

BMJ Open Effectiveness of a nurse educational oral feeding programme on feeding outcomes in neonates: protocol for an interrupted time series design

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ABSTRACT

Introduction: Oral feeding is a complex physiological process. Several scales have been developed to assess the ability of the neonate to begin suck feedings and assist caregivers in determining feeding advancement. However, feeding premature neonates remains an ongoing challenge and depends above all on caregivers' feeding expertise. We will evaluate the effect of a nurse training programme on the achievement of full oral feeding with premature neonates.

Methods and analysis: The study design will be an interrupted time series design with 3 phases: (1) A 6-month baseline period; (2) a 22-month intervention period and (3) a 6-month postintervention period. The intervention will consist of an educational programme, for nurses and assistant nurses, on feeding patterns in neonates. The training modules will be composed of a 2-day conference, 2 interactive multidisciplinary workshops, and routine practice nurse coaching. A total of 120 nurses and 12 assistant nurses, who work at the neonatal unit during the study period, will participate in the study. All premature neonates of <34 weeks postmenstrual age (PMA) will be included. The primary outcome will be the age of tube withdrawal PMA and chronological age are taken into account. The secondary outcomes will be the transition time, length of hospital stay, competent suckle feeding without cardiorespiratory compromise, rate of neonates presenting with feeding issues or feeding rejection signs, and current neonatal pathologies or deaths during hospital stay. A segmented regression analysis will be performed to assess the impact of the programme.

Ethics and dissemination: Approval for the study was obtained from the Hospital Ethics Committee, and the Institutional Review Board, as well as the French Data Protection Agency. The findings from the study will be disseminated through peer-reviewed journals, national and international conference presentations and public events.

Trial registration number: NCT02404272 (<https://clinicaltrials.gov>).

Strengths and limitations of this study

- This educational nurse programme is designed to include maximum participation of interested caregivers in neonatal feeding patterns.
- A coordinated multidisciplinary diagnostic and management approach will be implemented through the creation of an individualised feeding protocol combined with feeding specialists coaching.
- Moreover, we will designate 'local opinion leaders', otherwise experts in our study.
- The study aims to show that interactive workshops can result in considerable changes in professional practice.
- However, methods to implement continuous medical education for paramedical professions still need to be developed.

INTRODUCTION

Background and rationale

Poor oral-motor developments in neonates are common¹ and the prevalence of feeding dysfunctions in former premature infants is twice that of full-term born infants.² Oral feeding is a complex physiological process that depends primarily on the coordination of sucking, swallowing and respiration.³ Full term born children demonstrate such skills at birth. However, premature infants may experience delayed transition to independent oral feeding, which exposes them to the possibility of long-term tube feeding.⁴ There are several implications to delayed transition, such as delayed oral feeding autonomy, intrusive medical oral sphere care and impaired eating disorders, potentially resulting in delayed hospital discharge and increased financial burdens.^{5,6}

Different interventions have shown their efficacy in accelerating transition from tube

to full oral feeding, which can also reduce the duration of hospital stay. Non-nutritive sucking through the utilisation of a pacifier accelerates transition to full oral feeding and allows earlier tube withdrawal, while decreasing hospitalisation time.⁷ Early introduction to suck feedings also accelerates transition from tube to oral feeding and allows for earlier tube removal.^{8–9} Prefeeding oral and perioral stimulations (cheeks, lips, jaw, gums and tongue) result in earlier achievement of full oral feeding without noticeable impact on length of stay.^{10–11} Finally, oral-motor interventions (assisted movement to activate muscle contraction, and movement against resistance to build strength) prior to the introduction of oral feedings are also found to reduce the transition to full oral feeding autonomy.¹²

Yet, as Kish¹³ shows, oral feeding readiness is affected by adequate suck-swallow-breathe coordination and depends on gestational age, behavioural state organisation and physiological stability, as well as being influenced by caregivers and the environment. Several scales have been developed to assess the ability of neonates to start suck feedings and assist caregivers in determining feeding advancement.^{4–13–16} However, in spite of existing guidelines, feeding premature neonates remains an ongoing challenge and relies on caregivers' feeding expertise, often requiring multidisciplinary guidance.¹⁷ Negative oral stimulation as well as overzealous feeding practices may induce oral-motor disorganisation, potentially causing defensive feeding behaviour, and hinder the differentiation of feeding skills.^{18–19}

We hypothesise that an oral feeding training programme dedicated to the caregivers of a neonatal unit could (1) help the caregivers to reflect on their current feeding practices and enhance their diagnostic and management approach of infants presenting with feeding difficulties, (2) reduce the length of hospital stay for neonates and (3) reduce the rate of neonates presenting with oral-motor dysfunction or defensive feeding behaviour.

Aims of the study

The purpose of this study is to evaluate the impact of an educational oral feeding nurse training programme on the achievement of full oral feeding and transition time (initiation to full oral feeding) among all admitted neonates of <34 weeks postmenstrual age (PMA).

Caregivers' theoretical knowledge and practical feeding skills will be evaluated, as well as their satisfaction level with the educational oral feeding programme.

METHODS/DESIGN

Study design

The study design will be an interrupted time series design with three phases: (1) a 6-month baseline period; (2) a 22-month intervention period and (3) a 6-month postintervention period.

Setting and participants

The setting of this study is a 44-bed, level IIIC, Neonatal Intensive Care Unit (NICU)²⁰ of the Femme Mere Enfant Hospital, Bron, Lyon, France.

All nurses and assistant nurses (a total of 120 nurses and 12 assistant nurses) of the neonatal unit will participate in the study. All premature neonates of <34 weeks PMA, admitted to the unit during the study period, will be included. PMA will be used as the gestational age and postnatal age in weeks. Neonates who will have surgery with endotracheal intubation will not be included. Neonates will not be included if one of the parents refuse his/her participation in the study.

Group at baseline period

The baseline group will comprised premature infants who were hospitalised prior to the initiation of the educational nurses programme, at which time non-nutritive sucking is applied intermittently. Oral stimulations and oral-motor rehabilitation is performed during the baseline period by physiotherapists and speech therapists as it is usually done on infants presenting with feeding issues. Oral feeding is initiated between 32 and 34 weeks of PMA. No feeding protocol will be in place at the time, and parents participate in the feedings when present.

Intervention

The intervention will consist of an educational programme, for nurses and assistant nurses, on feeding patterns in neonates. Training modules will be composed of a 2-day conference, two interactive multidisciplinary workshops and routine practice nurse coaching (table 1).

The content of the trainings will be developed by a group of experts and adapted to nurse competency levels. A protocol leaflet will be produced for the personnel. The expert group will comprised two nurses specialised in developmental care, a speech therapist, a physiotherapist, a psychologist and a neonatologist. All the experts work in the neonatal unit. Six training modules will be scheduled over a 22-month period to include the group of 120 nurses and 12 nurse assistants from the unit.

Training modules

Each training module will last 4 months and will consist of a 2-day conference, held during the first month, followed by two multidisciplinary workshops. Routine practice nurse coaching will take place throughout this study period.

1. The conference will provide theoretical knowledge about feeding patterns in neonates. Anatomy, physiology and development of feeding milestones will be analysed. Different interventions, shown to accelerate the transition from tube to full oral feeding, will be presented. The impact of both environment and caregiver behaviour on feeding success will be evaluated. Feeding difficulty symptoms, patient

Table 1 Educational training programme

Multidisciplinary educational programme	Theoretical conference	Interactive workshop 1	Interactive workshop 2	Routine practice nurse coaching
Content	<ul style="list-style-type: none"> ▶ Theoretical knowledge about feeding pattern ▶ Introduction of the oral feeding protocol 	Video recordings	Video recordings	<ul style="list-style-type: none"> ▶ Routine feeding practice ▶ Oral feeding protocol ▶ Detection of infants presenting with feeding issues
Speech therapist	Instructor	Instructor	Instructor	Instructor
Physiotherapist	Instructor	Instructor	Instructor	Instructor
Paediatrician	Instructor	Instructor		
Psychologist	Instructor		Instructor	Instructor
Length	2 days	2 h	2 h	During the entire study period
Time frame	4 months			

management and feeding outcomes will also be reviewed, and feedback from the different experts regarding feeding patterns will be presented at the conference, at which time the standardised individualised feeding protocol will be introduced.

2. The multidisciplinary interactive workshops will consist of video presentations of neonatal bottle or breast feedings performed in the neonatal unit. Video presentations will demonstrate oral and perioral stimulation, non-nutritive sucking, oral-motor re-education and feedings. These workshops will focus on nursing neonate feeding practices in a multidisciplinary setting. Difficulties encountered during feedings, such as overzealous as well as passive nurse feeding behaviours, will be discussed, and optimal position and posture during feeding sessions will be evaluated. The standardised, individualised feeding protocol and its application to caregivers will be considered. Two members of the expert group will be present and lead workshop discussions.
3. The routine practice nurse coaching will be performed by a speech therapist and physiotherapist present at the neonatal unit. They will support nurses and assistant nurses in their routine feeding practice and application of feeding protocols. They will also assist caregivers with early detection of infants presenting with feeding issues, and help them apply the oral-motor rehabilitation protocol when necessary.

The standardised individualised feeding protocol

The standardised feeding protocol will be applied to neonates who present with physiologically stable conditions. The nurse will evaluate the infant's medical condition prior to the feeding and determine if the intervention will be possible. Infants with unstable cardiorespiratory function will not get the intervention. Unstable cardiorespiratory function will be defined as: more than one apnoea and/or bradycardia per hour (breathing pauses that last for >20 s or for >10 s if associated with bradycardia <80/min or oxygen desaturation), high oxygen use or tachypnoea (respiratory rate

>60/min), uncontrolled infection or haemodynamic support. Neonates' sleeping periods will be respected. If the neonate presents with signs of feeding rejection or symptoms of feeding difficulty, the intervention will be stopped and resumed at a later time. Rejection signs or feeding difficulties will be defined as no demonstration of hunger cues, bottle refusal, coughing, choking or vomiting during feedings, hypoxia or unstable heart rate during feeding sessions; feeding intake exceeding 30 min, excitement, discomfort or arching of the back during feedings, and gagging or falling asleep during feedings. With infants of at least 32 weeks PMA, parents will be able to participate in non-nutritive sucking as well as the feedings, with coaching by the bedside nurse.

Emphasis will be placed on optimal position and posture during feeding sessions and minimisation of negative environmental stimulations, such as stress, lighting and noise. The bedside nurse will keep a feeding record on oral feeding advancement (timing of feeding, amount of feeding, feeding difficulties, feeding progress). Each participating nurse and assistant nurse will have direct access to our protocol leaflet. Our educational nurse programme includes a combination of strategies shown to be effective in accelerating transition from tube to full oral feeding: non-nutritive sucking, oral and perioral stimulation, early sucking introduction for all neonates in the unit, as well as oral-motor interventions for infants presenting with feeding difficulties (figures 1 and 2).

Implementation strategies

Implementation support strategies will be introduced to facilitate the intervention. These methods consist of 'expert' feeding rounds that will take place on a regular basis of one round per day for the physiotherapist and one round per week for the speech therapist and the paediatrician. These expert feeding rounds will have multiple aims: (1) reinforce the key messages of the standardised feeding protocol, (2) monitor nurses' and assistant nurses' compliance with the feeding protocol (3) identify the neonates for whom the feeding protocol

	NONNUTRITIVE SUCKING	ORAL/PERIORAL STIMULATIONS	EARLY ORAL FEEDING	ORAL MOTOR REHABILITATION
Infant characteristics	<ul style="list-style-type: none"> • ≥24 weeks PMA • alert behavioural state • physiological stability • from day one of life 	<ul style="list-style-type: none"> • ≥24 weeks PMA • alert behavioural state • physiological stability • from day one of life 	<ul style="list-style-type: none"> • ≥29 weeks PMA • alert behavioural state • physiological stability • from day one of life 	<ul style="list-style-type: none"> • alert behavioural state • physiological stability • feeding difficulty symptoms • no full oral feeding at 35 wks PMA • refusing oral stimulations at 32 wks PMA
Intervention	<ul style="list-style-type: none"> • Pacifier • During tube feedings or outside feeding times. • The mouth is never entered by force. 	<ul style="list-style-type: none"> • Oral/perioral stimulations provide sensorimotor input to oral and perioral structures. • Gentle but firm pressure on the cheek, just below the ear, with a finger, followed by movement toward the mouth. • This procedure may be repeated three times on each side. • When neonate opens their mouth, a finger or swab with one or two drops of human milk may be introduced, followed by bottle or breast feeding. • Whenever the neonate does not open their mouth, the four cardinal points around the mouth and the lips are stimulated by applying a gentle pressure with a finger to achieve sucking. • The mouth is never entered by force. 	<ul style="list-style-type: none"> • Suck feedings start at one ml, twice per day, and progress according to age and feeding ability. • Feedings will be advanced every 24 hours - if in the previous 24 hour period the feeding was successful - determined by the attending nurse and medical staff. • Breast and bottle feeds are equally considered. • The mouth is never entered by force. 	<ul style="list-style-type: none"> • Assisted movements to activate muscle contraction and movements against resistance to build strength. • Prior to the intervention, assessment by language therapist or physiotherapist and decision of the type of intervention depending on severity of feeding difficulties. • Infants presenting with oral stimulation refusal or marked vomiting reflex, will benefit from diagram 1. • Infants presenting with feeding difficulties (excluding stimulation refusal or marked vomiting reflex), may benefit from diagram 1 and 2. • The procedure diagram is placed at the infant's bedside.
Time frame	<ul style="list-style-type: none"> • 5 to 10 minutes prior to feedings. • If the neonate is fasting they will receive the intervention during the care periods while awake 	<ul style="list-style-type: none"> • 5 to 10 minutes prior to feedings. • If the neonate is fasting they will receive the intervention during the care periods while awake 		<ul style="list-style-type: none"> • 5 to 10 minutes prior to feedings. • If the neonate is fasting they will receive the intervention during the care periods while awake

Figure 1 The standardised individualised feeding protocol. This figure describes the oral and perioral stimulation gestures. PMA, postmenstrual age.

is not applied correctly and (4) engage provider-focused feeding discussions.

Outcomes measures

The *primary outcome* to be measured will be the age of tube withdrawal. PMA will be described in weeks. Chronological age (CA) will be described in days, weeks or months.²¹ Data collection for the neonates will be obtained through their medical files: PMA will be determined from obstetrical records.

The *secondary outcomes* are described below:

- ▶ Transition time, which will be defined as the time frame between the start of oral feeding, and full oral feeding autonomy (date of tube removal). PMA and CA will be considered.
- ▶ Length of hospital stay.
- ▶ Competent suckle feeding without cardiorespiratory compromise (PMA and CA will be considered). Cardiorespiratory compromise during suckle feeding will be defined by apnoea and/or bradycardia (breathing pauses that last for >20 s or for >10 s if associated with bradycardia <80 bpm for 10 s or oxygen desaturation) occurring up to 30 min after feedings, and at least at two meals per day after tube removal.
- ▶ Current neonatal pathologies during hospital stay: bronchopulmonary dysplasia, necrotising enterocolitis, periventricular leucomalacia, intraventricular

haemorrhage, hypoxic ischaemic encephalopathy, retinopathy of the neonate, culture proven bloodstream infections.

- ▶ Deaths during hospital stay.

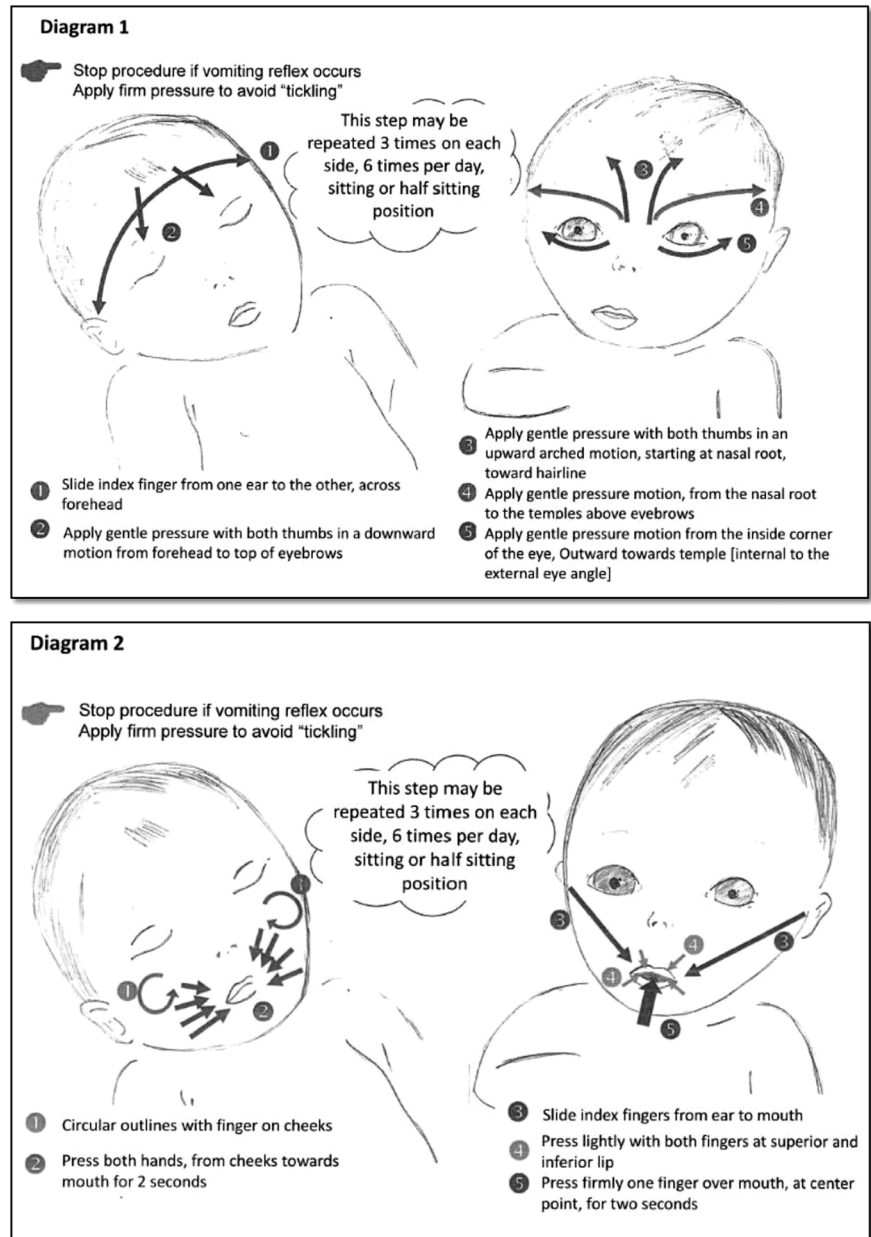
Process measures

- ▶ Nurses' involvement in the training modules will be evaluated through their presence at the training sessions.
- ▶ Caregivers' knowledge acquisition and satisfaction scores will be assessed through a questionnaire following each training module.
- ▶ Time dedicated to routine practice nurse coaching (also called feeding rounds) in their routine feeding practice and application of feeding protocols will be measured.
- ▶ Nurses' protocol compliance: to assess nurses' protocol compliance, a questionnaire will be developed by health providers working at the neonatal unit, and will be revised by questionnaire design experts. The instruments' question and response categories will be phrased in simple terms. They will be tested for comprehensibility by health providers from the neonatal unit who are not participating in the study protocol.

Balancing measures

Feeding difficulties or feeding rejection signs, defined in our study as no demonstration of hunger cues, bottle

Figure 2 Oral-motor rehabilitation. Infants presenting with an oral stimulation refusal or marked vomiting reflex will benefit from the oral-motor rehabilitation protocol described in diagram 1. Infants presenting with feeding difficulties (excluding the stimulation refusal or marked vomiting reflex) will benefit from the oral-motor rehabilitation protocol described in diagrams 1 and 2.



refusal, coughing, choking or vomiting during feedings, hypoxia or unstable heart rate during feeding sessions, feeding intake exceeding 30 min, excitement, discomfort or arching of the back during feedings, and gagging or falling asleep during feedings.

Other changes occurring in the NICU during the study period

All events, such as leadership changes, and protocol modifications that occur during the study period and may interact with the intervention or the study results will be recorded in a logbook.

Blinding

Owing to the nature of the intervention, healthcare providers, parents and researchers will not be blinded to the intervention phase.

Study sample size

According to a pilot study, the mean age of tube withdrawal is 35.7 ± 2 weeks PMA (data unpublished). We aim to detect a decrease of 5 days in the mean age of tube withdrawal. A sample size of 130 neonates in the baseline period and the postintervention period will be needed to detect this difference with a power of 80% and 5% risk of type I error.

The anticipated difference in outcome measure is based on the expected effectiveness of our educational programme and data from previous studies.^{9 11 22}

On the basis of the census data, it is anticipated that we will be able to recruit 20–25 new patients from 24 to 34 weeks PMA into the proposed study each month, which means that 138 premature infants may be included during the 6-month pre-educational programme period; 506 during the 22-month training

period, and 138 during the 6-month posteducational programme. A total of 680 premature infants may be included during the 34-month study period.

In interrupted time series studies, sample size calculations are related to the estimation of the number of observations or time points at which data will be collected. A sufficient number of time points before and after the intervention is needed to conduct a segmented regression analysis: a study of 34 months meets these conditions.²³

Statistical considerations

Data analysis will be performed by the data management and analysis centre using SAS/STAT software.

Statistical analysis will include the following steps:

- ▶ A descriptive and bivariate comparative study of the characteristics of the newborns, between the three periods of study (gestational age at birth; PMA, CA when neonates present with feeding difficulties; age (PMA, CA) at the initiation of bottle/breast feedings; age (PMA, CA) at full oral feeding autonomy; blood-stream infections; mortality; length of stay).
- ▶ A bivariate comparative study of the primary and the secondary outcomes between the baseline period and the postintervention period.
- ▶ A graphical analysis of the average age (PMA; CA) of tube withdrawal, by month, according to the method of statistical process control.²⁴
- ▶ A multivariate analysis by the method of segmented regression analysis to study the impact of training on the average age (PMA, CA) of tube removal by month.²³ The statistics of Durbin-Watson will be calculated to test the hypothesis of non-independence between the observations. Where appropriate, the segmented regression model will be adjusted to the autocorrelation parameters. An adjustment may be made on other aggregate covariates such as the number of professionals trained in oral and perioral stimulation gestures by month.

The secondary end points will be analysed with the same statistical method.

A descriptive analysis of the average scores of professional self-assessment of learning following training, and a descriptive analysis of the average level of satisfaction with the training module.

Dissemination

Healthcare staff consent was obtained prior to the study. As stipulated by French law, given the study design (lack of randomisation) and type of intervention (educational programme on recognised clinical practices), an instruction sheet will be given to the parents who will be permitted to refuse the inclusion of their infant in the study.

The results of our study will be disseminated on the Neonatology' unit's website. Additional dissemination will occur through presentations at conferences, such as neonatology conferences, regionally and nationally, and through articles published in peer-reviewed journals.

Presentations at International conferences as 'Hot Topics in Neonatology 2016' and national conferences as 'Journées Françaises de Néonatalogie (JFRN)' will take place from December 2016. Study results will be submitted from December 2016 in peer-reviewed journals.

DISCUSSION

Discussion of the intervention

In 1998, the American Academy of Pediatrics has established guidelines on discharge of high-risk neonates, including preterms. One of the three competencies recognised as essential before hospital leave is adequate oral feeding to support appropriate growth. However, no guidelines exist on clinical pathways for acquiring these feeding competencies.²⁵

A literature review demonstrates significant research on feeding development interventions, assessment of feeding readiness and feeding advancement algorithms. Different strategies have been shown to achieve earlier tube weaning: non-nutritive sucking,⁷ oral and perioral stimulation,^{10 11} oral-motor intervention¹² and early introduction of suck feeding.^{8 9} These methods are effective, either individually or in combination, to accelerate transition to independent oral feeding.^{10 22 26} Our educational nurse programme includes a combination of these strategies: non-nutritive sucking, oral and perioral stimulation, early sucking introduction for all neonates in the unit, as well as oral-motor interventions for infants presenting with feeding difficulties.

Oral Feeding readiness assessment scales have been established to evaluate neonates' ability to start suck feedings as well as detect infants presenting with suck difficulties.^{4 15 27} Researchers have also shown that protocol-driven clinical pathways permit earlier oral feeding autonomy.^{9 28}

However, these programmes are more effective when delivered by knowledgeable and skilled nurses, with the assistance of experienced feeding specialists.^{19 29 30} Similarly, infants presenting with feeding difficulties should be supported by individualised protocols.³⁰ Parent involvement in feedings is also important in maternal infant attachment and parent well-being.^{18 19 31} However, if not well controlled, this aspect could raise the anxiety level of already fragile parents.³²

This educational nurse programme contains essential elements to be effective. It will be coordinated by an expert group and designed to include maximum participation of interested caregivers in neonatal feeding patterns (nurses, assistant nurses, physiotherapists, language speech therapist, psychologist, neonatologists). The individualised feeding protocol will be adapted to daily practice in a multidisciplinary setting, utilising video recordings of neonatal feeding sessions. The protocol will be implemented in daily practice with coaching from physiotherapists and a speech language therapist. Parents can participate in non-nutritive sucking, and

feedings, with infants of at least 32 weeks PMA, with coaching from the bedside nurse.

Studies show that effective nurse training benefits from: (1) involvement of experts, considered by teams as 'local opinion leaders',³³ (2) interactive continuing medical education through real case studies, where better learning outcomes have been demonstrated compared with more traditional teaching,^{34 35} and (3) coordinated multidisciplinary diagnostic and management approach.

The study aims to show that interactive workshops can result in considerable changes in professional practice. Moreover, we will designate 'local opinion leaders', otherwise experts in our study. A coordinated multidisciplinary diagnostic and management approach will be implemented through the creation of an individualised feeding protocol combined with feeding specialists coaching. However, methods to implement continuous medical education for paramedical professions still need to be developed.³⁶

Discussion of study design

The interrupted time series design includes a data sequence before and after the implementation of the intervention.^{37 38} An interrupted time series design is an effective quasiexperimental approach for evaluating effects of interventions that are introduced at a specific point in time when a randomised controlled trial is not feasible.^{39 40} The analysis of a time series allows us to assess the initial value of the criteria of judgement (intercept), the underlying trend (slope) and the sustainability of the impact of the intervention.⁴¹ This design is effective if a fairly large number of measurements for the outcome of interest are available and a segmented regression can be used to analyse the data.⁴² The Effective Practice and Organisation of Care (EPOC) group recommends a minimum of three points before and six points after surgery. The intervention should be in place at one time or a specified period, and the measures of criteria must be objective.⁴³

Interrupted time series analysis depends on the availability of accurate and quality data.⁴⁴ In our study, data will be routinely collected in the computerised clinical records of newborns, ensuring successful execution of the study, and the collection of a sufficient number of measurements.

To utilise the strength of this design, a modification to standard regression analysis, such as segmented regression, is required. Segmented regression analysis is a powerful statistical method for evaluating intervention effects in interrupted time series studies.^{40 45} Segmented regression can identify sudden change due to an intervention, as well as more gradual changes over time.⁴²

We selected this study design due to its methodological quality and feasibility. One advantage is that it will permit us to separate results of individual training programmes and progression of underlying practices.⁴⁶ It will allow us to consider the secular trend (change in epoch). Indeed, we will analyse neonates' data during a

6-month period preceding the implementation phase. This baseline period will give us a temporal control that will help us to determine whether the particular intervention has a significantly greater effect than the underlying secular trend. Moreover, this type of study allows us to measure the learning progression of neonatal feeding patterns by caregivers. Effectively, we will establish a learning curve on feeding techniques and protocol compliance. However, the biggest threat to time series analysis is events occurring at the same time as the intervention and producing similar effects (ie, history).⁴⁷ One of the more notable strengths of interrupted time series studies is the intuitive graphical presentation of results. The first step when analysing data over time is the visual inspection of the series data.⁴⁸ This graphical representation is a useful tool for caregivers to visualise the impact of the training programme.

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Contributors All the authors have made substantial contributions to the development of this study. FP conceived this study with AB and designed it with ST, AD, HGM, SH and OC. AD and ST contributed to the statistical plan and are responsible for statistical analysis. AD and SH are responsible for the data management. ST, AB, FP and AD have contributed to the development of this protocol. ST wrote the first draft of the manuscript. All the authors read and approved the final manuscript.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval Approval for the study was obtained from the Hospital Ethics Committee, the Sud Est IV Institutional Review Board, as well as the French Data Protection Agency.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement All data from the study will be available for all TOP study investigators. All data will be published.

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