support during their stay at the NICU. Furthermore, weekly special rounds involving all specialties involved in the care of the infant were introduced. We proposed participating in regular specific educational and training sessions in small groups to the parents. Topics such as nutritional counselling, breastfeeding, infant handling, baby massage and correct handling techniques were taught in this setting.

The extensive materials are available in German language on reasonable request from the authors.

2.4 | Data collection from our department of neonatology

Data were collected from the infant's hospital records and the reporting forms that were sent to the BAQ. We analysed the length-of-stay, weight at discharge and Patel's growth velocity as well as clinical short-term outcome parameters such as the rate of late-onset Sepsis, NEC, BPD, IVH, PVL. NEC was defined as Stage II or III according to the revised Bell criteria.[16] BPD was classified as moderate or severe BPD defined by oxygen dependency at 36 weeks postmenstrual age to achieve >90% oxygen saturation.[17] Intraventricular haemorrhage (IVH) was defined as Grade II or higher according to Papile's

classification.[18] Sepsis was classified by clinical and laboratory findings according to criteria of the German national surveillance system for nosocomial infections in VLBW infants. Any sepsis was defined by the occurrence of either early-onset sepsis (EOS) (onset <72 h of life) and/or late-onset sepsis (LOS) (onset >72 h of life).[19] Infants who presented with both EOS and LOS were considered as a single episode of sepsis for the analysis of any sepsis. Growth velocity was calculated in g/kg/d with Patel's exponential model, which assumes that growth occurs as a constant fraction (k) of the previous weight.[20] We did not collect data for ROP, since the treatment protocol in our NICU was adapted fundamentally during the study period.

2.5 | BAQ data

Data of all Bavarian VLBW infants from the neonatology module for the years 2008–2017 ($n = 145\,849$) were obtained with permission from the BAQ, an external quality assurance agency with the mission to report quality of care in Bavarian hospitals. Data from each NICU in Bavaria was reported using a standardised template and no modifications were made to the survey during the study period for all reported data points.

In subsequent steps, data were prepared to match the previously described inclusion and exclusion criteria. Afterwards, linkage was performed to exclude patients from our facility from the data set. Using a vector of year of birth, birth weight and weight at discharge 268 of 289 neonates from Passau were identified and excluded from the data set. We were unable to identify 21 infants from Passau in the data set, most likely due to incomplete reporting to BAQ.

The final population before matching consisted of 8861 infants from other Bavarian NICUs.

2.6 | Matching

To establish a 1:1 matched control group, a matched pairs procedure, based on year of birth, birth weight, gestational age and CRIB-Score was performed. Therein each characteristic for participants and non-participants is checked for a match. Each participant in the intervention is assigned a non-participant whose characteristics match those of the participant. If the data set lacked a data twin, exclusion occurred. By applying coarsened exact matching (CEM), the probability of finding matching data twin was increased. This extension of the matched-pairing procedure combines the characteristics of multiple variables into groups. Matching was then performed based on grouped variables, which secured that distribution of the variables were statistically equivalent in both groups. The acceptable differences in matching parameters were determined by the algorithm and subsequently manually checked for significant differences between groups. No significant differences were identified in any of the matching parameters used.

2.7 | Statistical analysis

All statistical analysis was performed in R, Version 3.6.1. For descriptive statistics mean, median and standard deviation were used. The relative risk of the complications was calculated using the epitools package. The package MatchIt was used for CEM. Since the normal distribution assumption was violated, we used Mann–Whitney *U*-tests to compare results for length of stay, growth velocity and weight at discharge. Rates of infant complications between groups were compared using Fisher's exact test. A p-value of <0.05 was considered as statistically significant.

3 | RESULTS

3.1 | Infant characteristics

From the overall Bavarian cohort ($n = 8861$), matched controls were identified for 270 of 289 infants from our NICU. In the baseline period, both intervention and control group consisted of 111 VLBW infants. In the intervention period, 159 VLBW infants were included in each group. Birth weight and birth gestational age were not different between intervention (IG) and control groups (CG) in both baseline and intervention period (Table 1). In both IG and CG, two infants (both infants with 28–31 weeks GA) in the baseline period and four infants in the intervention period (three infants between 28 and 31 weeks GA and one ≥32 weeks GA) had a CRIB-Score >1.

3.2 | Weight at discharge and growth velocity

Table 2 displays weight at discharge and growth velocity for IG and CG in the respective periods, as well as for different gestational age groups. Because of a moderate correlation between length of stay and weight at discharge (rho = 0.708), Patels' growth velocity was calculated and included in the analysis. During the baseline period, we noted a significant difference in growth velocity between the IG and the CG, with the IG demonstrating higher growth rates (mean 13.9 vs. 13.0, $p = 0.001$). In the intervention period, the growth velocity remained consistent in the IG while increasing in the CG, leading to a slight but non-significant difference between the two groups (mean 13.9 vs. 13.5, $p = 0.085$).

While for the years 2008–2012 VLBW infants in the IG were consistently discharged with a significantly higher weight than infants from in the CG (2813 vs. 2615, $p \leq 0.001$), there was a trend for change during the year of implementation of NeoPAss in 2014 (Figure 1). In the years 2014–2017, infants in the IG were discharged with significantly less weight than controls (mean 2351 vs. 2539 g, $p = 0.013$), with the largest difference in the first 2 years after the implementation of NeoPAss.

TABLE 1 Clinical characteristics of the intervention and control group in the baseline and intervention period.

	Baseline period (2008–2012)		Intervention period (2014–2017)	
	IG	CG	IG	CG
Number of infants, *n* (%)	111 (100)	111 (100)	159 (100)	159 (100)
≥32 wkGA	19 (17)	19 (17)	28 (18)	28 (18)
28–31 wkGA	59 (53)	59 (53)	83 (52)	83 (52)
<28 wkGA	33 (30)	33 (30)	48 (30)	48 (30)
Birth weight (g), mean (SD)	1113 (287)	1118 (284)	1148 (258)	1145 (260)
≥32 wkGA	1405 (116)	1411 (113)	1384 (103)	1383 (112)
28–31 wkGA	1194 (208)	1195 (208)	1228 (182)	1225 (183)
<28 wkGA	798 (189)	811 (181)	871 (194)	870 (197)
Gestational age (completed weeks), mean (SD)	29.0 (2.7)	29.0 (2.7)	29.1 (2.7)	29.1 (2.7)
>32 wkGA	33.1 (1.1)	33.1 (1.1)	33.1 (1.3)	33.1 (1.3)
28–31 wkGA	29.4 (1.2)	29.4 (1.2)	29.6 (1.1)	29.6 (1.1)
<28 wkGA	25.8 (1.2)	25.8 (1.2)	26.0 (1.0)	26.0 (1.0)

Abbreviations: CG, Control group; IG, Intervention group; wkGA, weeks of gestational age.

TABLE 2 Weight at discharge and growth velocity in the baseline and intervention period.

	Baseline period (2008–2012)				Intervention period (2014–2017)			
	IG (*n* = 111)	CG (*n* = 111)		Mean difference (95% CI)	IG (*n* = 159)	CG (*n* = 159)		Mean difference (95% CI)
	Mean (SD)	Mean (SD)	*p*-Value[a]		Mean (SD)	Mean (SD)	*p*-Value[a]	
Weight at discharge (g)	2813 (425)	2615 (508)	**<0.001**	210 (107, 312)	2351 (298)	2539 (565)	**0.013**	−189 (−272, −106)
≥32 wkGA	2621 (418)	2215 (229)			2075 (254)	2105 (217)		
28–31 wkGA	2798 (441)	2571 (410)			2358 (275)	2496 (423)		
<28 wkGA	2950 (359)	2884 (596)			2499 (252)	2868 (712)		
Growth velocity (g/kg/d)	13.9 (1.97)	13.0 (2.26)	0.001	0.95 (0.48, 1.42)	13.9 (2.05)	13.5 (2.31)	0.085	0.51 (0.02, 0.82)
≥32 wkGA	14.5 (2.0)	12.7 (3.3)			14.6 (2.2)	14 (2.6)		
28–31 wkGA	13.5 (1.9)	13.2 (2.2)			13.8 (2.1)	13.6 (2.3)		
<28 wkGA	14.5 (1.9)	12.8 (1.8)			13.6 (1.8)	13.1 (2.1)		

Note: Statistically significant findings are marked in bold ($p < 0.05$).

Abbreviations: CG, Control group; CI, Confidence Interval; IG, Intervention group; wkGA, weeks of gestational age.

[a] Mann–Whitney *U*-test.

3.3 | Length of stay

Total length of stay in the years 2008–2012 was similar in IG and CG (mean 68.7 vs. 67.4 days, $p = 0.319$) (Table 3). During the intervention period, there was a 7.2-day difference in the mean length of stay between IG and CG (mean 53.6 vs. 60.8 days, $p = 0.064$). Furthermore, in the intervention period there was a significant difference of 5.6 days in length of stay in the subgroup of infants with 28 to 31 week's gestational age (mean 47.5 vs. 53.1 days, $p = 0.047$) and 12.5 days in infants <28 weeks' gestational age (mean 79.4 vs. 91.9d, $p = 0.007$), which was not observed in the baseline period. Analysis of Kaplan–Meier curves showed that the IG consistently had higher probabilities of being discharged with a shorter length of stay compared to controls in the intervention period (Figure 2).

3.4 | Short-term outcome

The occurrence of the important neonatal disease such as NEC, IVH and BPD before and after the intervention for IG and CG is depicted in Table 4. NEC rates were low in all groups and the difference between IG and CG was not significant in the baseline (3

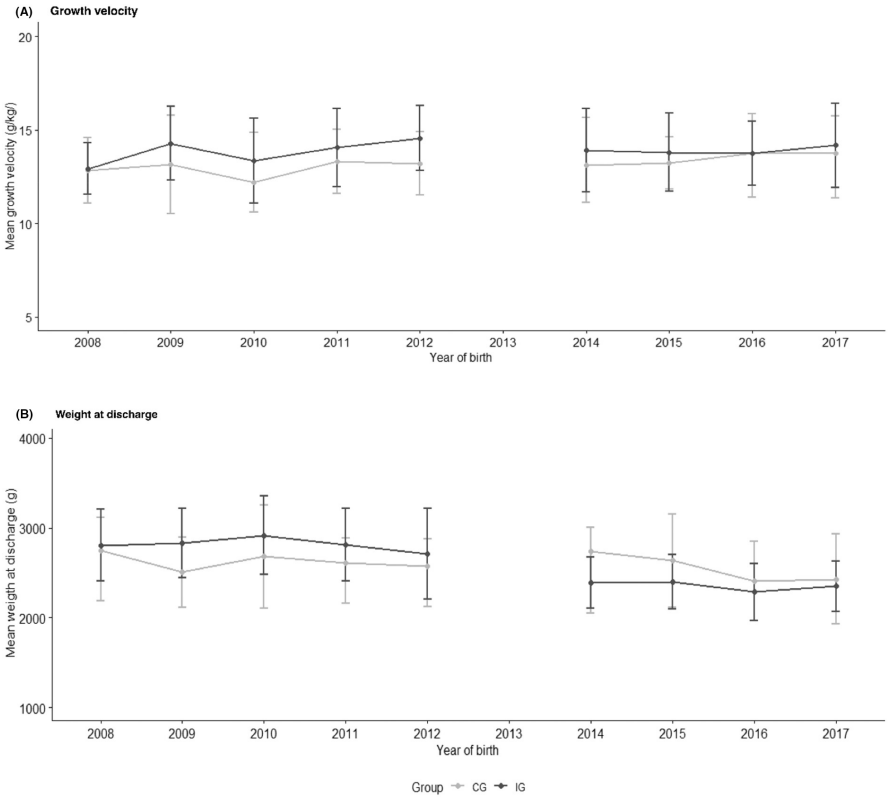

FIGURE 1 (A) Growth velocity (g/kg/d) and (B) weight at discharge are displayed over the study period before and after the implementation of NeoPAss for both Intervention (IG) and Control group (CG).

TABLE 3 Length of stay in the baseline and intervention period.

Length of stay (days)	Baseline period (2008–2012) IG ($n=111$) Mean (SD)	Baseline period (2008–2012) CG ($n=111$) Mean (SD)	p-Value[a]	Mean difference (95% CI)	Intervention period (2014–2017) IG ($n=159$) Mean (SD)	Intervention period (2014–2017) CG ($n=159$) Mean (SD)	p-Value[a]	Mean difference (95% CI)
All infants	68.7 (24.6)	67.4 (30.4)	0.319	1.5 (−4.59, 7.58)	53.6 (23.0)	60.8 (28.8)	0.064	−7.15 (−11.95, −2.36)
≥32 wkGA	43.7 (15.8)	35.5 (15.8)	0.088		27.5 (8.8)	30.3 (8.3)	0.080	
28–31 wkGA	63.6 (18.3)	58.7 (16.6)	0.126		47.5 (13.1)	53.1 (17.3)	**0.047**	
<28 wkGA	92.2 (18.3)	100.6 (25.8)	0.202		79.4 (16.7)	91.9 (24.2)	**0.007**	

Note: Statistically significant findings are marked in bold ($p<0.05$).

Abbreviations: CG, Control group; IG, Intervention group; wkGA, weeks of gestational age.

[a] Mann–Whitney *U*-test.

(2.7%) vs. 1 (0.9%), $p=0.622$) and intervention period (1 (0.6%) vs. 3 (1.9%), $p=0.622$). We observed a significant difference in the baseline period for BPD. While there were only eight cases of 111 (7.2%) in the IG, there were 22 cases (19.8%) in the CG ($p=0.009$). In the intervention period cases of BPD further declined in both IG and CG (0 (0%) vs. 11 (6.9%)). Indeed, we found not a single case of BPD in the IG in this time period. For the incidence of sepsis overall and for the incidence of EOS, there was no significant difference between the IG and CG in both periods. However, we observed a reduction of cases of LOS from baseline to intervention period in the IG (Figure 3A). While there was no significant difference in the incidence of LOS in the baseline period (IG 15.3% vs. CG 8.1%, RR 0.53, $p=0.143$), in the intervention period the occurrence of LOS was significantly lower in the IG compared to controls (IG 2.5% vs. CG 10.7%, RR 4.25, $p=0.005$). There was no significant difference in rates of IVH grade II–IV between IG and CG in both periods. However, the rate of IVH II-IV declined from 13.5% to 3.7% after the implementation of the programme in our department of neonatology and remained stable in the CG (8.1% and 8.2%). The occurrence of all IVH grades is displayed in Figure 3B.

4 | DISCUSSION

In this analysis, we evaluated the implementation of the family-centred clinical care pathway and case management programme termed "NeoPAss" for preterm VLBW infants in our department of

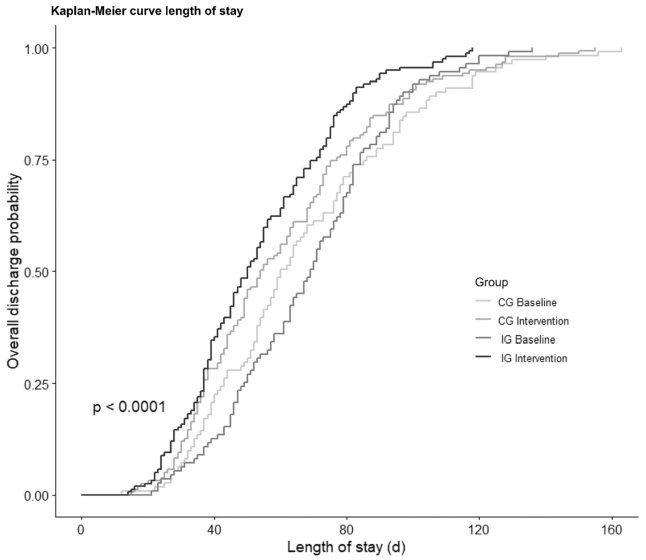

FIGURE 2 Kaplan–Meier curve displaying discharge probability over time for Intervention group (IG) and Control Group (CG).

neonatology at the Children's Hospital Passau. Using matched controls from the large Bavarian preterm cohort in the corresponding time periods we could detect a significant reduction in length of stay, weight at discharge and LOS in association with the programme. The rate of IVH, BPD and NEC tended to be lower in preterm in our intervention programme, but this was not significant, mainly due to the overall low numbers of cases. To the best of our knowledge, we present the first results from a structured FCC clinical care pathway and case management programme for preterm infants established in Germany. So far, FCC programmes have mainly been adopted in Scandinavia,[10] North America[5,11,12,21] and more recently in Asia.[7,9,13,14]

FCC programmes vary considerably in conception and scope and the categorisation of NeoPAss in this spectrum is challenging.[8] Differences in setting, target group, duration of interventions, mission statement, as well as character and scope of individual interventions vary considerably between different approaches to FCC and complicate the comparison of results from previous studies. However, most programmes aim to promote the involvement of the family in the care of their infant and most provide psychological support for parents and measures to support breast milk feeding and KMC. The principle of active family involvement as primary caregiver of their infants is the key criterion that links NeoPAss to the human care approach by Levin et al. and the FICare programme.[5,11,22,23] Moreover, there is a substantial overlap between the individual components of NeoPAss and FICare. The implementation of a guiding case management approach, which structures the treatment pathway and provides a constant contact person for parents, may be a unique strength of NeoPAss. Further strengths include a well-planned implementation phase, the detailed bundle of evidence-based measures, and the interdisciplinary collaboration.

FICare and subsequent modification to FICare have been rigorously evaluated in cluster randomised controlled trials in multiple settings.[5,6,9,21] However, studies evaluating FCC programmes in the NICU often adopted a quasi-experimental design, while only few randomised controlled trials are available.[7,14] Several factors make a prospective multigroup-controlled study design challenging, particularly in the analysis of multidimensional interventions such as FCC approaches. New health care models are therefore often evaluated using a non-randomised study design. In the context of limited resources and in the case of multidimensional interventions, a retrospective study with matched controls from secondary data is an inexpensive alternative to evaluate interventions and less prone to methodical limitations and risk of bias compared to other methods. For this analysis, we created a matched control group consisting of VLBW infants from the BAQ database comprising the majority of VLBW infants born in Bavaria. This strengthens the validity of our results and potentially reduces the possible confounding effect of time-associated improvements in neonatology practice and reduces the risk of systemic bias, but also has limitations. Firstly, the BAQ data set does not encompass 100% of the cases from all reporting hospitals and we were unable to identify all infants from Passau in the data sets. Some infants may be missing in the data set due to incomplete reporting by hospitals. Furthermore, potential anomalies are centrally reviewed and subsequently reported back to the respective hospital for investigation; however, these corrections may not be reflected in the BAQ data obtained for this study. Secondly, we do not have information on the specific NICUs the matched controls were retrieved from, and some may have adopted aspects of FCC, which could lead to variability in the quality of care provided to the control group. This also means that the control infants in the baseline and intervention period were likely obtained from different hospitals. Although various aspects of family-centred care are likely to be practised in many NICUs across Bavaria, none have implemented explicit programmes that incorporate all the central pillars of family-centred care.

Other options, such as establishing control groups from the same hospital or another single NICU are challenging, as the specifics of the individual setting and treatment would likely have a bigger influence on outcomes. Furthermore, these options would not provide matching as accurately due to limited sample size. For these reasons, we see the comparison to VLBW infants from Bavarian surveillance data as a strength of this study. Due to the nature of secondary data analysis and the matching method employed we were limited to the parameters available in the data set. Therefore, we were unable to report potential confounders such as gender or the use of antenatal steroids in the control group. This approach also restricted the selection of outcome variables, as other outcomes of interest such as breast milk feeding rates, neurological outcomes, patient and provider experience, and health economics analysis were not possible due to the nature of the database in this data set. However, the data obtained for this study originate from a standardised template and no modifications were made to the outcomes reported during the study period.

Despite these limitations, our study demonstrates that the inclusion of matched controls is a feasible and valuable option to improve

TABLE 4 Rates of infant complications in the baseline and intervention period.

	Baseline period (2008–2012)			Intervention period (2014–2017)		
	IG	CG		IG	CG	
	n (%)	*n* (%)	*p*-Value[a] (RR)	*n* (%)	*n* (%)	*p*-Value[a] (RR)
NEC	3 (2.7%)	1 (0.9%)	0.622 (0.33)	1 (0.6%)	3 (1.9%)	0.622 (3.0)
≥32 wkGA	0 (0.0%)	0 (0.0%)		0 (0.0%)	1 (3.5%)	
28–31 wkGA	2 (3.3%)	1 (1.6%)		0 (0.0%)	1 (1.2%)	
<28 wkGA	1 (3.0%)	0 (0.0%)		1 (2.1%)	1 (2.1%)	
IVH Grade II–IV	15 (13.5%)	9 (8.1%)	0.280 (0.60)	6 (3.7%)	13 (8.2%)	0.154 (2.0)
≥32 wkGA	0 (0.0%)	0 (0.0%)		0 (0.0%)	0 (0.0%)	
28–31 wkGA	4 (6.7%)	2 (3.3%)		0 (0.0%)	5 (6.0%)	
<28 wkGA	11 (33.3%)	7 (21.2%)		6 (12.5%)	8 (16.7%)	
BPD	8 (7.2%)	22 (19.8%)	**0.009 (2.75)**	0 (0.0%)	11 (6.9%)	-
≥32 wkGA	0 (0.0%)	1 (5.3%)		0 (0.0%)	0 (0.0%)	
28–31 wkGA	1 (1.6%)	4 (6.7%)		0 (0.0%)	1 (1.2%)	
<28 wkGA	7 (21.2%)	17 (51.5%)		0 (0.0%)	10 (20.8%)	
Any sepsis	21 (18.9%)	18 (16.2%)	0.725 (0.85)	11 (6.9%)	21 (13.2%)	0.092 (1.91)
≥32 wkGA	1 (5.3%)	1 (5.3%)		0 (0.0%)	1 (1.9%)	
28–31 wkGA	8 (13.5%)	8 (13.5%)		3 (3.6%)	7 (8.4%)	
<28 wkGA	12 (36.4%)	9 (27.3%)		8 (16.6%)	13 (27.1%)	
LOS	17 (15.3%)	9 (8.1%)	0.143 (0.53)	4 (2.5%)	17 (10.7%)	**0.005 (4.25)**
≥32 wkGA	1 (5.2%)	0 (0.0%)		0 (0.0%)	1 (1.9%)	
28–31 wkGA	8 (13.5%)	4 (6.8%)		1 (1.2%)	4 (4.8%)	
<28 wkGA	8 (24.2%)	5 (15.2%)		3 (6.3%)	12 (25%)	
EOS	5 (4.5%)	11 (9.9%)	0.193 (2.2)	7 (4.4%)	6 (3.8%)	1 (0.86)
≥32 wkGA	0 (0.0%)	1 (5.2%)		0 (0.0%)	0 (0.0%)	
28–31 wkGA	0 (0.0%)	5 (8.4%)		2 (2.4%)	3 (3.6%)	
<28 wkGA	5 (15.2%)	5 (15.2%)		5 (10.4%)	3 (6.3%)	

Note: Statistically significant findings are marked in bold ($p < 0.05$).

Abbreviations: *BPD*, *Bronchopulmonary dysplasia;* CG, Control group; EOS, early-*onset* SepsisIG, Intervention group; IVH, *Intraventricular haemorrhage; LOS*, *late-onset* Sepsis; NEC, Necrotizing enterocolitis; RR, Relative risk for CG compared to IG; wkGA, weeks of gestational age.

[a] *p*-value are calculated with Fisher's exact test.

the interpretation of outcomes following the implementation of multidimensional interventions in a single NICU.

The results of this analysis confirm other studies, demonstrating a beneficial effect of family-centred care programmes on length of stay and weight at discharge and provide evidence that structured parental involvement is not associated with increased risk of infection in a VLBW cohort.

Rates of NEC (0.6% vs. 2.7%), BPD (0% vs. 7.2%) and IVH II-IV (3.7% vs. 13.5%) in our NICU were lower in the intervention period than in the baseline period, but we found no significant difference compared to matched controls in the intervention period (IVH $p = 0.154$, NEC $p = 0.622$). However, this is likely due to the small number of observed cases. For BPD, we were not able to test for significance, as there were no observed cases in our NICU during the intervention period. While the incidence of sepsis overall and EOS were similar in both IG and CG in both periods, we observed a significantly lower incidence of LOS in the IG compared to controls after the implementation of NeoPAss. This finding is particularly significant, as the NeoPAss programme includes open access for parents to the NICU and active involvement of the family, both of which are often considered risk factors for nosocomial infection. Neonatal sepsis is a major contributor to long-term morbidity and these findings are even more important in the light of often posed concerns of family involvement due to fear of transmission of infections.[24] Our data clearly demonstrate that this is not the case. In fact, the presence of families and the associated effects might be protective against LOS. Possible explanations for the decrease in LOS incidence include increased breast milk feeding,[25] improvements in interdisciplinary communication, improved knowledge transfer regarding infection prevention,[26] improved hygiene routines,[27] and the promotion of KMC[28] and rooming-in,[29] all of which have been associated with lower risk of infection in infants.

While the length of stay was similar for IG and CG in the baseline period, we observed a significantly shorter length of stay in the group

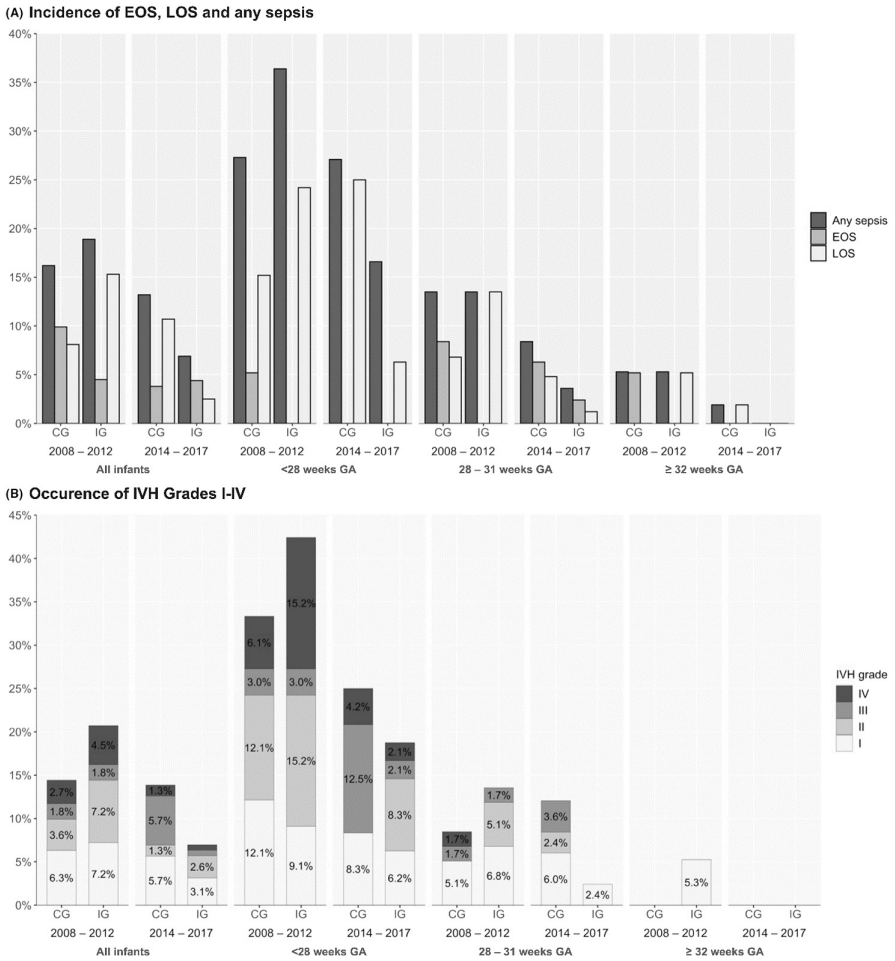

FIGURE 3 (A) The rates of Late-onset sepsis (LOS), Early-onset sepsis (EOS) and any sepsis are displayed for all infants and different gestational age (GA) groups in both Intervention group (IG) and control group (CG) during the baseline period (2008–2012) and intervention period (2014–2017). (B) The Percentage of Intraventricular Haemorrhage (IVH) Grades I–IV are shown for all infants and subgroups by gestational age.

of VLBW infants with 28–31 weeks of gestation and <28 weeks gestational age from our NICU compared to matched controls after the implementation of NeoPAss.

While it has often been hypothesised that involvement of the family in the NICU may reduce length of stay by improving parents' knowledge and readiness for discharge, the results of previous studies have been inconclusive.[5,30] In our study, we found a reduced length of stay in the most relevant gestational age groups compared to controls, which has been reported by previous studies. Ortenstrand et al. also found a significant difference in length of stay after the implementation of a FCC intervention, which was largely explained by observed differences between the most immature infants.[10] Likewise, Melnyk et al. found the largest difference in length of stay between intervention and control groups in the subgroup of VLBW infants.[12] More premature infants often require extended stays in the NICU and often have complex medical needs and might thus benefit most from FCC interventions, possibly explaining these findings.

We also observed that after the implementation of NeoPAss infants from our department were able to be discharged with significantly less weight than controls. One possible explanation for this observation could be increased parental confidence in discharging their children from the NICU earlier. We did not find any significant difference in weight gain compared to matched controls in the intervention period. Some previous studies have found better weight gain associated with FCC interventions,[6,11,13] while others have not.[21] The diverging outcomes concerning weight gain may be explained by our relatively high baseline growth velocity, different reporting time points, evaluation methods or differences in clinical practice and individual models of FCC. Additional research is required to explore the potential advantages of FCC models and specifically NeoPAss, especially regarding patient and provider experience and economic analyses.

5 | CONCLUSION

The implementation of the family-centred clinical care pathway and case management programme NeoPAss was safe and associated with low rates of infant complications and a significantly lower incidence of LOS compared to controls. Infants were able to be discharged with significantly less weight than controls, and we observed a shorter length of stay, especially for more premature infants. Using secondary data as synthetic controls is a feasible method to evaluate multidimensional interventions, when randomisation, blinding or establishing a control group is challenging.

AUTHOR CONTRIBUTIONS

R.P., J.P., M.K., M.Z. and S.MH. designed the study. M.K, M.Z. and F.B. were involved in planning and supervised the work, R.P. and J.P. collected the data, S.MH. and R.P. analysed the data. R.P. drafted

the manuscript and R.P. and S.MH. designed the figures. All authors discussed the results and commented on the manuscript.

ACKNOWLEDGEMENTS

We thank all parents and their infants who participated in the study. Open Access funding enabled and organized by Projekt DEAL.

FUNDING INFORMATION

No external funding.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

ORCID

Rafael Pricoco https://orcid.org/0000-0002-5223-5894

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How to cite this article: Pricoco R, Mayer-Huber S, Paulick J, Benstetter F, Zeller M, Keller M. Impact of a family-centred clinical care programme on short-term outcomes of very low-birth weight infants. Acta Paediatr. 2023;112:2368–2377. https://doi.org/10.1111/apa.16944