# Research Protocol for Sleep in Families With a Preterm Infant

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**Background:** Specificities regarding the quality and quantity of sleep of preterm infants and their parents following discharge of the preterm infant from the hospital are not well known. Given this lack of knowledge, the links between the sleep characteristics of these parents, family functioning, and their psychological well-being are also unclear.

**Objectives:** The purpose of this article is to summarize the research protocol of a cross-sectional, mixed-methods, convergent design study, which aims to evaluate the sleep patterns of preterm infants and both their parents and document the associations between sleep quality, parents' psychological well-being, and family functioning during the posthospitalization period.

**Methods:** A convenience sample is used to recruit 30 families. For quantitative data collection, a questionnaire booklet consisting of validated questionnaires is used to measure sleep quality of each family member, parental psychological well-being, and family functioning completed by each parent. An actigraph and a sleep diary measure sleep quantity of each parent and the preterm infant. Afterward, semistructured interviews are carried out with each parent to explore their perceptions and needs concerning their infant's and their own sleep quality. For data analysis, qualitative and quantitative data are analyzed separately and then merged to allow for an integrative interpretation of the results.

**Results:** The research project is ongoing; 25 of 30 families have completed the data collection. Data analysis is underway.

**Discussion:** This research will provide a global portrait of the families' sleep 1 month after the preterm infant is discharged from the hospital, which is not well known to date. The results will help healthcare providers involved with preterm infants and their families after discharge from the hospital to increase their comprehension of the families' reality and adapt their interventions to meet these needs.

**Key Words:** family functioning ● parents ● preterm infant ● psychological well-being ● sleep

Annually, about 15 million infants are born prematurely, prior to 37 weeks of gestation (World Health Organization, 2022). Depending on the degree of prematurity and the health condition of the preterm infant, hospitalization in the neonatal intensive care unit (NICU) or special care nursery may be required; it may last several weeks in this environment containing multiple sources of overstimulation that may alter the quality of the infant's sleep, such as high or variable light levels (Zores et al., 2018). Alteration of preterm infants' sleep may also continue beyond hospitalization. Indeed, when they are discharged from the hospital as they approach 40 weeks of postconceptional age, their sleep is still different from that of a newborn born at term (Gogou et al., 2019; Hoppenbrouwers et al., 2005). Their sleep is less organized and contains fewer periods of calm sleep than term-born infants. This difference between the sleep of preterm infants and those born at term is still present during the childhood period (up to 12 years), with preterm infants showing shorter daytime sleep (nap) duration, shorter nocturnal sleep duration, increased motor activity level, and lower awakening thresholds compared to term-born infants (Gogou et al., 2019; Yiallourou et al., 2018).

Results of previous studies have shown that impaired sleep, preterm birth, and prolonged hospitalization may induce neurodevelopmental and cognitive disorders in preterm infants (Pineda et al., 2014; White, 2015). In addition, a lack of sleep during and after hospitalization may interfere with brain plasticity, the development of primary sensory systems, and the formation of memory and long-term memory neural circuits (Graven & Browne, 2008). Results of previous studies also indicate that these factors may adversely affect the development of parent–child attachment (Holditch-Davis et al., 2014) and the establishment of breastfeeding (Flacking et al., 2011).

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Parents of a preterm infant have reported altered sleep during NICU hospitalization (Lebel et al., 2022) and for several months after (Edéll-Gustafsson et al., 2015). In fact, according to results from a study on 170 parents, after discharge, 48% of mothers and 32% of fathers perceive that they have insufficient sleep, and 47% of mothers and 44% of fathers report that insufficient sleep is still occurring 12 months after childbirth (Blomqvist et al., 2017). This sleep disturbance can last for more than 18 months (Yiallourou et al., 2018) and is particularly present among parents of a preterm infant. A study with 834 mothers of preterm infants aged 0–36 months showed that those mothers reported more disturbed sleep than mothers of term-born infants (Lupini et al., 2021). Unfortunately, to our knowledge, no similar studies have been done on fathers.

These sleep disturbances may also occur concurrently with symptoms of postpartum depression (Cherry et al., 2016) and posttraumatic stress disorder (associated with birth and postpartum events) because many parents report being affected with these conditions for up to 18 months after the birth of their preterm infant (Malouf et al., 2022). Finally, parents of a preterm infant who reported higher levels of anxiety and symptoms of depression also reported a lack of sleep and rest when questioned about their quality of life (Amorim et al., 2018).

Family functioning refers to the social and structural components of the family environment. It includes the interactions and relationships within the family (Alderfer et al., 2008). It is reported that parents experience altered family functioning during the first few months following the discharge of their preterm infant (Pinelli et al., 2008). In addition, the association between impaired psychological well-being and poor family functioning has been established for mothers during their infant's hospitalization in the NICU (Ballantyne et al., 2013). On the other hand, the relationship between family functioning and parental sleep following discharge from the NICU is uncertain, given the lack of evidence on this topic. However, it is documented that parental fatigue may affect family functioning, contributing to adverse parental practices and experiences (Cooklin et al., 2012).

Furthermore, there appears to be a link between infant sleep and family functioning. Indeed, as suggested by Sadeh and Anders' (1993) conceptual model (the transactional model of sleep–wake regulation), there are bidirectional links between the infant sleep and intrinsic infant factors (e.g., temperament) and parental factors (e.g., personality and cognitions). Once sleep difficulties are present, this model states that family functioning, parental well-being, and parent–infant relationships are negatively affected (Sadeh & Anders, 1993).

Several studies concerning parental sleep focused on the first weeks after childbirth during the infant's hospitalization in the NICU (Marthinsen et al., 2018). Of the studies addressing parental sleep after NICU hospitalization, several were conducted with a sample including only or mostly mothers or with a data collection period occurring several months after the transition home with the preterm infant (Hwang et al., 2021; Kim et al., 2020). Fathers are underrepresented in these studies, and sleep characteristics of families during the first weeks after discharge are not precisely described. Because the first few weeks after the transition home with the preterm infant are particularly difficult for parents who must assume all the care on their own while attending to their other obligations (Amorim et al., 2018; Pinelli et al., 2008), it is crucial to know more about their sleep patterns and the effect on their psychological well-being and family functioning. The present study will therefore address a gap in the knowledge regarding fathers' sleep characteristics after their infant discharge from the NICU, as well as the links between family sleep following the neonatal hospitalization period, parental psychological well-being, and family functioning. In addition, this mixed design study is unique because it will provide an in-depth description of sleep (quality and quantity), psychological well-being, and family functioning in Canadian families discharged from the NICU within the last month and identify relationships between these variables. In addition, it will allow identification of similarities and differences among the collected data, permitting a more complete understanding of the measured variables.

The research protocol presented here was designed to evaluate the sleep patterns of preterm infants and both parents and document the associations between sleep quality, parents' psychological well-being, and family functioning during the posthospitalization period. Specific objectives are presented in Table 1.

## METHODS

This research project is a cross-sectional, mixed-methods, convergent design, which has the advantage of providing complementarity of collected data, allowing a broader understanding of the phenomena being studied, as well as improved validity considering the various data collection methods used (Creswell & Plano Clark, 2018). The quantitative methods will assess the sleep habits of preterm infants and their parents and the psychological well-being of parents and family functioning. The qualitative data will describe parents' perceptions concerning their needs and concerns related to their infant's sleep, their own sleep, and the factors influencing each.

### Setting and Sample

Recruitment is taking place in a Level 3 NICU ward in a university hospital in Montreal, Canada. The target sample size is 30 families for a total of 60 parents and their preterm infants. This sample size will allow the identification of associations between mothers' and fathers' sleep quality (dependant variable) and these independent variables: parental psychological well-being, the infant's quantity of sleep, and family functioning. It is generally accepted that the sample size includes at least 10 participants for each independent variable included in the regression model (Field, 2018). This sample size is also appropriate

**TABLE 1. Study Objectives and Data Analysis Plan**

| Specific objectives | Data analysis plan |
|---|---|
| 1 To document the sleep patterns of prematurely born infants discharged from the NICU for at least 1 month, as well as the sleep patterns of both parents. | Data from the parent (PSQI) and preterm infant (BISQ) sleep questionnaires, as well as data from actigraphs and sleep diaries (sleep duration per night, sleep duration during the day, frequency of sleep interruption during the night) will be analyzed with descriptive statistics. |
| 2 To assess the psychological well-being of parents by documenting the prevalence of parents' symptoms of depression, stress, anxiety, and posttraumatic stress. | Data from questionnaires on parents' psychological well-being (PSI, EPDS, PPQ, STAI) will be analyzed using descriptive statistics. |
| 3 To explore correlations and associations between preterm infant sleep quantity, parental sleep quality, parental psychological well-being, and family functioning. | Pearson correlations will be performed to identify correlations between these variables for mothers and fathers: PSQI, PSI, EPDS, PPQ, STAI, ICE-EFFQ, and sleep duration per night (in minutes; actigraphy). In addition, this variable will be added to the correlation matrix: infant's mean sleep duration per night (in minutes; actigraphy). |
| | To explain mothers' sleep quality as measured with the PSQI (dependent variable), a multiple linear regression model will be conducted with these independent variables: EPDS (a predominant variable for measuring parents' psychological well-being; Cherry et al., 2016), ICE-EFFQ, and infant's mean sleep duration per night (actigraphy). If appropriate, additional analyses will be conducted with the other measures of parental psychological well-being (PSI, PPQ, and STAI). |
| | The same multiple linear regression model will be conducted with fathers' variables. |
| | Multiple pregnancy (dichotomous variable) will be added in the regression model as a control variable. |
| 4 To explore the perceptions of parents regarding the sleep of their preterm infant and their own sleep, their psychological well-being, and family functioning. | A thematic analysis will be performed to identify emerging themes and subthemes. For this purpose, the research team, based on the interview guide, developed a coding tree. |
| 5 To identify similarities and differences regarding preterm infant sleep patterns, parental sleep patterns, parental psychological well-being, family functioning, and parental perception (qualitative data) of their preterm infant and their own sleep, their psychological well-being, and family functioning. | Quantitative and qualitative results will be compared. This comparison in a specific table and the description of their complementarity or discrepancies will allow researchers to provide a more complete overview of the phenomenon under study, i.e., the quality and quantity of sleep of preterm infants and their parents following discharge from the NICU (Creswell & Plano Clark, 2018). |

_Note_. NICU = neonatal intensive care unit; PSQI = Pittsburgh Sleep Quality Index; BISQ = Brief Infant Sleep Questionnaire; PSI = Parenting Stress Index; EPDS = Edinburgh Postnatal Depression Scale; PPQ = Perinatal Post Traumatic Stress Disorder Questionnaire; STAI = Spielberger State–Trait Anxiety Inventory; ICE-EFFQ = Iceland–Expressive Family Functioning Questionnaire.

to obtain data saturation with interview data (Creswell & Plano Clark, 2018), and a convenience sampling method is used. To participate in the study, parents must be over 18, speak and write French or English, and be the biological parent of an infant born preterm at 32 weeks of gestation or less. Families with an infant born at 32 weeks gestation or less are targeted to participate because their period of hospitalization is generally longer (Blomqvist et al., 2017). In addition, both parents must participate (father and mother, or same-sex partners), because both partners are often greatly involved in preterm infant's care and their sleep may be disturbed (Amorim et al., 2018; Pinelli et al., 2008). Parents with

a single or multiple pregnancy are eligible to participate in the study. Given the high percentage of newborns from multiple pregnancies in neonatology, this criterion will ensure the representativeness of the sample. The study was approved by the ethics committee of the hospital center where the recruitment is taking place.

## Study Procedure and Measures

A research team member meets eligible parents at the NICU when the infant reached 34 weeks postconception, as discharge planning is usually underway at this time. If parents agree to take part in the study, data collection occurs 1 month

after the infant's discharge from the hospital, in two steps. First, quantitative data collection takes place using an actigraph (Micro Motionlogger watch), a sleep diary, and a questionnaire booklet. Actigraphy is a simple, objective, less invasive tool to estimate sleep than polysomnography. It has been validated in adults, children, and infants as a good measure of sleep–wake patterns (Meltzer et al., 2012; Tikotzky et al., 2015). The sleep diary is a log form where participants may indicate every detail about their sleeping habits. These data will support the interpretation of the data recorded by the actigraphs. The questionnaire booklet consists of sociodemographic and validated questionnaires measuring infant and parent sleep, parent psychological well-being, and family functioning. Questionnaires included in the booklet are described in Table 2. According to the

parents' availability, a research assistant drops off the quantitative instruments at their house. Each parent completes the questionnaire booklet and sleep diary over the next four consecutive days. Thirty to 45 minutes are needed to complete the booklet. Each parent completes each questionnaire, apart from the questionnaire regarding the infant's sleep (see Table 2), which is completed by one of the two parents. In addition, each parent and preterm infant (each infant if twins or triplets) wears an actigraph continuously for a period of 72 hours (3 days and 3 nights) on weekdays only, because sleep routines may be different on weekends (each parent wore the actigraph on the nondominant hand, and the infant wore it on the ankle). When participants must remove the actigraph, they are asked to indicate this in the sleep diary (reason and duration of the

**TABLE 2.  Description of Questionnaires**

| Questionnaires | Measures | Questions/items | Psychometric qualities | Scores/interpretation |
|---|---|---|---|---|
| 1. Brief Infant Sleep Questionnaire (BISQ; Sadeh, 2004) | Infant sleep habits in the last 7 days (0–3 years). | 10 questions | • Test–retest reliability: $r = .82$ (Sadeh, 2004) | Descriptive data = characteristics of the preterm infant 'sleep |
| 2. Pittsburgh Sleep Quality Index (PSQI; Backhaus et al., 2002) | Sleep quality and sleep disturbances in the last month | 19 items answered on a 4-point Likert scale. | • Test–retest reliability: $r = .87$ (Backhaus et al., 2002) | Total score = 0–21 >5 = significant sleep disturbances |
| 3. Parenting Stress Index (PSI; Abidin, 1990) | Parental stress | 36 items rated from 1 = *strongly agree* to 5 = *strongly disagree* | • Internal consistency: $\alpha = .70–.95$ (Haskett et al., 2006) | Total score = 36–180 Higher score indicates higher parental stress |
| 4. Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987) | Postpartum depression symptoms in the last 7 days (excluding somatic symptoms) | 10 items answered on a 4-point Likert scale | • Internal consistency: $\alpha = .76–.88$ • Test–retest reliability: $r = .98$ • Validated with both mothers and fathers (Matthey et al., 2001) | Total score = 0–30 >12 = at risk for depression |
| 5. Perinatal Post Traumatic Stress Disorder Questionnaire (PPQ; Callahan et al., 2006) | Posttraumatic stress symptoms associated with childbirth and postpartum events | 14 "yes" or "no" items Parents answer "yes" if their experience/ symptom lasted more than 1 month | • Internal consistency: $\alpha = .85–.90$ • Test–retest reliability: $r = .92$ • Used with mothers and fathers of preterm infants (Malouf et al., 2022) | Total score = 0–14 >6 clinical perinatal posttraumatic stress disorder |
| 6. Spielberger State–Trait Anxiety Inventory (STAI; Spielberger et al., 1970) | State and trait anxiety | 2 subscales of 20 items | • Internal consistency: $\alpha = .89$ • Used with parents of preterm infants (Greene et al., 2015) | Subscales score = 20–80 ≥30 moderate anxiety ≥45 severe anxiety |
| 7. Iceland Expressive Family Functioning Questionnaire (ICE-EFFQ; Sveinbjarnardottir et al., 2012) | Dimensions of family functioning | 17 items rated from 1 = *almost never* to 5 = *all of the time* | • Internal consistency: $\alpha = .89–.96$ (Sveinbjarnardottir et al., 2012) | Total score = 17–85 Higher score indicates a better family functioning |

interruption). All instructions regarding the data collection are given over the phone or sent by e-mail to parents. At the end of the 4 days of data collection, the research assistant returns to the family's home to pick up data collection tools. Second, qualitative data collection occurs during an individual semistructured interview conducted over Zoom with each parent separately, at a time of their choosing. Research assistants conducting interviews with an interview guide have been trained by the principal investigator to ensure scientific rigor. The interviews are recorded for the purposes of later transcription by a member of the research team. Figure 1 illustrates the course of the study.

## Data Analysis Plan

Sociodemographic data will be analyzed with descriptive statistics. The actigraphy data will be scored using the Sadeh algorithm for infants with 1-minute epochs (Sadeh et al., 1995). Then, data will be extracted and transferred in SPSS for quantitative analyses. Quantitative data (questionnaire booklet, sleep diary, and actigraphic data) will be analyzed using descriptive statistics, Pearson correlations, and multiple linear regression analyses (see Table 1 for more details). All quantitative data will be analyzed with SPSS Statistics for Windows (Version 28). Qualitative data codification and analysis will be completed with NVivo qualitative data analysis software (Version 12), according to a thematic analysis process (see Table 1 for more details). Integration of quantitative and qualitative results will be achieved as a final step of data analysis. This integration will allow the description of complementarity or discrepancies of the quantitative and qualitative results (see Table 1 for more details).

To ensure scientific rigor, coding is performed by two research assistants. Coding fidelity is validated by the principal investigator. The coding tree was first developed with the interview guide, using an inductive approach, and is adapted and completed according to the information in the interviews, using a deductive approach. Triangulation of data collection methods also ensures scientific rigor. Data credibility is also enhanced by member checking during the data collection and analysis phases.

## DISCUSSION

To date, a total of 30 families have been recruited. Of these, 25 have completed the study protocol, and five families dropped out after providing consent to participate in the study but before the beginning of data collection (no data were collected). Families who chose to withdraw from the study indicated that they no longer had time to devote to the study. Transcription and codification of data are underway, and it is anticipated that data saturation will be reached, as it is nearly reached with the recruited families.

The main challenges encountered have been posed by the COVID-19 pandemic, leading to changes in the protocol in order to allow the study to be conducted in compliance with the restrictions imposed by the authorities. First, recruitment of the families was delayed by 6 months because all research projects in the care setting were put on hold. In addition, at the beginning of recruitment, questions about the influence of the pandemic on sleep, psychological well-being, and family functioning were added to the sociodemographic questionnaire to consider the effects of the pandemic on the main variables of the study. Moreover, the research team has been meeting with the families via Zoom to avoid contact given the sociosanitary restrictions. Some limitations are anticipated, such as limited duration of the study and small sample size for the quantitative
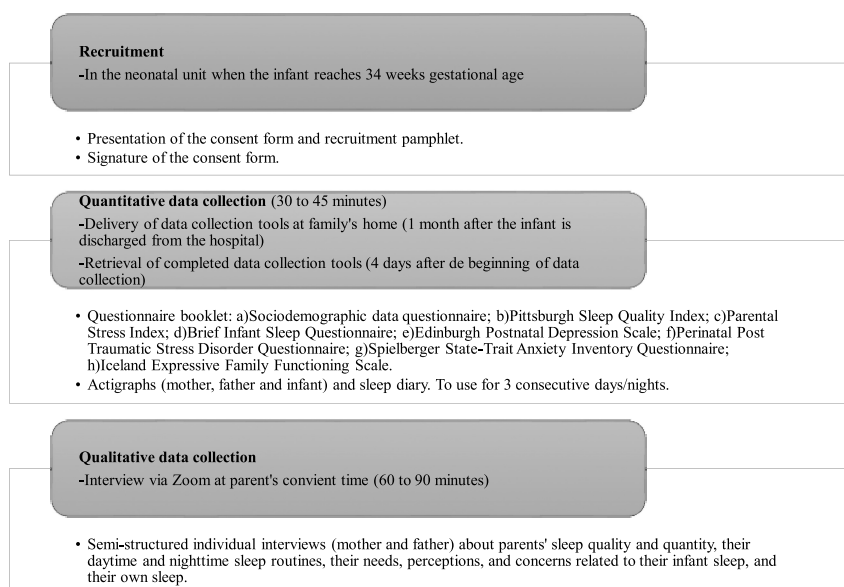


**Recruitment**
-In the neonatal unit when the infant reaches 34 weeks gestational age

• Presentation of the consent form and recruitment pamphlet.
• Signature of the consent form.

**Quantitative data collection** (30 to 45 minutes)
-Delivery of data collection tools at family's home (1 month after the infant is discharged from the hospital)
-Retrieval of completed data collection tools (4 days after de beginning of data collection)

• Questionnaire booklet: a)Sociodemographic data questionnaire; b)Pittsburgh Sleep Quality Index; c)Parental Stress Index; d)Brief Infant Sleep Questionnaire; e)Edinburgh Postnatal Depression Scale; f)Perinatal Post Traumatic Stress Disorder Questionnaire; g)Spielberger State-Trait Anxiety Inventory Questionnaire; h)Iceland Expressive Family Functioning Scale.
• Actigraphs (mother, father and infant) and sleep diary. To use for 3 consecutive days/nights.

**Qualitative data collection**
-Interview via Zoom at parent's convient time (60 to 90 minutes)

• Semi-structured individual interviews (mother and father) about parents' sleep quality and quantity, their daytime and nighttime sleep routines, their needs, perceptions, and concerns related to their infant sleep, and their own sleep.

**FIGURE 1.** Data collection process.

portion. As mentioned above, these limitations will be minimized by performing quantitative analyses accounting for the small sample size and by comparing the quantitative data to the qualitative data. For feasibility and acceptability reasons, the study was not conducted with multiple measurement points. However, it would be interesting to carry out a longitudinal study in the future to measure the sleep of preterm infants and their parents during the first year following hospital discharge.

## Conclusion

This research protocol is interesting and innovative because it involves comprehensive data collection, including quantitative and qualitative data. It will provide a global portrait of the families' sleep 1 month after the preterm infant is discharged from the hospital—which is not well known to date. Therefore, the results will help healthcare providers working with these families to adapt their interventions to their realities and needs. The numerous efforts invested by the research team to adapt the protocol to the pandemic situation will be useful for researchers currently developing a research project with this population. The next steps for this research project involve completing the data collection and data analysis. In addition, data interpretation will be carried out in consideration of the study limits, as well as of the richness of collected data.

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