Sleep and Health-Related Quality of Life in Parents of Preterm and Full-Born Infants

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Gunhild Nordbø Marthinsen,
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Sammendrag

Bakgrunn: Etter en fødsel kan foreldrene oppleve endringer i søvnmønsteret, spesielt de første månedene. Det nyfødte barnet kan ha en uforutsigbar døgnrytme som påvirker foreldrenes søvn, mange foreldre opplever allikevel barseltiden som en gledelig periode i livet. Derimot kan en prematur fødsel oppleves som en krise for familien. Det premature barnet kan trenge avansert medisinsk behandling i nyfødt intensivavdeling, og høyt stressnivå kan påvirke foreldrenes søvn negativt. Søvn er viktig for mental og fysisk helse; søvnforstyrrelser og dårlig søvnkvalitet kan føre til helseproblemer og redusert helserelatert livskvalitet (HRLK) for foreldre. I starten av dette prosjektet var det sparsomt med systematisk kunnskap om søvn og helse hos foreldre til premature barn. Det var også begrenset kunnskap om hvorvidt denne gruppen var mer utsatt for lite og dårlig søvnkvalitet og redusert HRLK, sammenlignet med foreldre til terminfødte barn.

Hensikt: Det overordnede målet med denne avhandlingen var å studere søvn og forholdet mellom søvn og HRLK hos foreldre til premature barn i barselfasen (barnet er 2-12 måneder). Videre var hensikten å sammenlikne søvn og HRLK hos mødre og fedre til terminfødte barn i samme periode.

Design, utvalg og metoder: Studien var designet som en komparativ longitudinell kohortstudie med tre målepunkter (2, 6 og 12 måneder etter fødsel). Søvn- og helserelaterte utfall fra to foreldregrupper (foreldre til premature og terminfødte barn) ble evaluert og sammenlignet prospektivt. Foreldre ble rekruttert fra nyfødt- og barselavdelinger ved flere sykehus.

For å kartlegge forskningsbehov knyttet til søvn hos foreldre til premature nyfødte, ble det først gjennomført en systematisk kunnskapsoppsummering (scoping review) i 2018. I forbindelse med gjennomføringen av den longitudinelle studien ble det påvist store utfordringer knyttet til rekruttering og innsamling av data fra foreldre til premature barn. Det ble derfor besluttet å gjennomføre en systematisk analyse av gjennomførbarheten av en longitudinell studie og publisere resultatene, da dette ble ansett å ha stor verdi for fremtidige studier. Datainnsamlingen i den longitudinelle studien ble utført like før og under den første bølgen av koronavirussykdommen 2019-pandemien, noe som skapte ytterligere utfordringer;

studien ble likevel fullført. Data om søvn, psykososiale variabler og HRLK ble samlet inn ved hjelp av validerte metoder (aktigrafer og spørreskjemaer) fra foreldre til premature og terminfødte barn.

Resultat: Den systematiske kunnskapsoppsummeringen (Artikkel 1) viste at de fleste studiene som hadde undersøkt søvn og helse hos foreldre til premature barn, var geografisk lokalisert i USA. De fleste studiene var kvantitative og fokuserte på mors søvn de første 2 ukene etter fødselen, både objektive og subjektive søvnmål var benyttet. Den systematiske kunnskapsoppsummeringen viste at få longitudinelle studier hadde evaluert begge foreldrenes søvn over tid i barseltiden. Det manglet også studier som hadde vurdert styrken på mulige sammenhenger mellom søvn, psykososiale faktorer og HRLK over tid, og sammenlignet disse utfallene mellom foreldre til terminfødte og premature barn. Litteraturgjennomgangen bekreftet behovet for å designe en komparativ longitudinell studie designet for å vurdere søvn og helse hos foreldre til premature og terminfødte barn over tid, sammenligne og identifisere mulige forskjeller mellom foreldregrupper (premature og terminfødte) og undersøke forskjeller mellom mødre og fedre.

I det empiriske prosjektet var målet å rekruttere 75 foreldrepar til begge gruppene. For gruppen med terminfødte barns foreldre ble det rekruttert 76 foreldrepar fra to barselavdelinger ved to sykehus. Rekrutteringen av foreldre med premature barn var imidlertid utfordrende. Mellom juni 2019 og mars 2020 ble 25 foreldre til premature rekruttert fra fire nyfødtintensivavdelinger og en barselavdeling ved fire ulike sykehus i Norge.

For å systematisk evaluere muligheten for å gjennomføre en prospektiv sammenlignende longitudinell kohortstudie, var feasibilitystudien (Artikkel 2) primært rettet mot å vurdere rekruttering og frafall, og det sekundære målet var å beskrive og sammenligne deltakernes egenskaper, evaluere måleinstrumenter og utfall og identifisere mulige sammenhenger mellom utvalgte variabler og frafallsrater. Et viktig funn var at det var vanskeligheter med å rekruttere til den premature gruppen, muligens på grunn av våre valgte inklusjonskriterier og at mange foreldre ikke ønsket å delta. Et annet funn var at frafallstendensen var høy i begge foreldregruppene ved 6 og 12 måneder. Ingen sosiodemografiske kjennetegn ved foreldrene var assosiert med frafall ved 6 måneder. Ved 12

måneder hadde frafallet statistisk signifikant lavere alder i terminfødtgruppen (begge foreldre) og høyere alders- og kroppsmasseindeks i den premature gruppen (fedre). Måleinstrumenter (aktigraf, søvndagbok og spørreskjema) ble vurdert som egnet for bruk i fremtidige studier.

Ved vurdering av søvn, insomnisymptomer og HRLK hos mødre og fedre til premature og terminfødte barn over tid (Artikkel 3) ble det ikke funnet signifikante forskjeller i total søvntid mellom prematur og terminfødt gruppen ved 2 måneder, men foreldre i den premature gruppen hadde statistisk signifikant lavere søvneffektivitet sammenlignet med foreldre i termingruppen. Mødre sov generelt dårligere enn fedre ved 2 måneder og hadde signifikant lavere søvneffektivitet og total søvntid sammenlignet med fedre ved 2 måneder. Forekomsten av insomni ved 2 måneder var høy blant foreldrene i begge gruppene – spesielt i prematurgruppen, hvor andelene var 62,5 % (mødre) og 71,4 % (fedre). Blant foreldre til terminfødte barn var forekomsten lavere: 53,4% (mødre) og 43,5% (fedre). For mødrene i begge gruppene var forekomsten av insomni fortsatt høy (> 50%) ved 6 og 12 måneder, men mødrene i den terminfødte gruppen hadde høyest forekomst. For fedre i begge gruppene sank forekomsten over tid. Det ble ikke funnet statistisk signifikante forskjeller i HRLK mellom gruppene over tid (2, 6 og 12 måneder). Fedre hadde signifikant høyere fysisk HRLK enn mødre ved alle måletidspunkter. Insomni var den eneste søvnvariabelen som ble funnet å være statistisk signifikant assosiert med redusert HRLK i begge gruppene (alle tre målepunktene). I vår kohort var derfor insomni den sterkeste prediktive faktoren for mental HRLK hos foreldre.

Konklusjoner: Våre resultater tyder på at foreldrenes overgang til foreldrerollen er krevende, med redusert søvn tidlig etter fødselen som krever økt oppmerksomhet fra helsepersonell. Funnene understreker viktigheten av å støtte søvn og forebygge søvnforstyrrelser, spesielt for nye mødre. Forebygging av insomni kan bidra til å fremme god HRLK hos foreldre. Vi anbefaler at søvnscreening innføres som en standard klinisk rutine i svangerskapsomsorgen, slik at foreldre med søvnforstyrrelser kan identifiseres tidlig og få hjelp.

Våre resultater viste at det er mulig å gjennomføre en longitudinell studie som sammenligner søvn og HRLK hos foreldre til premature og terminfødte spedbarn, men i mye mindre skala enn opprinnelig tenkt. Det er viktig at omfanget av

datainnsamlingen ikke blir for belastende for foreldre med premature barn. Det er også viktig å være aktiv og støttende i oppfølgingen av inkluderte foreldre i longitudinelle studier for å forebygge frafall.

Summary

Background: After childbirth, parents may experience sleep pattern changes, especially in the first few months. The newborn child may have an unpredictable circadian rhythm that affects the parents' sleep, yet many experience new parenthood as a joyful period. In contrast, a premature birth can be experienced as a crisis for the family. The premature baby may need advanced medical treatment in the neonatal intensive care unit, and high stress levels can negatively affect the parents' sleep. Sleep is important for mental and physical health; thus, sleep disturbances and poor sleep quality can lead to health problems and reduced health-related quality of life (HRQoL) for parents. There was sparse systematic knowledge about the sleep and health of parents of premature children at the start of this project. There was also limited knowledge about whether this group is more prone to having too little and poor sleep quality and reduced HRQoL compared to parents of full-born children.

Aim: The overall aim of this thesis was to study sleep and the relationship between sleep and HRQOL in parents of preterm infants in the postpartum phase (the child is 2-12 months). Furthermore, the purpose was to compare sleep and HRQoL in mothers and fathers of preterm infants with mothers and fathers of full-born infants in the same time period.

Design, sample and methods: The study was designed as a comparative longitudinal cohort study with three measurement points (2, 6 and 12 months after childbirth). Sleep and health-related outcomes from two parent groups (parents of preterm and full-born infants) were evaluated and compared prospectively. Parents were recruited from neonatal and maternity wards at several hospitals.

To identify research needs related to sleep in parents of premature newborns, a systematic knowledge summary (scoping review) was first performed (2018). Regarding the longitudinal study, major challenges associated with recruiting and collecting data from parents of premature children became apparent. It was therefore decided to conduct a systematic analysis of the feasibility of a longitudinal study and publish the results, as this was considered to have a great value for future studies. Data collection in the longitudinal study was performed

just before and during the first wave of the coronavirus disease 2019 pandemic, which created further challenges; nevertheless, the study was completed. Data on sleep, psychosocial variables and HRQoL were collected using validated methods (actigraphs and questionnaires) from parents of premature and full-born children.

Results: The systematic knowledge summary (Paper 1) revealed that most of the studies that had examined sleep and health in parents of premature children were geographically located in the US. Most studies were quantitative and focused on maternal sleep during the first 2 weeks after birth, and both objective and subjective sleep measures were used. The scoping review demonstrated that few longitudinal studies had evaluated both parents' sleep over time during the postpartum period. There was also a lack of studies that had assessed the strength of possible relationships between sleep, psychosocial factors and HRQoL over time during the postpartum period and compared these outcomes between parents of full-born and preterm infants. The literature review confirmed the need to design a comparative longitudinal study designed to assess sleep and health in parents of premature and full-born children over time, compare and identify possible differences between parent groups (preterm and full-born) and investigate differences between mothers and fathers.

In the empirical project, the goal was to recruit 75 parent pairs to both groups. For the full-born group, 76 pairs of parents were recruited from two maternity wards at two hospitals. However, the recruitment of parents with premature infants was challenging. Between June 2019 and March 2020, 25 parents of premature infants were recruited from four neonatal intensive care units and one maternity ward at four different hospitals in Norway.

To systematically evaluate the feasibility of conducting a prospective comparative longitudinal cohort study, was the feasibility study (Paper 2) primarily aimed at assessing recruitment and attrition rates, and the secondary aims were to describe and compare the participants' characteristics, evaluate measures and outcomes and identify possible associations between the selected variables and attrition rates. An important finding was the difficulty in recruiting for the preterm group, possibly due to the chosen inclusion criteria and high refusal rate. Another finding was that dropout tendency was high in both parent groups at 6 and 12 months. No sociodemographic characteristics of the parents were associated with dropout at 6

months. At 12 months, dropouts had a statistically significantly lower age in the full-born group (both parents) and higher age and body mass index in the preterm group (fathers). Measures (actigraphs, sleep diaries and questionnaire) were evaluated as feasible for use in future studies.

In assessing sleep, insomnia symptoms and HRQoL in mothers and fathers of preterm and full-born infants over time (Paper 3), no significant differences were found in total sleep time between the premature and full-born groups at 2 months, but the preterm group had statistically significantly lower sleep efficiency compared to the full-born group. Mothers generally slept worse than fathers at 2 months and had significantly lower sleep efficiency and total sleep time compared to fathers at 2 months. The incidence of insomnia at 2 months was high among the parents in both groups – especially the premature group, where the proportions were 62.5% (mothers) and 71.4% (fathers). Among parents of full-born babies, the incidence was lower: 53.4% (mothers) and 43.5% (fathers). For the mothers in both groups, the incidence of insomnia remained high (> 50%) at 6 and 12 months, but the mothers in the full-born group had the highest incidence. For fathers in both groups, the incidence decreased over time. No statistically significant HRQoL differences were found between the groups over time (2, 6 and 12 months). Fathers had significantly higher physical HRQoL than mothers at all measurement times. Insomnia was the only sleep variable found to be statistically significantly associated with reduced HRQoL in both groups (all three measurement points). Thus, in our cohort, insomnia was the strongest predictive factor for mental HRQoL in parents.

Conclusions: Our results indicate that parents' transition into the parenting role is demanding, with reduced sleep outcomes early postpartum that require increased attention from health professionals. The findings emphasize the importance of supporting sleep and preventing sleep disorders, especially for new mothers. Insomnia prevention can help to promote good HRQoL in parents. We recommend that sleep screening be introduced as a standard clinical routine in maternity care so that parents with sleep disorders can be identified early and receive help.

Our results revealed that it is feasible to conduct a longitudinal study comparing sleep and HRQoL in parents of preterm and full-born infants, however on a much smaller scale than originally intended. It is important that the scope of the data

collection does not become too burdensome for parents with premature children. It is also important to be active and supportive in the follow-up of included parents in longitudinal studies to prevent dropouts.

List of papers

Paper 1

Marthinsen, G. N., Helseth, S., & Fegran, L. (2018). Sleep and its relationship to health in parents of preterm infants: A scoping review. *BMC Pediatrics*, *18*(1), Article 352. https://doi.org/10.1186/s12887-018-1320-7

Paper 2

Marthinsen, G. N., Helseth, S., Småstuen, M., Bjorvatn, B., Bandlien, S., & Fegran, L. (2022). Sleep patterns and psychosocial health of parents of preterm and full-born infants: A prospective, comparative, longitudinal feasibility study. *BMC Pregnancy and Childbirth*, *22*(1), Article 546. https://doi.org/10.1186/s12884-022-04862-1

Paper 3

Marthinsen, G. N., Helseth, S., Småstuen, M., Bjorvatn, B., & Fegran, L. (2024). A comparison of subjective and objective sleep measures, insomnia symptoms, and health-related quality of life between mothers and fathers of preterm versus full-born infants: A longitudinal study from Norway [Manuscript submitted for publication].
Department of Health and Nursing Science, University of Agder

Abbreviations

BIS: The Bergen Insomnia Scale
CBT-I: Cognitive behavioural therapy for insomnia
CFQ: The Chalder Fatigue Questionnaire
COVID-19: Coronavirus disease 2019
DSM-IV: Diagnostic and Statistical Manual of Mental Disorders (4th ed.)
ELBW: Extremely low birthweight
EPDS: The Edinburgh Postnatal Depression Scale
FSSQ: The Duke-University of North Carolina Functional Social Support Questionnaire
GA: Gestational age
GSE: The Generalized Self-Efficacy Scale
HRQoL: Health-related quality of life
LMM: Linear mixed model
ANOVA: Analysis of variance
NICU: Neonatal intensive care unit
NREM: Nonrapid eye movement
PROM: Patient-reported outcome measure
PSG: Polysomnography
PSQ: The Perceived Stress Questionnaire
QOL: Quality of life
RAND-36: RAND Medical Outcomes Study 36-Item Short-Form Health Survey
REM: Rapid eye movement
SE: Sleep efficiency
SOL: Sleep-onset latency
TIB: Time in bed
TST: Total sleep time
UiA: University of Agder
WASO: Wake after sleep onset
WHO: World Health Organization

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1 Introduction

Sleep is important for good physical and mental health (Cirelli et al., 2019). After childbirth, parental sleep is often fragmented, shorter and less efficient compared to earlier times (Hunter et al., 2009). Sleep pattern can be particularly disturbed the first few months, resulting in considerable daytime sleepiness and fatigue for new parents. However, most parents experience the birth of an infant as a positive life event (Lee & Hsu, 2012a).

Around 13.4 million infants were born prematurely worldwide in 2020 (World health organization, 2023). The WHO (2023) defines preterm births as "all births before 37 completed weeks of gestation." Prematurity can be further subdivided according to gestational age (GA): extremely preterm (< 28 weeks), very preterm (28 to less than 32 weeks) and moderate-to-late preterm (32–37 weeks). In Norway, approximately 5.6% of all liveborn infants are born prematurely every year, 0.4% extremely prematurely, 0.5% very prematurely and 4.7% moderate/late prematurely (Oakley et al., 2022).

Preterm birth represents a global health issue (World health organization, 2023). A lower GA has been associated with a higher risk of mortality and morbidity (Harrison & Goldenberg, 2016). Infant birthweight is often used in evaluations of infant risk of mortality and morbidity (Brumbaugh et al., 2019). Low birthweight is described as less than 2,500 g, very low birthweight as less than 1,500 g and extremely low birthweight (ELBW) as less than 1,000 g (Wold health organization, 2019/2021). Extremely preterm infants still have a high risk of mortality and morbidity, despite medical care advancing over the last few decades (Aronsson et al., 2023; Cheong et al., 2021; Myrhaug et al., 2019; Norman et al., 2019). A systematic review highlighted that the survival rate for preterm infants born in high-income countries increases from nearly 0% when born at 22 weeks GA to 80% when born at 27 weeks GA (Myrhaug et al., 2019). The chance of survival without impairment increases from 1.2% to 9.3% for 22–24 weeks GA and from 40.6% to 64.2% for 25–27 weeks (Myrhaug et al., 2019). Depending on GA level, preterm infants may need medical treatment for weeks or even months in advanced neonatal intensive care units (NICUs; (Myrhaug et al., 2019).

A preterm birth has the potential to cause long-term negative effects for the infant and parents (Starke et al., 2023; Suonpera et al., 2023). The early period in the NICU has been described as challenging, characterized by high levels of parental stress, anxiety, depression, fatigue and sleep disruption (Busse et al., 2013). Parents of preterm infants are at risk of experiencing psychological stress and mental disorders, including depression, anxiety and posttraumatic stress disorder both during and after NICU hospitalization (Roque et al., 2017). Stress has been identified as a source of sleep disruption for these parents (Al Maghaireh et al., 2017; Busse et al., 2013; Lee & Hsu, 2012a). Over time, stress and family burden is described as higher for parents of preterm infants compared to those of full-born infants (Treyvaud et al., 2011). Parents of preterm infants have reported concerns for the infant's health condition and long-term health outcomes (Al Maghaireh et al., 2017; Roque et al., 2017). Parents' health and well-being play an important role in the infant's development (Hartzell et al., 2023; Treyvaud et al., 2009; Treyvaud et al., 2010), and support of parents' mental health has had an increasing focus within maternity care (Baldwin et al., 2022).

The WHO considers well-being and health-related quality of life (HRQoL) as important goals for public health promotion (WHO, 1995). HRQoL is a multidimensional concept covering physical, psychological, social and spiritual aspects of life (Post, 2014). Postpartum parents' HRQoL can be impacted by several factors (Bai et al., 2019). Knowledge of parents' HRQoL can guide the development of targeted support and interventions (McAndrew et al., 2019). At the beginning of this project, there was a lack of research on sleep and the association between sleep and HRQoL over time for parents of preterm infants. It was also necessary to expand existing knowledge and study if parents of preterm infants were more susceptible to experiencing poor sleep and HRQoL compared to parents of full-born infants. Knowledge of sleep and HRQoL can be the first step towards developing new ways to support a healthy parent population.

2 Background and theoretical framework

2.1 Parental sleep in the postpartum phase

Sleep is a multidimensional phenomenon that can impact many aspects of life and is considered essential for healthy living (Carscadon & Dement, 2017). Sleep can be defined as a "reversible behavioural state of perceptual disengagement from and unresponsiveness to the environment" (Carscadon & Dement, 2017, p. 15). The sleep-wake pattern is primarily regulated by the circadian rhythm, sleep homeostasis and habits/behavioural factors (Bjorvatn, 2012). Healthy sleep comprises an adequate duration, good quality, appropriate regularity and timing and absence of sleep disturbances or sleep disorders (Watson et al., 2015). Sleep need varies between individuals, but having 7–9 hours of nighttime sleep has been recommended for adults (Hirshkowitz et al., 2015). Sleep of less than 6–7 hours per night has been associated with increased blood pressure, inflammatory cytokines and stress hormone levels (Mullington et al., 2009). Sleep loss can lead to several negative health outcomes, such as early death (Khan et al., 2018), cardiovascular disease (Meisinger et al., 2007), cancer (Medic et al., 2017), obesity (Stranges et al., 2008) and diabetes (Khandelwal et al., 2017). Poor sleep can also negatively affect mood and cognition (Medic et al., 2017) and heighten the risk of accidents (Vargas-Garrido et al., 2021).

Different terms are used to describe sleep, including sleep duration, sleep quality, sleep continuity and sleep architecture (Hall, 2013). Sleep duration refers to the total amount of sleep during nocturnal sleep or across a 24-hour period and is commonly studied in relation to health and well-being (Hall, 2013). Sleep duration needs vary across lifespan and between individuals. Both short and long sleep duration have been associated with adverse health outcomes (Alvarez & Ayas, 2004; Cappuccio et al., 2010; Jike et al., 2018). The relationship between sleep and health has been described as u-shaped, and both short and long sleep duration have been associated with an increased risk of mortality (Cappuccio et al., 2010). Two frequently used parameters in relation to sleep duration are "time in bed" (TIB) and "total sleep time" (TST). TIB refers to the number of hours between getting into bed to sleep at night ("good nighttime") and waking up in the morning ("good morning time"). TST may be operationalized as TIB minus the amount of time

needed to fall asleep (sleep onset latency [SOL]) and amount of time spent awake at night (wake after sleep onset [WASO]; (Hall, 2013).
Sleep quality can be used to refer to individuals' subjective perceptions of their own sleep (Hall, 2013) and can be determined by the number of arousals (or awakenings) at night, as well as the duration and sleep stage type (Cirelli et al., 2019). Several awakenings or arousals can lead to reduced sleep quality and increased daytime sleepiness, as well as performance deficits (Redeker & McEnany, 2011). Sleep continuity refers to individuals' ability to initiate and maintain sleep. SE refers to the percentage of TIB spent asleep and is calculated in minutes as "(total sleep time/time in bed) × 100" (Bjorvatn, 2012, p. 41). SE is often used to determine how well or poor an individual's sleep is. For adults, a score above 85% is considered "normal" (Bjorvatn, 2012, p. 40).

Sleep architecture is often divided into two electrophysiological states: nonrapid eye movement (NREM) and rapid eye movement sleep (Landis, 2011). Sleep normally onsets through NREM sleep and progresses through deeper NREM stages (Carscadon & Dement, 2017). NREM consists of three stages (N1–N3). N1 is a transitional stage between sleepiness and sleep (Landis, 2011). Few minutes are spent in this stage, followed by a shift to N2. A large portion of the night is spent in the N2 stage. Stage N3 is often referred to as the slow-wave sleep stage. Rapid eye movement sleep follows NREM sleep and is typically characterized by rapid side-to-side eye movements and muscle atonia (Landis, 2011). Sleep follows a cyclic pattern across the night. Nocturnal sleep patterns often consist of four to six cycles of 60–110 minutes each (Landis, 2011).

The postpartum period has been described as a transitional time for parents with social, physiologic and psychological changes that may extend for months after the childbirth (Almalik, 2017; Haas et al., 2005; Schobinger et al., 2022). The postpartum period begins immediately after childbirth: the initial or acute postpartum phase refers to the first 6–12 hours after childbirth, the subacute postpartum period refers to 2–6 weeks after childbirth and the delayed postpartum period refers to the period up to 6 months after birth (Romano et al., 2010). The postpartum period has often been associated with substantial changes in parental sleep patterns, especially in new mothers (Horwitz et al., 2023; Montgomery-Downs et al., 2010; Richter et al., 2019).

Sleep pattern is often characterized by a shorter sleep duration and frequent nocturnal awakenings (Gay et al., 2004; Hunter et al., 2009; Signal et al., 2007). Sleep fragmentation can be caused by natural physiologic alterations following childbirth, together with interruptions from the infant's sleep and feeding schedule (Hunter et al., 2009). Compared to fathers, mothers sleep less hours at night and more during the day for a few weeks after childbirth (Gay et al., 2004). In (Montgomery-Downs et al., 2010) study, mothers' total nocturnal sleep time was around 7.2 hours between Weeks 2 and 16 postpartum, and sleep efficiency (SE) increased from 79.7% (Week 2 postpartum) to 90.2% (Week 16 postpartum). Thus, for both parents, sleep satisfaction and sleep duration declines and reaches a nadir (lowest value) during the first 3 months before gradually improving (Richter et al., 2019). Around 11–12 weeks postpartum, the infant establishes a more stable circadian rhythm, and parental sleep pattern begins to normalize (Nishihara et al., 2000). However, large individual variations exist; for some parents, sleep does not fully recover before 6 years after childbirth (Richter et al., 2019).

Parents with sick or preterm newborns who are admitted to the NICU have reported that they sleep poorly and can experience a combination of different emotional responses and sleep alterations (Al Maghaireh et al., 2017; Busse et al., 2013). Emotions such as anxiety, depression, stress and sleep disturbances have been reported (Al Maghaireh et al., 2017; Busse et al., 2013; Heidari et al., 2013). Concerns for the infant's medical situation, the unfamiliar NICU environment and an altered parental role are often sources of stress (Alkozei et al., 2014; Heidari et al., 2013). The NICU environment is often highly technological and dedicated to the medical treatment of preterm or sick infants rather than parental sleep. Parents are often present around the clock and do not prioritize their own sleep (Stremler et al., 2014). Mothers with hospitalized preterm infants have evaluated their own sleep as poor, which further led to a high level of daytime sleepiness and fatigue (Baumgartel & Facco, 2018; Blomqvist et al., 2017; Lee & Hsu, 2012a). Although most of the focus has been on mothers' sleep during this period, some studies have also examined fathers' sleep (Al Maghaireh et al., 2017). Al Maghaireh et al. (2017) reported that mothers of preterm infants experienced higher stress levels compared to fathers, with the high stress levels being associated with anxiety, depression and sleep disturbances. After discharge from hospital, parents have continued to report high stress levels and anxiety, and some have developed posttraumatic stress disorder symptoms (Holditch-Davis et al., 2003; Holditch-

Davis et al., 2015; Kong et al., 2013; Roque et al., 2017; Shaw et al., 2009). (Suonpera et al., 2023) found that in the early postpartum years, parents with extremely preterm infants experienced higher levels of parenting stress, which was associated with reduced HRQoL. However, none of these studies reported sleep outcomes in the first months after discharge or evaluated if sleep was more compromised in parents of preterm infants compared to those of full-born infants.

Although some parents can be at risk of sleep disturbances due to the burden from a preterm birth (Al Maghaireh et al., 2017; Busse et al., 2013), sleep disturbances has been described as a quite normal phenomenon for all postpartum parents (Horwitz et al., 2023; Swanson et al., 2020). Hence, the consequences of sleep loss can vary, depending on how long it lasts and how well individuals tolerate it (Banks, 2017). An occasional night or two of poor sleep can often be quite well tolerated, particularly if there is an opportunity to nap during the day (Lee, 2011; Saletin et al., 2017). However, sleep loss that lasts over longer periods can have more negative consequences (Banks, 2017; Gallicchio & Kalesan, 2009; Medic et al., 2017). Research has shown that some parents develop more sleep problems that becomes chronic during the postpartum period (Baglioni et al., 2022; Sivertsen et al., 2015; Sivertsen et al., 2017; Sultan et al., 2023; Swanson et al., 2020). While insomnia can occur among both mothers and fathers, postpartum mothers are at a higher risk (Bhati & Richards, 2015; Goyal et al., 2007; Lawson et al., 2015; Letourneau et al., 2012; Okun, 2015; Ross et al., 2005; Stremler et al., 2020). According to the *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.)/*International Classification of Sleep Disorders* (3rd ed.) diagnostic criteria (American Psychiatric Association, 2013), insomnia disorder is characterized by a predominant dissatisfaction with sleep despite the opportunity for sleep and includes difficulties in initiating sleep and/or maintaining sleep and/or early-morning awakening with the inability to return to sleep. The sleep disturbance must cause clinically significant distress or impairment in daytime functioning, and the sleep difficulties need to occur at least 3 nights/week for at least 3 months.

Insomnia in adolescence has been associated with an increased risk of mental and physical health problems (de Zambotti et al., 2018; Sivertsen et al., 2014). Sleep problems in the postpartum period can have a negative impact on diverse psychosocial health factors (Smith & Saleh, 2021), and has been associated, for example, with fatigue (Hunter et al., 2009; Iwata et al., 2018; McBean &

Montgomery-Downs, 2015), stress (Lee & Hsu, 2012a) and anxiety and postpartum depression (Baglioni et al., 2022; Dorheim et al., 2014; Sultan et al., 2023; Swanson et al., 2020; Thomas & Spieker, 2016). Sleep loss followed by fatigue has been identified as having a negative impact on QOL (Lee & Kimble, 2009). In a study from Norway, insomnia prevalence was high for mothers (60.8%) at Week 32 in pregnancy and was still high (60%) at Week 8 postpartum. The prevalence remained high (41%) at 2 years after childbirth (Sivertsen et al., 2015; Sivertsen et al., 2017). Pregnancy and childbirth itself have been identified as precipitants of insomnia, where the life stress and transitional processes themselves have a negative impact on sleep (Swanson et al., 2020).

To our knowledge, there is a lack of research comparing insomnia tendency between populations of preterm and full-born infants' parents. (Blomqvist et al., 2017) reported that in the early postpartum period, mothers of preterm infants reported a higher insomnia prevalence compared to fathers. This disparity occurred only during the hospitalization period. Parents who reported insomnia early postpartum continued to do so at 2 and 12 months after childbirth (Blomqvist et al., 2017). Generally, more prospective studies are needed to better understand both risk factors and protective factors for how insomnia develop in the perinatal period (Swanson et al., 2020).

2.2 Quality of life and HRQoL

HRQoL in postpartum parents is considered an important outcome in this thesis. However, the terms quality of life (QOL) and health-related quality of life are often used with different meanings in literature, and it is necessary to introduce, clarify and define these closely related terms.

QOL has been established as an important outcome and evaluation criterion in health and nursing and is often a focus for research and clinical treatment (Wyrwich & Gross, 2008). In the last few decades, research has increasingly focused on patients' QOL, attempting to evaluate treatment and include the patient's perspective (Wyrwich & Gross, 2008). Despite increasing focus, QOL has been used with different meanings, and there has been a growing debate regarding how it should be measured (Haraldstad et al., 2019). Different

disciplines have often used QOL with various definitions, reflecting psychology, sociology, medicine and nursing perspectives (Wyrwich & Gross, 2008). On the individual level, QOL concerns the value individuals give their different areas of life; thus, QOL often means different things to different people (Fayers & Machin, 2016). Despite disagreement, there is some agreement on some characteristics of QOL: first, QOL is a subjective experience that includes the individual's own perspective of their well-being, and second, it is a multidimensional concept that includes physical, mental, social and spiritual dimensions of life (Fayers & Machin, 2016; Klopstad Wahl & Rokne Hanestad, 2004). Third, QOL is a normative concept that concerns a person's expectations, values, goals and understanding of meaning in life (Fayers & Machin, 2016; Klopstad Wahl & Rokne Hanestad, 2004; Spilker, 1996). The World Health Organization Quality of Life Assessment Group (The World Health Organization, 2012, p. 1405) defined QOL as "individuals' perception of their position in life in the context of the culture and the value system in which they live and in relation to their goals, expectations, standards and concerns."

From a healthcare perspective, QOL has been described with different levels (Spilker, 1996). (Spilker, 1996) introduced QOL as consisting of three areas/levels (Figure 1). The top level reflects overall global QOL and the individual's satisfaction, happiness, meaning or realization of goals related to life as a whole. The second level represents broad domains with generic assessment of broad life domains, such as psychological, physical, social, economic and spiritual aspects of life. This level is often referred to as the level of individuals' HRQoL (Wahl, 2004). The bottom level includes components of each domain and disease specific symptoms or disability – reflecting, for example, individuals' experiences living with specific diseases or conditions. Each level in the pyramid can include multidimensional dimensions (physical, mental, social, spiritual, economic and material aspects) and impact each other (Spilker, 1996).

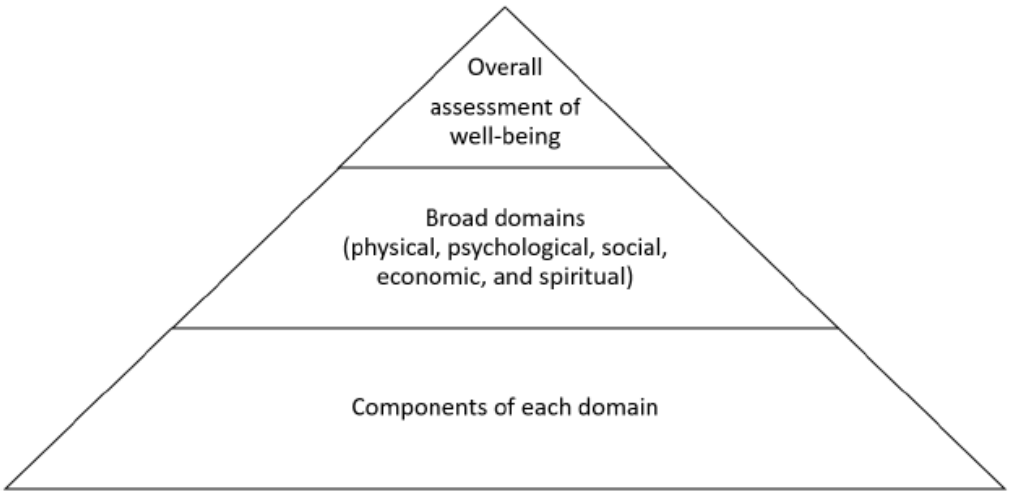


Figure 1. Spilker's quality of life model (Spilker, 1996)

Spilker's second level represents HRQoL in this thesis. As a concept, HRQoL was introduced to distinguish between QOL and elements of health, function and well-being experienced by individuals in relation to health and treatment (Wyrwich & Gross, 2008). In general, QOL is regarded as a broader construct encompassing HRQoL. HRQoL focuses specifically on how an individual's health affects their QOL. It includes physical, mental, emotional and social functioning, as it relates to health conditions or treatment (Karimi & Brazier, 2016). In this thesis, HRQoL is viewed as a dynamic, subjective and dimensional construct based on the following definition: "a multidimensional construct covering physical, emotional, mental, social, and behavioral components of well-being and functioning as perceived by patients and/or other observers" (Erhart & Ravens-Sieberer, 2006, p. 2). The definition highlight a holistic perspective, subjectively experienced by each individual. HRQoL has been stated as a goal for people at different life stages by leading health organizations (Bakas et al., 2012).

HRQoL is regarded as an important outcome in research by reflecting the experiences and perspectives of patients (parents) and can inform more personalized and family-centred care (Bai et al., 2019). Self-reports or subjective measures are often referred to as person- or patient-reported outcome measures (PROMs), which can be used to assess HRQoL (Wilson & Cleary, 1995). This might be crucial in addressing the unique needs of parents of newborn infants. The multidimensional concept of HRQoL covers a broad range of individuals' experiences of their own health (Wyrwich & Gross, 2008). HRQoL models often

reflect WHO's definition of health (World Health Organization, 2014, p. 1) as "a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity." In the definition, psychological and social dimensions of well-being are included, which bring a new perspective to health.

To cover the wide range of relationship between sleep and health and possible consequences for postpartum parents, HRQoL is considered an important concept in this thesis. Within research, several theoretical models have been introduced to provide an understanding of HRQoL (Bakas et al., 2012). A frequently used model within nursing and healthcare disciplines is (Wilson & Cleary, 1995) model, which links different HRQoL dimensions (Bakas et al., 2012): biological/physiological factors (objective health variables), symptom status, functional health, general health perceptions and overall QOL. The levels are further influenced by characteristics of the individual and the environment. The model suggests that there are causal relationships between the different levels. An understanding of relationships in the light of this contextual model can help researchers to design effective interventions to promote HRQoL (Ojelabi et al., 2017; Wyrwich & Gross, 2008).

(Ferrans et al., 2005) published a revised version (Figure 2) of Wilson and Cleary's HRQoL model to be used in nursing and health research, adding arrows to indicate that biological functions are influenced by the environment and the individual. Nonmedical factors and the labelling on the arrows were deleted (Ferrans et al., 2005). In a systematic review, (Bakas et al., 2012) determined Ferrans et al.'s revised model to be the HRQoL model with the greatest potential for future research. In this thesis, the revised model was used as a theoretical background to better understand and illustrate the complexity of postpartum parents' HRQoL. While we never used the model to examine different causalities in the longitudinal study, some of the factors we described can be placed in the model.

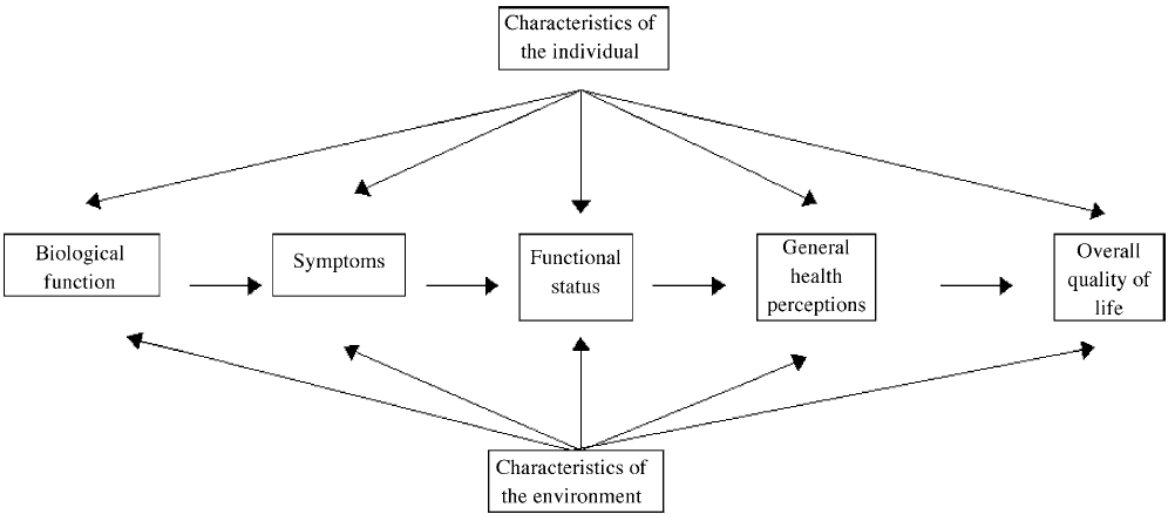


Figure 2. Conceptual health-related quality of life model. Revised by Ferrans et al. (used with permission from the author).

2.2.1 Parental QOL/HRQoL in the postpartum period

Parents' transition to parenthood includes social, physical and mental changes (Haas et al., 2005; Schobinger et al., 2022). HRQoL is today considered an important focus in maternity care and public health promotion (Bai et al., 2019). Research has identified several factors that can reduce the HRQoL of full-born infants' parents, such as physical conditions (headache, fatigue and birth complications), low infant gestational weight and infant hospitalization (Bai et al., 2019). Feelings of motherhood joy, high relationship satisfaction and stable infant sleep pattern have been associated with a higher QOL (Valla et al., 2022). A higher income, living in a stable marital union, a higher level of social support, living in a family with optimistic view and a higher level of social support have also been linked with a higher QOL for parents of preterm infants (Amorim et al., 2018).

Compared to parents of full-born infants, parents of preterm may be more vulnerable to experiencing reduced HRQoL in the early postpartum period because of the many challenges following the preterm birth. The period in the NICU has generally been described as stressful, with concerns for the infant's medical condition, infant hospitalization in the NICU, an altered parental role and emotional responses associated with fatigue, depression and sleep deprivation (Busse et al., 2013; Ionio et al., 2016; Obregon et al., 2019). The negative

consequences following a preterm birth can last for a while, and parents have reported various stressors as the child grows (Huhtala et al., 2011). Parents have particularly expressed concerns about the infant's health and cognitive development (Davis et al., 2003; Huhtala et al., 2011). Preterm birth has been associated with behavioural, developmental and chronic health issues, particularly for infants with ELBW (Cheong et al., 2021; Lee et al., 2020). Recent research has indicated that parents of infants with ELBW have reduced HRQoL compared to other parents during NICU hospitalization and that complex home care is associated with lower parent HRQoL after discharge (McAndrew et al., 2019). Being the parent of a child with complex healthcare needs and long-term morbidity can lead to sleep problems, burnout and increased psychological stress (Feeley et al., 2014; Lappalainen et al., 2021). Over time, the family burden has been reported as higher for parents of preterm infants compared to families with full-born infants (Treyvaud et al., 2011). High stress levels have also been associated with reduced HRQoL for parents of preterm infants (Shelton et al., 2014; Suonpera et al., 2023).

2.3 Knowledge gaps

Sleep plays an important role in physical and mental health (Cirelli et al., 2019). Therefore, it is important to achieve knowledge about sleep and its consequences for parents during the childbearing period (Redeker, 2020). Research has demonstrated that poor sleep is associated with reduced QOL (Al Rehaili et al., 2023; Barandon et al., 2023; Simard et al., 2021; Valla et al., 2022) and HRQoL (LeBlanc et al., 2007) for general postpartum parents. Longitudinal studies have reported that poor sleep has a negative impact on the QOL of postpartum mothers of full-born infants (Simard et al., 2021) up to 5 years (Carlander et al., 2015) after childbirth. However, studies have not clearly reported if parents of preterm infants report poorer HRQoL over time compared to parents of full-born infants. Some longitudinal studies have reported that HRQoL is lower for parents of preterm infants compared to those of full-born infants (Klassen et al., 2004; McAndrew et al., 2019; Suonpera et al., 2023; Witt et al., 2012), while others have not found any differences between these parent groups (Donohue et al., 2008; Eiser et al., 2005). Neither of these groups of studies has included sleep or insomnia measures. Based on this gap in the literature, we designed a comparative longitudinal cohort study

of sleep and health-related outcomes comparing two parent groups (parents of preterm and full-born infants) at three measurement points (2, 6 and 12 months).

Our presumptions in this project were as follows:

1. Parents of premature infants sleep poorly in the postpartum period.
2. Parents of premature infants sleep poorer than parents of full-born infants (comparison group) in the postpartum period.
3. Mothers sleep worse than fathers, regardless of whether the infant is premature or not.
4. Poor sleep can reduce HRQoL in parents postpartum.
5. It is possible to conduct a longitudinal study involving parents of premature and full-born infants.

3 Aim of the thesis

The overall aim of this thesis was to study sleep and the relationship between sleep and HRQOL in parents of preterm infants in the postpartum phase (the child is 2-12 months). Furthermore, the purpose was to compare sleep and HRQoL in mothers and fathers of preterm infants with mothers and fathers of full-born infants in the same time period.

The thesis comprises three papers with the following aims:

Paper 1: To identify and map information on sleep and its potential relationships to parental health in parents of preterm infants.

Paper 2: To evaluate the feasibility of a prospective, comparative, longitudinal study of the sleep and psychosocial health of preterm and full-born infants' parents during the first postpartum year. The primary aim was to assess recruitment and attrition rates, the secondary aims were to 1) describe and compare the characteristics of the participants, 2) evaluate measures and outcomes and 3) identify possible associations between the selected variables and attrition rates.

Paper 3: To describe and compare sleep and HRQoL in mothers and fathers of preterm and full-born infants over time. We also assessed possible associations between sleep, insomnia and HRQoL over time in the total sample.

4 Design and methods

This project was designed as a comparative longitudinal study of sleep and the relationship between sleep and HRQoL in parents of preterm infants in the postpartum phase (the child is 2–12 months). Furthermore, the purpose was to compare sleep and HRQoL in mothers and fathers of preterm infants with mothers and fathers of full-born infants in the same time period.

Initially, a scoping review was performed to identify knowledge gaps regarding sleep and health in parents of preterm infants. The results of the scoping review confirmed there was a lack of longitudinal research on the sleep of both parents of preterm infants. The scoping review gave valuable input to the knowledge gaps and choice of measurements in the longitudinal study.

In spring 2019, a pilot study evaluating recruitment and baseline (2 month) data collection in the longitudinal study was conducted. Three parent couples with preterm and three parent couples with full-born infants were invited to participate in the pilot study (Appendix 1). The parents wore actigraphs and filled out a sleep diary for 2 weeks (Weeks 6–8 postpartum) before they responded to a questionnaire (2 months postpartum). Thereafter, they were interviewed over the phone about their experiences with data collection (Appendix 2). The pilot study results led to minor changes in the recruitment procedure (we changed from digital to paper registration). There were no other changes, and we continued with conducting a longitudinal study.

However, in time, it became clear that there were major challenges associated with recruiting and collecting data from vulnerable parents with premature children, including the first wave of the coronavirus disease 2019 (COVID-19) pandemic, which hindered collecting objective sleep data with actigraphs. Since the recruitment process was slower than anticipated and we encountered several unforeseen logistical challenges, we decided to conduct a systematic evaluation of the process in the form of a feasibility study. Therefore, Paper 2 presents a description of the psychosocial variables to provide estimates of typical values and spread for these variables to enable better planning of future studies. In the original plan for the longitudinal study, we intended to include selected psychosocial

factors as covariates in the analyses of possible associations between sleep and HRQoL. However, our sample was too small and we only managed to collect a rather limited amount of data for all the preplanned analyses. Moreover, it was impossible to conduct the originally planned regression analyses, as our sample did not have sufficient statistical power. However, since our data did not reveal any differences between the two groups (parents of preterm and full-born infants) in terms of HRQoL, it was possible to treat the sample as a cohort study. Therefore, to increase statistical power and enable regression modelling, we decided to present the longitudinal data in a cohort study. Figure 3 presents an overview of the study design and papers in this thesis.

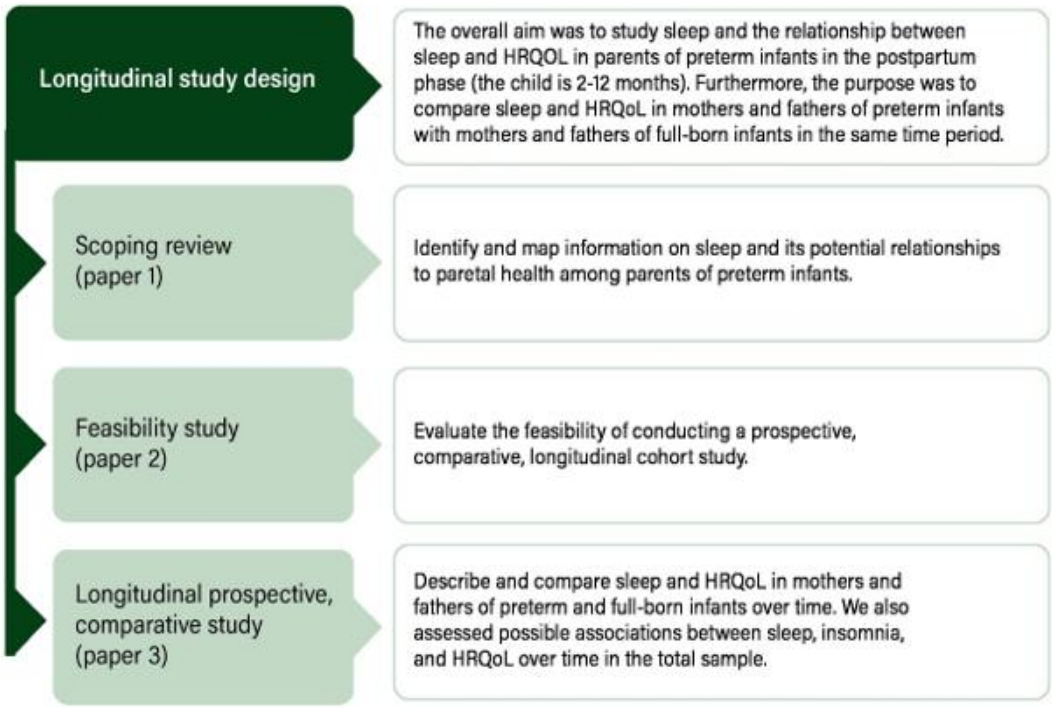


Figure 3. Overview of the study design and three interrelated papers

4.1 Systematic review (Paper 1)

Scoping reviews have demonstrated great utility for synthesizing research evidence and are often used to map existing literature in a field in terms of its nature, features and volume (Arksey & O'Malley, 2005; Peters et al., 2015). The scoping review was based on the methodology for scoping reviews published by

(Arksey & O'Malley, 2005) and expanded by (Levac et al., 2010). Levac et al.'s (2010) suggestions for refining the methodology included clearly articulating the research questions and linking the aim and research questions (stage one); combining feasibility with the range and extensiveness of the scoping process (stage two); using an iterative team-based approach in the study selection process (stage three); extracting the data (stage four); integrating a numeric summary and qualitative thematic analysis, reporting outcomes and considering the consequences of study results for policy practice or research (stage five); and finally, incorporating discussions with stakeholders as a compulsory knowledge translation part of the scoping process (stage six).

Data for the scoping review (Paper 1) concerning the sleep and health of parents of preterm infants was collected from seven electronical databases (CINAHL Plus with Full Text (EBSCOhost), MEDLINE, Embase, PsycINFO (all via Ovid SP), Proquest, and Web of Science). The review used the following inclusion criteria: quantitative or qualitative primary studies, published in English, reporting on the sleep and health of parents of preterm infants up to 1 year after childbirth. The exclusion criteria were the following: not primary studies, studies published in languages other than English and studies not reporting on parental sleep and health. The WHO's (2023) definition for "preterm" was adopted: infants "born before completed 37 weeks of pregnancy." Health aspects were understood according to the WHO's definition of health (World Health Organization, 2014, p. 1) and categorized as "social, physical, or psychological well-being." Settings of interest were all settings where parents might sleep – both the hospital and home.

A total of 2,706 citations were identified in the electronical searches for literature. Identified papers were transferred to Endnote Reference Manager for removal of duplicates and then exported into the Microsoft Excel for the screening of titles and abstracts. Research was screened for inclusion and mapped logically according to the scoping review's objectives. Only studies that met the inclusion criteria were included, and relevant studies were assessed for full-text eligibility.

During the screening process, the team members met to discuss decisions surrounding the inclusion and exclusion of papers. The screening was done independently by two reviewers, and disagreements regarding inclusion/exclusion were resolved. Reviewers met at the beginning, midpoint and end stage to discuss

challenges and uncertainties related to study selection, as recommended by (Levac et al., 2010). Forward and backward citation included reference lists of all included studies to search for additional literature. Searches in Google Scholar, Scopus, Ovid SP, PubMed and Web of Science were performed.

To answer the review's research questions, a data extraction sheet was developed to determine which variables to extract. Information according to author, publication year, country of origin, study design, purpose of study, population and research instruments used to study sleep and health were extracted. One reviewer collected data, and uncertainties and disagreements were resolved through discussions with coreviewers. The methodological process of analysis and synthesis was performed in three distinct steps, following the methodology described by (Arksey & O'Malley, 2005) and expanded by (Levac et al., 2010). First, analyses of the included data were performed. Second, the results were presented in tabular form, and third, meaning was applied to the results. Through repeated readings of each article, a thematic analysis was performed according to the purpose and research questions of the review. The process was similar to (Booth et al., 2016) analytical technique used for qualitative data. (Levac et al., 2010) suggested that (Arksey & O'Malley, 2005) original description of thematic analysis required an additional detail to assist researchers with understanding and completing this step, suggesting both content analytical techniques and qualitative software as part of the analysis phase. During the process in the scoping review, all authors discussed the meaning of the findings as they related to the review's aim and research questions. Qualitative software was not used during the analysis process. The final outcomes and findings were finally presented in tabular form. Paper 1 (scoping review) confirmed our anticipations about gaps in existing knowledge regarding the long-term sleep and health outcomes of parents of preterm infants over time and provided valuable input to the design of the longitudinal study.

4.2 Feasibility study (Paper 2)

The term *feasibility study* is often used broadly to refer to any study that can be used to prepare a future full-scale study (Bowen et al., 2009; Shanyinde et al., 2011). Feasibility studies often have a flexible design and ask whether something can be done, if it should be done and, if so, how it should be done (Eldridge et al., 2016). A feasibility study represents an important step in research processes, where the results can inform of important parts of a future study (Bugge et al., 2013; Donald, 2018). This type of research can identify parts of research methods that may need modification (Bowen et al., 2009). Useful information can be provided on estimations of study samples, the eligibility of participants and follow-up response rates to questionnaires so that these important elements can be evaluated before a full study is performed (Arain et al., 2010).

4.3 Longitudinal prospective comparative study (Paper 3)

Longitudinal designs are designed to collect data at more than one point of time; in contrast to cross-sectional studies, longitudinal study designs are useful for studying changes over time (Polit et al., 2021). With the confirmation of research gaps identified in the scoping review (Paper 1) regarding the sleep and HRQoL of parents of preterm infants, a longitudinal comparative study design was considered appropriate. "Prospective" means that the same participants are followed over time (Caruana et al., 2015). "Comparative" means that a group of study participants are used to evaluate the outcomes of the group of primary interest. Parents of preterm infants were considered the group of primary interest in this longitudinal study, and parents of full-born infants were used as a comparison group. To increase statistical power and enable regression modelling, we decided to present the longitudinal data as a cohort study (Paper 3).

4.3.1 Study sample and settings in the longitudinal study (Papers 2 and 3)

The longitudinal study (Papers 2 and 3) recruited parent couples for two groups: parents of preterm infants (born *before* the 37th week of pregnancy) were included in Group A, while parents of full-born infants (born *after* the 37th week of

pregnancy) were included in Group B (comparison group). The sample for Papers 2 and 3 was the same.

To determine the number of participants required to detect significant differences within and between groups in the longitudinal comparative study, sample size calculations were performed initially. The sample size was estimated using data from two previous studies reporting on TST, measured with actigraphs, in mothers of pre- and full-born infants (Lee & Hsu, 2012a; Montgomery-Downs et al., 2010). Based on the literature, we anticipated the difference between both groups to be 1 hour, and the standard deviation to be 2 hours; thus, to reveal such a difference between group differences as statistically significant (significance level of 5% and power of 80%), we needed at least 64 parents. Since we also had to consider dropouts of around 10%–20% (in connection with a 12-month follow-up); adjust for additional variation sources, as the recruitment was from several centres (hospitals); and include covariates such as socioeconomic status, age, education level, number of children from before, gender and body mass index, and ethnicity in the regression analyses, we calculated that we had to include a total of 100 mothers and 100 fathers for each group (400 participants in total).

However, when recruitment began, we decided to reevaluate the project's sample size, as we suspected it was based on unrealistic estimates. Hence, a new power calculation was conducted, which indicated that it would be sufficient to recruit 75 pairs of parents to each group. The calculation of the second and final sample size is presented in Appendix 3. We present both a calculation based on anticipated differences with and without correction for multiple testing. The final estimate of 75 pairs is adjusted for multiple testing—, significance level is lowered to 0.01.

Parents were recruited from hospitals in regions of south-eastern Norway. Parents with preterm infants were recruited from four different NICU wards at four hospitals and from one maternity ward. Three of the NICUs were at Level 3c (highest medical competence to treat extremely preterm infants down to GA 23), and the last one was at Level 3b (second-highest competence, providing medical treatment to preterm infants from GA 26; (The Norwegian Directorate of Health, 2007). Parents with full-born infants were recruited from two maternity wards. Both wards treat healthy mothers with uncomplicated childbirths.

Eligible parents were over 16 years of age, lived together and had sufficient command of a Nordic language (written and oral). Both mother-father parents and same-sex parents (referred to as birthgiving and non-birthgiving mothers) were included. Parents were recruited within the first 5 weeks after childbirth. They were excluded if they had a serious drug addiction (recorded in the patient journal; cf. *International Classification of Mental and Behavioural Disorders* [10th ed.] or *Diagnostic and Statistical Manual of Mental Disorders* [4th ed.; *DSM-IV*] (American Psychiatric Association, 2000), the newborn had serious deformities or a life-threatening condition that could affect survival, the mother had given birth to multiple infants or the mother had a condition/diagnosis which made participation in the project ethically challenging (e.g. serious, life-affecting health issues). Parents with shift work were excluded since working at night may affect sleep. Parents with sleep diagnoses were also excluded. Lastly, we decided to exclude parents in contact with child welfare services.

4.3.2 Recruitment procedure

Recruitment to the longitudinal study (Papers 2 and 3) started with the first author contacting the leaders of different NICU and maternity wards. Aforehand, the Norwegian Regional Committees for Medical and Health Research Ethics (Appendix 4), the Norwegian Centre for Research Data (Appendix 5), and the Faculty of Health and Sports Sciences' Research Ethics Committee (Appendix 6) had approved the study. Each leader received a phone call with a request to participate in the project. If positive, the leaders received a written formal application about collaboration regarding the recruitment of parents to the study (Appendix 7). Permission to conduct the study was requested from research committees and leaders in each hospital (Appendix 8). Information about the project was distributed to nurses in the wards via e-post (Appendix 9).

I visited each ward to inform the staff about the project's goals and content. Information about the project was given on "education days" (days involving theory/teaching of staff). In each ward, a cooperating nurse was chosen to collaborate with the candidate on the recruitment of parents. The nurses were responsible for identifying eligible parents and asking if parents were willing to participate in the project. The nurses were also informed about how to identify

eligible parents and demonstrate actigraphs and sleep diary use for parents willing to participate. At one of the hospitals, I demonstrated the use of the actigraphs/sleep diary and gave information to parents who wanted to hear more about the project.

Parents who were willing to hear about the project received a brochure with information (Appendix 10) and were informed about the project's digital homepage (https://foreldresovn.uia.no/). The brochure and web page were informative for parents who wanted to learn more about the project. Parents consented to participate in the project in a written form. On the same paper, parents filled out their home postal and email addresses and reported the gestational levels of their infants (for placement in Group A [preterm] or B [full-born]). Collaborating nurses returned written consents to the candidate via post (Appendix 11). Parents who wanted to withdraw from the study could send an email to the candidate. Figure 4 illustrate how the sample of parents was recruited to the longitudinal study (Figure 4).

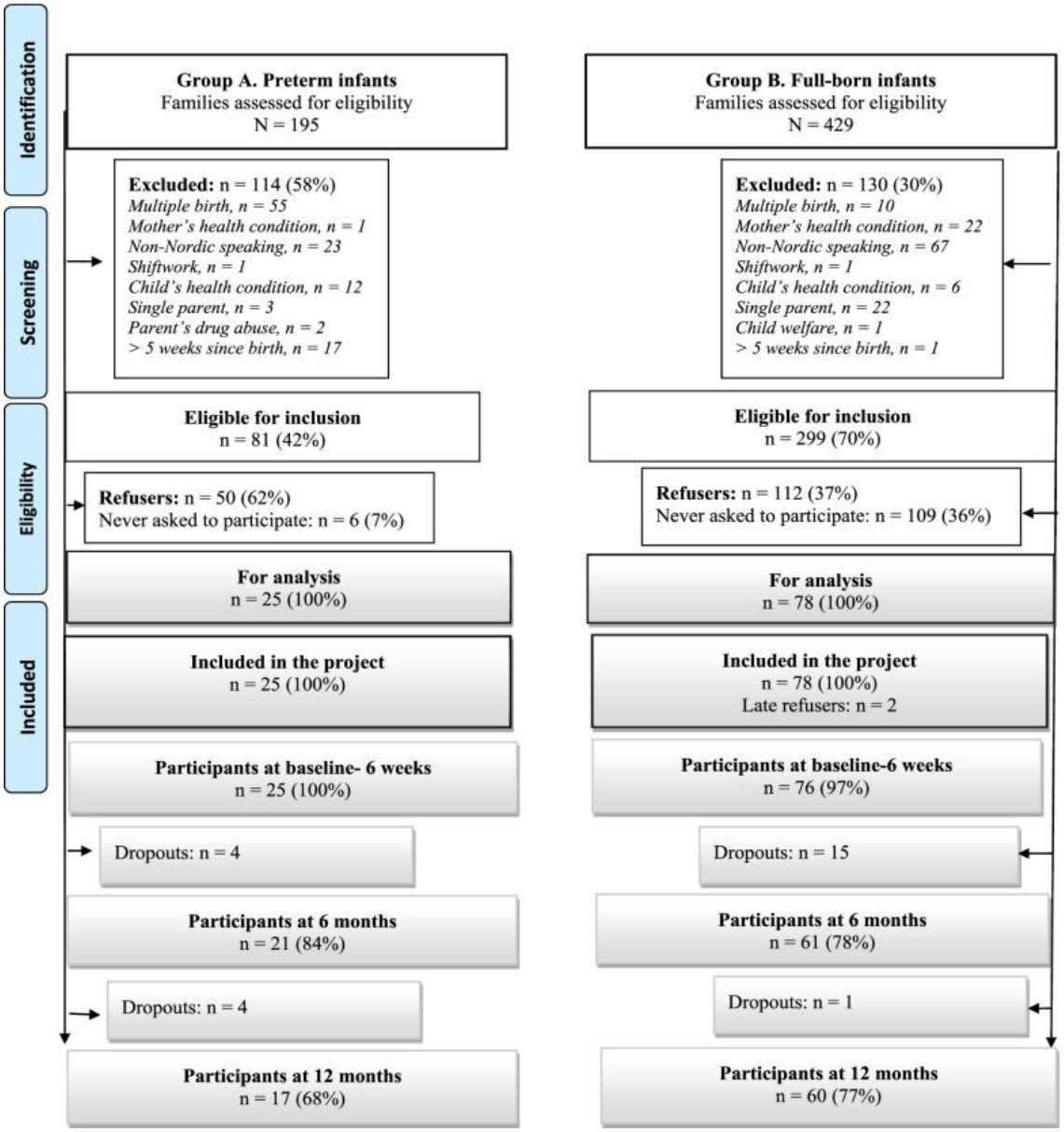


Figure 4. Flow chart of participants in the longitudinal study.

Of the 195 parent couples who were assessed for eligibility for Group A, 114 (58%) couples were excluded. Eighty-one (42%) couples were found eligible for inclusion; of these, 50 (62%) refused to participate in the study. Finally, 25 (100%) parent couples were included in the study. At 6 months, 21 (84%) couples participated, and at 12 months, 17 (68%) were present in the study (Figure 4).

For Group B, 429 parent couples were assessed for eligibility. Of these, 130 (30%) couples were excluded. Two hundred and ninety-nine couples were found eligible for inclusion (70%); of these, 112 (37%) refused to participate. Finally, 78 (100%)

couples were included in the study. Seventy-six (97%) couples participated at baseline (2 months), 61 (78%) at 6 months and 60 (77%) at 12 months (Figure 4).

4.3.3 Data collection and measures

In the longitudinal study (Papers 2 and 3), different measurements were used to provide information on postpartum parents' sleep, psychosocial factors and HRQoL (2, 6 and 12 months postpartum). The data collection occurred before and during the first wave of the COVID-19 pandemic. The pandemic introduced great uncertainties regarding how the virus was spread; hence, we decided not to distribute actigraphs and sleep diaries to parents after March 2020. Sleep data from actigraphs and sleep diaries were therefore only collected at 6–8 weeks postpartum (2 months). The questionnaire was distributed digitally to parents at all three measurement points (2, 6 and 12 months). Figure 5 illustrates the data collection in the project.

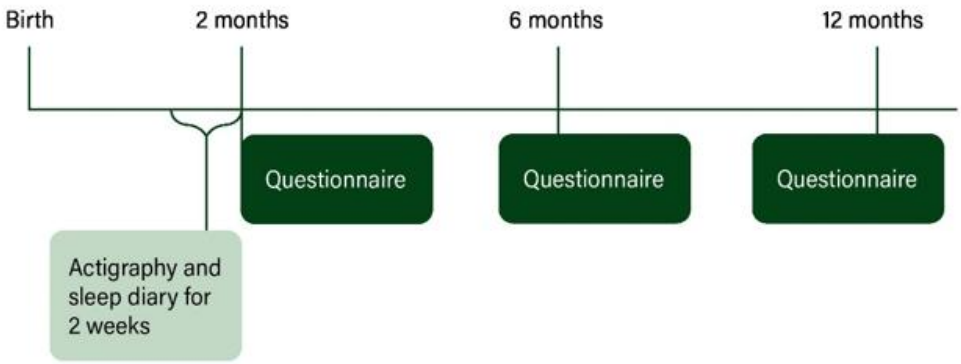


Figure 5. Data collection in the longitudinal study

The following measurements were used in this thesis:

- Sociodemographic data (2 months)
- Actigraphy and sleep diaries (6–8 weeks postpartum)
- Questionnaire (2, 6 and 12 months).

Parents received a postal package containing two preprogrammed Respironics Actiwatch 2 (Philips Healthcare, Philips.com) actigraphs and preplotted (dates only) sleep diaries (Appendix 12). Actigraphs and sleep diaries were returned to the researcher in a prepaid envelope (2 months only).

A questionnaire consisting of seven PROMs was used to assess stress, depression, fatigue, social support, self-efficacy, HRQoL and insomnia and distributed digitally at 2, 6 and 12 months (Appendix 13). Parents were also asked about sleep habits after childbirth, and sleep diagnoses, including medication use, were reported together with the digital questionnaire at each measurement point.

The questionnaire was distributed to the parents' private email addresses via a secure web platform called "Nettskjema," a commonly used platform with high security for research data collection in Norway (https://nettskjema.no/). Table 1 presents an overview of measures completed by parents in Papers 2 and 3.

Table 1. Overview of questionnaires completed by parents

Measure	Paper	Number of items	Cronbach's alpha
RAND-36 Medical Outcomes Study Short-Form Health Survey	2 and 3	36	All scales < 0.8
The Bergen Insomnia Scale	2 and 3	6	0.769
The Generalized Self-Efficacy Scale	2	5	0.739
The Edinburgh Postnatal Depression Scale	2	10	0.745
The Duke-University of North Carolina Functional Social Support Questionnaire	2	5	0.745
The Chalder Fatigue Questionnaire	2	13	0.765
The Perceived Stress Questionnaire	2	30	0.745

4.3.4 Sociodemographic variables

The baseline data collection (2 months) included demographic data on each parent's ethnicity, education, income, occupation, weight, height and age. Parents were asked about parity, as well as the newborn's birthweight and GA at birth.

4.3.5 Sleep

Actigraphy

Actigraphs are small noninvasive sleep trackers used to detect sleep at a behavioural level (Stone, 2017). Objective sleep-wake patterns were measured using Actiwatch 2. Actiwatch 2 has been tested and found reliable compared to the gold-standard polysomnography (PSG; (Marino et al., 2013; Shin et al., 2015; Weiss et al., 2010). Activity counts from the device are used to determine sleep and wake intervals (Marino et al., 2013). The actigraphs were set to collect data in 30-second epochs, with the sensitivity set to medium. Parents wore actigraphs continuously during the data collection period and were instructed to use an event marker to indicate bedtime (lights-off time) and rising time (lights-on time). The following measures were derived from the actigraphs: SOL, TIB, SE, WASO, total wake time and TST (Fekedulegn et al., 2020). After 2 weeks of sleep recordings, data from Actiwatch 2 were downloaded via a computer for processing. Actigraphy can be less accurate if sleep is very fragmented or there are long wake intervals at night (Van de Water et al., 2011). A good supplement in such cases can be to use subjectively reported sleep data (e.g. from sleep diaries) to control for artefacts and uncertainties (Mazza et al., 2020). Large cohort studies have successfully used actigraphy to study sleep over time (Stone, 2017). Actigraphs and sleep diaries are well validated and often used in combination to collect subjective and objective sleep data (Aili et al., 2017; Martin & Hakim, 2011; Sadeh, 2011; Stone, 2017).

Sleep diary

We used a modified version of (Carney et al., 2012) sleep diary (Appendix 14). The diary consisted of questions regarding number of daytime naps, daytime nap duration, daytime function (1, *very good*; 5, *very poor*) and parents' perceived sleep quality (1, *very restless*; 5, *very poor*). The diary also included a question regarding the use of sleep medication and alcohol intake. The following measures were derived from the sleep diary: SOL (number of minutes to fall asleep), WASO (number of minutes awake between sleep onset and sleep offset), number of nighttime awakenings, early-morning awakening, total wake time (SOL + WASO + early-morning awakening), TST (number of minutes asleep in bed after "lights

off," considered nighttime sleep), TIB (duration spent in bed) and SE (TST as a percentage of TIB; (Bjorvatn, 2012; Fekedulegn et al., 2020)

Insomnia

In Papers 2 and 3, insomnia was evaluated with the Bergen Insomnia Scale (BIS; (Pallesen et al., 2008). The BIS consists of six items and was developed according to the diagnostic criteria for insomnia (American Psychiatric Association, 2000). The BIS originally defined insomnia as symptoms experienced during the past month but was modified to a wider time frame of the last 3 months in the updated *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.)/*International Classification of Sleep Disorders* (3rd ed.) diagnostic criteria (American Psychiatric Association, 2013). The items are scored along an eight-point scale, the scorings indicate how many days per week for which a specific insomnia symptom is experienced (0–7 days; (Bjorvatn, Berge, et al., 2018). Chronic insomnia disorder is defined as scoring 3 days per week or more on at least one of the first three items, as well as 3 days per week or more on at least one of the latter two items (Pallesen et al., 2008). If this requirement is not met, the patient does not have insomnia, according to the BIS (Pallesen et al., 2008). The BIS has demonstrated an acceptable Cronbach alpha value (Bjorvatn, Waage, & Pallesen, 2018), test-retest reliability and good validity in relation to other self-report measures and PSG (Pallesen et al., 2008).

4.3.6 HRQoL

We chose to use the RAND Medical Outcomes Study 36-Item Short-Form Health Survey (RAND-36) to measure HRQoL in postpartum parents (Papers 2 and 3). The RAND-36 is a generic HRQoL questionnaire that includes eight subscales/domains: general health, bodily pain, physical functioning, role limitation (physical), mental health, vitality, social function and role limitation (emotional). The domains can be combined into physical and mental scales reflecting both physical (physical component summary) and mental (mental component summary) well-being (Hays & Morales, 2001; Ware & Sherbourne, 1992). Both physical and mental health outcomes are scored using the eight subscales. The RAND-36 scale is scored using values from 0 to 100, with 100

representing optimal health (Kvien et al., 1998). The Norwegian version of the RAND-36 has been reported as a valid and reliable instrument for assessing HRQoL (Garratt & Stavem, 2017).

4.3.7 Psychosocial variables

Five different questionnaires were selected to measure psychosocial factors. As we only managed to collect a very limited amount of data for these variables, the originally planned analysis could not be conducted. Hence, these variables were presented only descriptively in Paper 2.

Stress

Stress was assessed using the Perceived Stress Questionnaire (PSQ; (Fliege et al., 2005; Levenstein et al., 1993). The PSQ measures individuals' subjective experiences of perceived stressful situations and stress reactions, recognizing cognitive perceptions more than emotional states or specific life events (Kocalevent et al., 2007). The form is a 30-item questionnaire referring to the past 4 weeks. The PSQ consists of positive and negative sentences, each item is rated from 1 (*almost never*) to 4 (*almost always*). Answers were recoded so that higher values indicated higher stress levels. In the analysis, the total PSQ score was a number between 0 and 1: PSQ = Raw value − 30/90. The recommended cut-off level of perceived stress for the PSQ are as follows: low: < 0.33, medium: 0.33–0.45, moderate: 0.45–0.60 and severe: > 0.60 (Østerås et al., 2018). The Norwegian version of the PSQ has been validated feasible to assess stress in adolescents (Østerås et al., 2018).

Fatigue

The Chalder Fatigue Questionnaire was originally developed to assess the severity of fatigue in patients with chronic fatigue syndrome (Chalder et al., 1993). The original version was revised and is today often used to measure the severity of "tiredness" rather than just chronic fatigue syndrome (Chalder et al., 1993). The Norwegian version of the Chalder Fatigue Questionnaire was used in Paper 2, and the psychometric properties has been reported to correspond well with the English

version (Loge et al., 1998). The form consists of questions about fatigue symptoms during the last month. Eleven of the items measure physical and mental components of fatigue rated as *less than usual, same as usual, more than usual* and *much more than usual*. Additionally, two items ask about the duration and extent of fatigue (Loge et al., 1998). Scoring may be bimodal or continuous; in our analyses, we applied continuous scoring. Scores on this scale range from 0 to 33. For all scales, higher scores indicate greater fatigue severity.

Depression

Depressive symptoms were assessed with the Edinburgh Postnatal Depression Scale, a 10-item questionnaire for measuring depressive symptoms experienced over the past 7 days (Cox et al., 1987). We used a Norwegian-translated version of the Edinburgh Postnatal Depression Scale in this study (Eberhard-Gran et al., 2001). Each question has four possible responses, and the respondent is asked to indicate which of the four statements best fits the last 7 days: 0, *no, never*; 1, *rarely*; 2, *yes, sometimes*; and 3, *yes, very often*. The total score ranges between 0 and 30, and higher scores indicate greater depressive symptoms (Dorheim et al., 2014; Eberhard-Gran et al., 2001). The Norwegian version, with the cut-off ≥ 10, is evaluated to be a highly sensitive, valid screening instrument for detecting major depression according to the *DSM-IV* criteria (Eberhard-Gran et al., 2001).

Self-efficacy

Self-efficacy refers to persons beliefs of how capable they are in performing behaviours necessary to reach a desired outcome, and how they cope with daily demands and adapt after stressful experiences (Bandura, 1982). We assessed self-efficacy using the short-form version of the Generalized Self-Efficacy Scale (GSE; (Leganger et al., 2000). The questionnaire has a four-point scale, where 1 is the lowest (*completely wrong*) and 4 (*completely right*) represents the highest GSE value. The scores are summed and divided by 5 to produce a GSE score between 1 and 4. A higher score indicates higher generalized self-efficacy. The Norwegian short form of the GSE has been found valid and reliable (Leganger et al., 2000).

Social support

Social support was assessed with the eight-item version of the Duke-University of North Carolina Functional Social Support Questionnaire (FSSQ; (Broadhead et al., 1988), which was developed to measure social support. Affective support was also included in the measurement tool, addressing the areas of love and caring (Isaacs & A. Hall, 2011). The form has been internationally validated and found reliable for several samples (Broadhead et al., 1988; Isaacs & A. Hall, 2011). Respondents indicate how much social support they receive in relation to how much social support they would like. Responses are rated from 1 to 5 (1, *much less than I would like*; 5, *as much as I want*). The responses are summed up to produce a total score, higher scores indicating more perceived social support (Broadhead et al., 1988; Isaacs & A. Hall, 2011).

The FSSQ has not been translated to Norwegian; hence, we used Wild et al.'s (Wild et al., 2005) translation framework: 1) preparation, 2) forward translation, 3) reconciliation, 4) back translation, 5) back translation review, 6) harmonization, 7) cognitive debriefing, 8) review of cognitive debriefing results and finalization, 9) proofreading and 10) final report. Two independent native English-speaking persons performed the forward translation of the form to Norwegian. In Step 3, the PhD project manager, a forward translator and I resolved discrepancies between the translated versions. This resulted in one final reconciled forward-translation version. Thereafter, the reconciled version was back-translated into English for quality control. Finally, the form was reviewed in a cognitive debriefing and proofread. The final version of the form was used to collect data on social support (Appendix 15). Step 10 (the final report) was never conducted.

4.4 Statistical analyses

In Papers 2 and 3, different statistical methods were used, depending on the research questions. Statistical analyses were conducted using IBM SPSS Statistics (versions 26 and 27) and Stata (version 16). In the statistical analyses, a p-value below 0.05 was considered significant (Altman, 1990). Table 2 provides an overview of the aims, designs, samples, methods, data collection, measurements and analyses of the studies.

Table 2. Aims, design, sample, methods, data collection, measurements and analyses of the studies

Population	Parents of preterm and full-born infants		
Aim	The overall aim of this thesis was to study sleep and the relationship between sleep and HRQOL in parents of preterm infants in the postpartum phase (the child is 2-12 months). Furthermore, the purpose was to compare sleep and HRQoL in mothers and fathers of preterm infants with mothers and fathers of full-born infants in the same time period.		
Design	Comparative longitudinal study		
	Paper 1	**Paper 2**	**Paper 3**
Sample	Parents of preterm infants n=11 studies	n= 25 parent couples with preterm and n= 78 couples with full-born infants (comparison group)	
Methods	Scoping review	Feasibility study	Prospective, comparative, longitudinal study
Aim	To identify and map information on sleep and its potential relationships to parental health among parents of preterm infants.	To evaluate the feasibility of conducting a prospective, comparative, longitudinal cohort study. The primary aim was to assess recruitment and attrition rates, and the secondary aims were to 1) describe and compare the characteristics of the participants, 2) evaluate measures and outcomes, and 3) identify possible associations between the selected variables and the attrition rates.	To describe and compare sleep and HRQoL in mothers and fathers of preterm and full-born infants over time. We also assessed possible associations between sleep, insomnia, and HRQoL over time in the total sample.
Measurements/	Qualitative/quantitative research	Demographic variables (2 months) Actigraphy (2 months)	Demographic variables (2 months) Actigraphy (2 months)

time assessments point		Sleep diary (2 months) BIS (2, 6, 12 months) RAND- 36 (2, 6, 12 months) PSQ (2, 6, 12 months) EPDS (2, 6, 12 months) FSSQ (2, 6, 12 months) CFQ (2, 6, 12 months) PSQ (2, 6, 12 months)	Sleep diary (2 months) BIS (2, 6, 12 months) RAND- 36 (2, 6, 12 months)
Data analysis	Qualitative thematic analysis	Descriptive statistics Chi square test Nonparametric Mann-Whitney- Wilcoxon test for two independent samples	Descriptive statistics Bivariate and multiple regression analysis Multiple linear regression analysis for repeated measures

RAND-36: RAND 36-Item Short Form Health Survey
BIS: The Bergen Insomnia Scale
GSE: The Generalized Self-Efficacy Scale
EPDS: The Edinburgh Postnatal Depression Scale
FSSQ: The Duke-University of North Carolina Functional Social Support Questionnaire
CFQ: The Chalder Fatigue Questionnaire
PSQ: The Perceived Stress Questionnaire

4.4.1 Descriptive analyses

Descriptive statistics were used to describe the study sample (Papers 2 and 3). Categorical data were presented as counts and percentages. Given the limited sample size, continuous data were considered "not normally distributed" and therefore presented as median and minimum, maximum (range) values. We plotted all the continuous variables, and a visual inspection revealed they were skewed.

In Paper 2, descriptive analysis was used to describe sociodemographic variables, the sample, feasibility outcomes (recruitment and attrition rates), sleep outcomes (actigraphy, sleep diary) and descriptive outcomes of psychosocial factors (insomnia, depression, fatigue, social support, stress and HRQoL). In Paper 3, descriptive analysis was used to describe the sample, subjective and objective sleep (actigraphy, sleep diary) and HRQoL outcomes.

4.4.2 Bivariate analyses

In Paper 2, chi-square tests (Pallant, 2020) were used to assess crude differences between completers and dropouts for categorical variables. Continuous variables were compared using a nonparametric Mann–Whitney–Wilcoxon test (Pallant, 2020) for two independent samples. Mann–Whitney–Wilcoxon tests were used when continuous data were not normally distributed. As the sample size was quite limited, nonparametric methods were the preferred choice, as they are more robust compared to parametric methods (Pallant, 2020).

4.4.3 Regression

In Paper 3, linear regression (Pallant, 2020) was used to assess possible associations between HRQoL and selected variables. We fitted four different linear regression models with sleep length and sleep efficacy as the dependent variables and parent (mother versus father) and group (parents of preterm and full-born infants) as the independent variables. To investigate any interactions between the group and parent variables in addition to the additive effect of group and/or gender (e.g. if the combination of being a mother of a preterm infant presented an

additional burden to the additive effect of parent and group), we fitted an interaction term (group * parent). This interaction was not statistically significant for any of the models, so we presented models fitted with group and parent variables only.

4.4.4 Linear mixed models for repeated measures

In Paper 3, we used linear mixed models (LMMs) for repeated measures (West et al., 2015) as a statistical method to assess the impact of selected possible predictive factors on HRQoL outcome over time, with a special focus on parents' insomnia. LMMs are a more modern and preferred approached as compared to analysis of variance (ANOVA) because LMM does not require complete data sets—for example, in case of missing data in studies (Boisgontier & Cheval, 2016); hence, no imputation of missing data was necessary. Given that our sample was of a rather limited size, we would have been unable to perform any model-based imputation of missing data, and utilising simple imputation methods would only increase possible selection bias. Thus, we required an approach that could handle missing data. Moreover, LMMs enable researchers to include random factors and model the covariance structure of data to test the treatment effects (Arnau et al., 2013). These models are referred to as 'mixed' because they include both fixed and random effects (Detry & Ma, 2016). The results are expressed as estimated regression coefficients and 95% confidence intervals.

5 Ethical considerations

Previous research has reported that the postpartum period can be a stressful period for parents, posing a risk of heightened stress and sleep deprivation (Epifanio et al., 2015; Medina et al., 2009). For parents of preterm infants, the transition to parenthood might be extra burdensome. Consequently, they might be considered vulnerable research participants. Our research group thoroughly discussed ethical and moral aspects concerning the recruitment of parents for the feasibility study – particularly inclusion criteria and the recruitment process – to ensure that the research agrees with important ethical declarations, such as the Declaration of Helsinki (World medical association, 2009). At the beginning of the project, one of the supervisors and I met the leaders of the NICUs and maternity wards to discuss some of the ethical challenges concerning the inclusion criteria. Additionally, nurses in the wards were asked to provide input and feedback on such matters.

According to the inclusion criteria, it was discussed whether certain participants should be excluded if, for example, serious, life-affecting diagnoses (infants or mothers) were present. Such circumstances could have represented a substantial burden on the parents and made participation in the study ethically difficult. It was also discussed how recruitment could best be done to avoid harm to already burdened parents – for example, parents of preterm infants in a temporarily difficult situation.

After thorough discussions and consideration with the leaders and nurses, it was decided to operate with quite open and discretionary exclusion criteria. We decided to exclude parents if they had a serious drug addiction (recorded in the patient journal; cf. *International Classification of Diseases and Related Health Problems* [10th ed.] or *DSM-IV*) (American Psychiatric Association, 2013), the newborn had serious deformities/or a life-threatening condition that could affect survival or the mother had a condition/diagnosis which made participation in the project ethically challenging (serious life-affecting health issues). It was also decided that parents who were in contact with child welfare services should be excluded from participation since this could be a demanding situation for the parents. Finally, the research team discussed whether parents should report why they declined to

participate in the project. After thorough consideration, it was decided against to avoid further burdening parents.

It was a carefully thought-out plan to let nurses within the wards be responsible for the recruitment of parents. The nurses were close to each family and had updated knowledge of their daily situation. If parents had a temporarily difficult situation (e.g. unstable medical infant), recruiters postponed the formal request of participation to the next possible recruitment day. This was important to not "overload" the already burdened parents. The tight collaboration with clinical staff was highly necessary to overcome the many ethical aspects in the recruitment of parents. The nurses maintained a unique ability to adapt the formal request of participation to the best of each family's situation.

Nurses can play an important role in recruitment and serve as an important link between researchers and study participants (Shiely et al., 2023). Thus, it is important that nurses are aware of their ethical responsibility during this process. The use of nurses as recruiters can influence parents to feel obligated to participate since they might be in a type of addictive relationship with nurses. This is in conflict with an important research principle and the idea of autonomy stating the individual's right and opportunity to decide about their own life (McGraw et al., 2015).

In such situations, it is important that nurses are aware of honouring individuals' privacy interests and autonomy, which is the heart of the social compact between study participants and researchers (McGraw et al., 2015). In this study, all collaborating nurses were educated to be sensitive to parents' wishes regarding participation. They were also informed about ethical implications concerning how to achieve valid consent from parents. Parents eligible for inclusion were given time to evaluate their decision regarding participation so that a valid consent could be made. Time to consider the question of participation has been reported as important for parents' ability to give a valid informed consent (Wilman et al., 2015).

Overall, it was considered that for parents, participation in the project overweighed the potential risks that might have existed. The use of actigraphs, sleep diaries and questionnaires were not considered harmful to the participants, and all study

instruments used are well established for use in such research. Parents received oral and written information about the study before they consented and were informed about how they could withdraw from the study.

Papers 2 and 3 were designed and implemented according to the Declaration of Helsinki (World medical association, 2009) and standard common principles of clinical research (2009). The Regional Committees for Medical and Health Research Ethics approved the project (reference no. 2018/1025; Appendix 4). Data were stored on Service for Sensitive Data (University of Oslo, n.d.), a secure digital platform for collecting, storing, analysing and sharing sensitive data in compliance with the Norwegian privacy regulation. We used Nettskjema, a secure tool for designing and managing data collection using questionnaires. Submissions could be delivered fully encrypted to our secure work area. The Norwegian Centre for Research Data (Appendix 5) and the Faculty of Health and Sports Sciences' Research Ethics Committee (Appendix 6) reviewed the ethical aspects of the study, and necessary approvals were obtained for the study.

6 Summary of results

This section presents the main results from Papers 1–3. Papers 1 and 2 have been published (Marthinsen et al., 2018; Marthinsen et al., 2022), while Paper 3 has been submitted for publication.

6.1 Paper 1: Sleep and Its Relationship to Health in Parents of Preterm Infants: A Scoping Review

This paper aimed to identify and map evidence on sleep and its relationship to health in parents of preterm infants. Eleven studies were included in the review; 10 of the included studies used a quantitative design, while the last one used a qualitative design. Among the quantitative studies, five had a cross-sectional design, and three were cohort studies. Two studies were trials.

We found that several research instruments had been used to collect the sleep and health data of mothers of preterm infants. Actigraphs and sleep diaries had been used to assess maternal sleep for short periods (2–3 days) during hospitalization of the infant and never after discharge from the hospital (Lee & Hsu, 2016; Lee et al., 2013; Lee et al., 2012b; Lee & Hsu, 2012a; Lee & Kimble, 2009; Shelton et al., 2014). Different questionnaires had been used to report sleep when parents were in the NICU, sleep disturbances (Lee & Hsu, 2016; Lee et al., 2013; Lee et al., 2012b; Lee & Hsu, 2012a; Lee & Kimble, 2009; Shelton et al., 2014), sleep quality (Schaffer et al., 2013), sleep characteristics (McMillen et al., 1993) and sleepiness (Gennaro & Fehder, 2000; McMillen et al., 1993) were used. Only two longitudinal studies reported on sleep over time: one studied daytime sleepiness in mothers (Gennaro & Fehder, 2000) and the other maternal sleep characteristics (McMillen et al., 1993).

Important findings in the scoping review were that most of the existing research was quantitative, was from the US and was focused on maternal sleep early postpartum. There was a lack of qualitative research and studies of both parents' sleep and health outcomes over time. In the early postpartum weeks, the sleep quality and quantity of mothers of preterm infants was poor. The review

highlighted the need to evaluate sleep over time and compare with parents of full-born infants, as well as include fathers and more cultural and geographical breadth in research (Marthinsen et al., 2018).

6.2 Paper 2: Sleep Patterns and Psychosocial Health of Parents of Preterm and Full-Born Infants: A Prospective Comparative Longitudinal Feasibility Study

This paper aimed to evaluate the feasibility of conducting a prospective comparative longitudinal study of the sleep and psychosocial health of preterm and full-born infants' parents during the first postpartum year. The primary aim was to assess recruitment and attrition rates, and the secondary aims were to 1) describe and compare the characteristics of the participants, 2) evaluate measures and outcomes and 3) identify possible associations between the selected variables and attrition rates.

The results demonstrated that a longitudinal study could be conducted but highlighted several changes (e.g. in the recruitment procedure and attrition support). Feasibility was predefined as recruiting ≥ 75 parents each of preterm and full-born infants. Twenty-five parents of a preterm infant and 76 parents of a full-born infant were recruited from four Norwegian hospitals. The target for the full-born group was reached. However, the preterm group recruitment was challenging.

Evaluations of the parent sample showed that for socioeconomic class, the parent sample were representative of the parent population. Only one extremely preterm infant were recruited for the study, despite the recruitment of parents from three large Level 3c units with high admission of extremely preterm infants (The Norwegian Directorate of Health, 2007) per year. The baseline characteristics of the infants indicated that most of the preterm infants were in the least serious preterm category – moderate/late gestational level (GA: 32–36). Only one infant was categorized as "extremely preterm" (GA < 28), and only one was "very preterm" (GA: 28–31).

Actigraphs, sleep diaries and questionnaires were evaluated as feasible for use in a future study. Selected outcomes for sleep and health variables indicated that the frequency of insomnia was high at 2 months, and the prevalence remained high for mothers. Fatigue was also high for mothers at 6 and 12 months. Attrition rates were high in both groups at 6 and 12 months. No parent-related characteristics were associated with participation at 6 months. At 12 months, dropouts had a statistically significantly lower age in the full-born group (both parents) and higher age and body mass index in the preterm group (fathers).

6.3 Paper 3: A Comparison of Subjective and Objective Sleep Measures, Insomnia Symptoms, and Health-Related Quality of Life Between Mothers and Fathers of Preterm Versus Full-Born Infants: A Longitudinal Study From Norway

The sample for Papers 2 and 3 was the same. The purpose of Paper 3 was to describe and compare the sleep and HRQoL of mothers and fathers of preterm and full-born infants over time. We also assessed possible associations between sleep, insomnia and HRQoL over time in the total sample.

Data from actigraphs and sleep diaries was compared between groups (preterm and full-born) and genders (mothers and fathers) at 2 months. There were no statistically significant differences in TST actigraphy and sleep diary between the parent groups. SE was significantly lower for parents of preterm infants (actigraphy and sleep diary). When sleep was compared between mothers and fathers for the same period, mothers (preterm and full-born) reported significantly shorter TST and lower SE compared to fathers (sleep diaries).

The incidence of insomnia was high for the whole parent sample at 2 months. Parents in the preterm group reported the highest baseline values (62.5% for mothers, 71.4% for fathers). The prevalence for the full-born group was lower (53.4% for mothers and 43.5% for fathers). For mothers (preterm and full-born), the prevalence remained high (> 50%) over time, and mothers of full-born infants reported the highest proportions at the 6- and 12-month measurements.

For HRQoL, there were no statistically significant differences between the parent groups (preterm and full-born) over time. Fathers (preterm and full-born) reported significantly higher levels on the physical component summary as compared to mothers. The difference did not change over time. Insomnia was statistically significant associated with reduced HRQoL at all measurement points (2, 6 and 12 months postpartum). Gender or group did not affect the negative association between insomnia and HRQoL. Insomnia had a more pronounced effect on the mental component summary.

7 Discussion

In this section, methodological considerations, main results, implications for practice and further research needs will be discussed.

7.1 Methodological considerations

This study was planned as a comparative longitudinal cohort study with three measurement points (2, 6 and 12 months). To explore and compare sleep and HRQoL outcomes from parents with preterm infants with parents of full-born infants (comparison group) over time, a longitudinal study design was applied. Longitudinal study designs are important to advance the understanding of cause-and-effect relationships that might impact individuals' health outcomes (Polit et al., 2021).

However, the chosen longitudinal study design posed several methodological challenges. A common challenge in longitudinal study design is the loss of study participants over time (Polit et al., 2021). Recruitment and retainment were a challenge in our longitudinal study. Attrition refers to loss of participants over the course of a study, and it can generate bias and change the composition of the sample recruited (Polit et al., 2021). Attrition at 6 and 12 months was high for both parent groups in the present study. This was a problem since it reduced the power for the statistical analyses, as originally planned. High attrition could have limited the results of the study because it can lead to the loss of statistical power and increase the risk of selective attrition bias (Gul & Ali, 2010). Bias is expected in study results if attrition exceeds 20% (Dumville et al., 2006; Launes et al., 2014). Future research should investigate testing methods to better address attrition.

Different factors might have impacted the high attrition in this study. The long-term data collection, with repeated measurements, probably increased our attrition rates. The data collection procedure itself could have been too burdensome for parents. Parents were asked to wear actigraphs and fill out a sleep diary for 2 weeks before responding to a questionnaire (consisting of seven PROMs). An easier procedure with a less extensive data collection could help to reduce attrition in similar studies. These suggestions are based on the results of a previous

longitudinal study (Teague et al., 2018). A shorter questionnaire with less PROMs (e.g. collecting data on sleep, insomnia, depression and HRQoL only) could be less burdensome for the parents.

Another explanation for the high attrition rates was that parents lost interest in the project; this was perhaps also amplified by the COVID-19 outbreak. We should have paid more attention to encouraging parents' participation, which may have increased parents' response rate to the questionnaire. All nonresponders automatically received email reminders (up to three reminders could be sent). However, this was probably inadequate to encourage participation. We suggest that future research evaluate how parents can be better supported to increase response rates in similar studies.

7.2 Sample and representativeness

To reduce selection bias in the longitudinal study, all parents in the wards were screened systematically for potential inclusion on inclusion days. It was a strength that the same nurses performed this screening so that the process was done systematically by personnel who were well informed about the project.

The targeted sample of 75 parent couples was never reached for the preterm group. It might have been a barrier that we recruited parents as couples; this probably heightened the risk of refusal from one of the parents. If one parent was found ineligible or refused, the couple was excluded. This probably heightened the exclusion rates. The high volume of twins (48.2%) and non-Nordic parents (20%) in the preterm group contributed to many exclusions. It could have strengthened our study if we had investigated these matters aforehand. The refusal rate was nearly twice as high (62%) for the preterm group compared to the full-born group (37%).

For parents of extremely preterm infants, we had clearly overestimated the potential of these parents' opportunity to be recruited for our study. Recruitment was prolonged by several months (after December 2019). Additionally, we added one larger NICU unit to increase the potential of recruitment. Our recruitment efforts ended when the COVID-19 outbreak restricted the opportunity to recruit

parents. Nevertheless, it was a strength that we conducted the study and can use the results to inform future researchers.
The inclusion/exclusion criteria could have been designed more broadly; we could have given parents the opportunity to use English versions of questionnaires and thereby succeeded in producing a more representative ethnic group of parents. However, it was a strength that we evaluated the representativeness of our parent sample and compared sociodemographic data regarding education and income with the general Norwegian population for the same geographic area. The comparison indicated that we had succeeded in recruiting a representative parent sample, strengthening our results' representativeness.

For infants, the sample was only found representative of moderate/late preterm (GA $\geq$ 33 weeks) infants with birthweight $\geq$ 1,500 g. It was a limitation that our sample was not representative of the most preterm infants (very/extremely preterm groups). Despite that we recruited parents from large university hospitals with the highest rates of preterm infants per year. One explanation might be that many of the extremely preterm infants were excluded for medical reasons since they often have a higher risk of developing medical issues (Harrison & Goldenberg, 2016). It was a strength that our exclusion criteria contributed to excluding the most vulnerable parents from participating in this study. A second explanation might be that the parents were too burdened to participate; this was never examined in our study. Data on refusers could have been used to design a more robust study and could be helpful for other researchers.

Overall, we encountered many barriers against parent recruitment to the longitudinal study. We recruited parents early in the postpartum period, a vulnerable period in many parents' lives (Da Costa et al., 2021; King et al., 2020; Stremler et al., 2017). Some of the issues might have been more reinforced for vulnerable parents of preterm infants (Baraldi et al., 2020; Hartzell et al., 2023; Thivierge et al., 2023). It was often difficult to find the "right" moment to ask parents about participation in the project. We tried to develop flexible solutions to meet parents demands. If the parents were in a temporarily difficult situation (e.g. related to infant care or unstable medical situation of infants in the NICU), the recruiters postponed the formal request of participation until the next possible moment. This was a strength since participants' willingness and ability to give valid consent to research can be impacted by different factors – for example, a

demanding situation and their emotional state (Bracken-Roche et al., 2017). Thus, the collaboration with in house-nurses ensured that parents who accepted to participate in the study were fully informed about the project.
Overall, the feasibility study provided new knowledge that can be valuable for the research field. Aforehand, we had suspected that parents with extremely preterm infants could be more difficult to recruit since the literature has reported that these parents have many concerns after childbirth (Baraldi et al., 2020; Thivierge et al., 2023). Difficulties with recruitment was confirmed as a problem in our study. Recently, research has reported on similar experiences with recruitment of parents of preterm infants (Bagge et al., 2017; Mörelius et al., 2020). It is important that researchers share their experiences so that future research can build robust studies with similar study samples.

7.3 Reliability and validity

7.3.1 External validity

External validity refers to the degree to which study results might be true for other people and settings (Polit et al., 2021). When planning this research, our goal was for the study to be representative of parents with preterm and full-born infants for the same geographical area. It was a challenge that the proportion of non-Nordic-speaking parents and parents of multiples was higher than we had anticipated when we planned the study. The high proportion of parents excluded for these reasons means that our results cannot be easily applied to parents with such a background, representing a limitation in the transferability of the results. In future studies, it is important to be aware that within the premature group, it will be necessary to create inclusion criteria that account for this limitation so that studies can be created that are representative of parents with nonethnic Norwegian background and multiple parents.

External validity can be affected by sample size (Heale & Twycross, 2015). Very small samples pose a higher risk of not being representative of populations of interest (Faber & Fonseca, 2014). Our sample for preterm infants was much smaller than we had planned. If participants with certain characteristics refuse to participate in a research project, a segment of the population may be

underrepresented, and a biased sample might occur, posing a problem for the external validity of the study (Polit et al., 2021). However, it was a strength of our study that our parent samples were found representative for the same geographic area when we compared the sample with data from Statistics Norway.

External validity can also be affected if participants who drop out have unique characteristics making the remaining sample not representative of the intended population (Polit et al., 2021). Selective attrition reduces statistical power and is associated with external generalizability issues (Shadish & Luellen, 2005). Attrition is problematic when those who drop out differ in important areas from those who continue to participate, leading to generalizability problems (Polit et al., 2021). The high attrition rates in our study were a challenge and probably impacted negatively on our results, reducing the opportunity for the generalizability of findings and external validity. High attrition can pose serious threats to a study's internal and external validity; attrition rate > 20% is generally associated with the risk of biased results (Gul & Ali, 2010). Considering the high dropout rate in this study, it was important to investigate whether the selective attrition could have influenced our results. It strengthens our results that at the 6-month evaluation, we did not find any unique characteristics of those who dropped out. At 12 months, we found that those who dropped out had certain characteristics, and it is important to particularly focus on strengthening their participation in future studies to strengthen validity.

7.3.2 Internal validity

The psychometric properties of research instruments are important to consider (Polit et al., 2021). The reliability of an instrument relates to the consistency and accuracy of the results of a study and its research instruments A reliable instrument measures something in a consistent, repeatable and reproduceable manner on different occasions (test-retest reliability; (Pallant, 2020). Validity also concerns the accuracy of results and the degree to which an instrument measures what it is supposed to measure (internal consistency). A common way to assess internal validity is to calculate Cronbach's alpha, which has a maximum value of 1 (Pallant, 2020). Values above 0.7 are considered acceptable reliability (Pallant, 2020). In this study, the Cronbach's alpha values were above 0.7 for all the selected PROMs (Table 1), which is regarded as good internal consistency and reliability of this

present study. Overall, for the questionnaires, it was a strength that our questionnaire pack included well-established and well-validated questionnaires for the Norwegian context, except for the FSSQ. The FSSQ had been used but not formally translated and validated in Norwegian. We translated the questionnaire before use, but it was not validated (Appendix 15).

It was a strength that we operated with both self-reported measurements (questionnaires and sleep diary) and objectively measured (actigraphy) sleep data in the empirical study. Actigraphy and sleep diaries are validated research instruments that have been well established to assess sleep (Aili et al., 2017; Ibanez et al., 2018; Stone, 2017). Actiwatch 2 has been tested and found reliable compared to the gold-standard PSG (Marino et al., 2013; Shin et al., 2015; Weiss et al., 2010). Actigraphy represents a cost-effective method and can assess sleep over time in different settings (Stone, 2017). Data from at least 5 nights are recommended when assessing SE, and at least 7 nights are recommended for TST measurement (Aili et al., 2017). To increase the amount of data for statistical analyses, compliant data from the actigraphs and sleep diaries were defined as ≥ 1 day with ≥ 24 hours of daily wear time (Papers 2 and 3). This represents a limitation for our results since studies have demonstrated that actigraphs should be used for at least 7 nights to measure TST and that SE should be measured for at least 5 nights (Aili et al., 2017).

It was also a strength that we operated with self-reported sleep measurements. Self-reported sleep data is considered to be very valuable in evaluations of sleep since it reflects an individual's perspective of sleep sufficiency (Bjorvatn, 2012). Sleep diaries present the advantage of being prospective and producing accurate descriptions of individuals' sleep patterns over time (often 1 or 2 weeks; (Short et al., 2017). However, recall bias has been described as an issue with self-reported sleep measures and PROMs (Ibanez et al., 2018). In this study, recall bias might have been present, but it could also have been reduced since the sleep diary was filled out every morning and was not so dependent on memory. For insomnia, the issue of recall bias might have been more pronounced since this questionnaire (BIS) assesses sleep as far back as 3 months.

7.4 Discussion of main results

The overall aim of this thesis was to study sleep and the relationship between sleep and HRQOL in parents of preterm infants in the postpartum phase (the child is 2-12 months). Furthermore, the purpose was to compare sleep and HRQoL in mothers and fathers of preterm infants with mothers and fathers of full-born infants in the same time period.

7.4.1 Sleep in parents of preterm infants

Our presumption was that parents of premature babies sleep poorly in the postpartum period and even poorer than parents of full-born infants (comparison group). The results from Paper 3 indicated that mothers of preterm infants slept very poorly at 2 months postpartum. SE was also significantly lower for the preterm group at 2 months. These results demonstrate that sleep disruption was a greater issue for parents of preterm infants in the early postpartum weeks compared to parents of full-born newborns. This is of concern since sleep disruption has been associated with several negative health outcomes for parents, including postpartum depression (Dørheim, Bondevik, Eberhard-Gran, & Bjorvatn, 2009; Dørheim, Bondevik, Eberhard-Gran, & Bjorvatn, 2009). Our findings of poor sleep for parents of preterm infants are supported by two recent reviews (Baumgartel & Facco, 2018; Haddad et al., 2019). Both parents sleep poorly while their infants are admitted to the NICU (Haddad et al., 2019).

Several factors can explain why our preterm group slept poorly at 2 months. A factor that seems to affect the sleep of parents of preterm infants is a high stress level (Haddad et al., 2019). Stress is a well-known precipitant of poor sleep outcomes (Åkerstedt et al., 2012) and has been correlated with anxiety, depression, sleep disturbances (Al Maghaireh et al., 2017) and reduced HRQoL (Lee & Hsu, 2012a). Parents of preterm infants in the NICU have reported that they experience alterations in parental role, prolonged separation from the infant and stress related to the infant's critical illness (Wallace et al., 2020). Mothers have reported that they experience higher stress levels in the weeks after childbirth compared to fathers (Al Maghaireh et al., 2017; Matricardi et al., 2013). Higher stress levels in mothers can explain why the sleep of mothers of preterm infants was even more

compromised compared to fathers and why such mothers reported the lowest SE of all participants at 2 months.

However, another explanation of the sleep difference between mothers and fathers of preterm infants at 2 months can be that mothers sleep is often more fragmented after childbirth as a result of hormonal fluctuation and nightly feedings (Hunter et al., 2009). Thus, the difference can also be a result of differences in parental roles. In previous research, mothers have reported that, to a greater extent than fathers, they felt they lost their role as the primary caregiver when the infant was hospitalized in the NICU (Heidari et al., 2013). Mothers have also expressed feeling a higher degree of guilt for the preterm birth incidence (Fowler et al., 2019). Gender differences in emotional responses and role expectation may be a plausible explanation for the poor sleep outcomes for these mothers. This factor may also explain why one of the included studies in Paper 1 reported that mothers slept poorly and reported high stress levels despite sleeping at home and not participating in the care of their premature infant (Lee & Kimble, 2009).

Overall, our results indicate that in the early weeks after childbirth, sleep is a challenge for parents of premature babies. The results highlight the importance of sleep promotion for these parents in the early postpartum period. The implementation of family-centred care in neonatal caregiving underlines a focus on both parents, not only mothers. Family-centred care includes providing care for children and their families, ensuring that the whole family is recognized as care recipients (Shields, 2015). In (Edell-Gustafsson et al., 2015) study, emotional feelings such as anxiety, uncertainty, powerlessness and the inability to change the situation impacted negatively on the sleep of both parents of preterm infants while the infant was hospitalized in the NICU. To prevent such feelings, continuous information, guidance and support for the parents was important (Edell-Gustafsson et al., 2015). Keeping the family together in a private room and the promotion of skin-to-skin contact was described as stress reducing and was associated with better sleep for parents in this early phase (Edell-Gustafsson et al., 2015). We recommend more research on how family-centred care can impact both parents' long-term sleep and health outcomes. It would also be interesting to study if and how stress-reducing interventions can impact sleep over time (Al Maghaireh et al., 2017).

7.4.2 Sleep and associations with HRQoL in postpartum parents

Early in this project, it was our assumption that little and poor sleep can impact negatively on postpartum parents' HRQoL over time. In Paper 3, insomnia had a statistically significant negative impact on postpartum parents' HRQoL, particularly their mental well-being. Insomnia symptoms were associated with reduced mental and physical HRQoL at all three measurement points (2, 6 and 12 months). Recent studies support our results regarding negative association between insomnia and reduced parental HRQoL (El-Sherbeeny et al., 2022; Sivertsen et al., 2017). The significant association between insomnia and impaired health emphasizes the importance of identifying, preventing and treating insomnia for parents (Sivertsen et al., 2017). Sleep deprivation and poor sleep has the potential to negatively affect physical, emotional/cognitive and social aspects (El-Sherbeeny et al., 2022). A lack of sleep itself, together with the cumulative health effects, can greatly affect parents' daily lives, which may in turn affect daily functioning, interaction with the infant and the family as a whole (Baglioni et al., 2022).

Promotion of good HRQoL is an important public health focus and is essential for parents after childbirth. Our findings underline the importance of insomnia prevention and detection for postpartum parents to support their HRQoL. Improved parental HRQoL can also positively affect the development and health of preterm infants (Hatzmann et al., 2008; Treyvaud et al., 2009). Parents at risk of poor sleep should receive educational and supportive sleep-optimizing strategies (Redeker, 2020). Today, the most frequently used and efficacious treatment of insomnia are nonpharmacologic behavioural interventions and cognitive behavioural therapy for insomnia (CBT-I; (Baglioni et al., 2022). CBT-I is a multicomponent treatment that combines several approaches, including cognitive, behavioural and educational components (Bjorvatn, 2012). CBT-I has also been used successfully within the postpartum period (Manber et al., 2023; Swanson et al., 2013). Treatment trials to promote sleep problems and sleep disorders during the postpartum period should be prioritized. Ferrans et al.'s (2005) revised HRQoL model has been suggested to serve as a useful approach to understanding how different factors impact HRQoL (Duangchan & Matthews, 2021). In this project, we only used the model as a background to understand

HRQoL. However, the model might provide potential to further examine how various factors are associated with postpartum parents' HRQoL.

7.4.3 Sleep in postpartum mothers

It was our presumption that mothers sleep more poorly than fathers, regardless of whether the infant is premature. Our results in Paper 3 confirmed our assumption: mothers in both groups experienced significantly shorter TST and SE compared to fathers at 2 months postpartum. Our results are comparable with those of other studies indicating that mothers' sleep is often more fragmented compared to fathers' sleep in this early phase (Insana & Montgomery-Downs, 2013; Richter et al., 2019). Mothers tend to have more awake time at night (Insana et al., 2014) and a higher degree of performance deficits (Insana & Montgomery-Downs, 2013) compared to fathers in the early postpartum weeks.

However, the consequences of sleep loss should be viewed according to the length of time of the sleep loss. Some occasional nights with poor sleep can often be quite well tolerated by most mothers, especially if daytime naps can compensate for the reduced nocturnal sleep (Milner & Cote, 2009). Thus, the long-term impact of poor sleep is of more concern, as sleep deprivation that lasts over longer time can have a profound impact on health outcomes (Cirelli et al., 2019; Medic et al., 2017). An important finding in our study was the high prevalence of long-term sleep disturbance and insomnia in the whole parent sample (2 months) and for mothers (both groups) over time (Paper 3). The high prevalence of insomnia was of concern since insomnia has been associated with several negative health outcomes (Baglioni et al., 2022; de Zambotti et al., 2018; Sivertsen et al., 2021). Our findings are in line with those of other studies that have reported that the pregnancy and postpartum period poses the risk of developing insomnia, particularly for mothers (Kissling, 2020; Sivertsen et al., 2015; Sivertsen et al., 2017; Swanson et al., 2020).

Thus, it was surprising that mothers of full-born infants reported the highest incidence of insomnia at 6 and 12 months. We expected that mothers of preterm infants would present the highest prevalence, considering that the burden on these mothers is often high (Alkozei et al., 2014; Fowler et al., 2019). Our results indicate that it is important to prevent insomnia in the postpartum period to

promote good HRQoL in parents. It is also important that research identify reasons why insomnia occurs in this period, as well as prioritize the prevention and detection of this sleep disorder (Swanson et al., 2020).
Overall, the high prevalence of insomnia in our total parent sample requires further attention. It is important that parents with sleep problems receive help. In Gellerstedt et al.'s (Gellerstedt et al., 2019) study, sleep was an underprioritized topic that was often overlooked within many healthcare settings, with few departments having any kind of policy documents or clinical guidelines regarding patients' sleep. Nurses need more evidence-based knowledge about sleep and sleep-promoting interventions rather than basing caregiving on "common sense" or personal experiences (Gellerstedt et al., 2015). Clearly, sleep is an important topic to prioritize within postpartum caregiving. We suggest a strengthened focus on healthcare personnel education and training, considering that our results revealed that many postpartum parents struggle with sleep problems and insomnia.

7.4.4 Feasibility of a longitudinal study

It was our presumption that it is possible to conduct a longitudinal study with parents of premature and full-born infants. Our findings confirmed the feasibility of a longitudinal study; thus, it was important for the data collection to not be too burdensome for the parents. An active and supportive role in the follow-up of included parents to prevent dropouts was also emphasized. Another important finding was that it is difficult to recruit parents of preterm infants to a longitudinal study. The recruitment of parents of preterm infants was a challenge, raising many ethical questions and representing barriers in the recruitment process. Recently, our finding of difficult recruitment was supported by another study (Mörelius et al., 2020). Here, physical barriers, frequent relocation of premature infants and low inclusion rates ended the study, denoting it is necessary to be aware of these matters in designing future robust longitudinal studies. Particularly, recruitment and attrition should be prioritized and supported so that the problems we experienced with low number of the infant sample (preterm infants) and reduced statistical power can be avoided.

Based on our study results, we recommend considering the possibility of including a broader group of parents in future studies, including families with multiple births,

English-speaking parents and minority groups. This action would possibly heighten the inclusion rate. Additionally, we strongly recommend researchers to collaborate with nurses within wards in the recruitment of parents. It was a strength that we cooperated with such nurses so they could be flexible and find appropriate moments to ask parents about participation. It is also important to teach clinical personnel about recruitment procedures so that ethical aspects regarding the recruitment of vulnerable participants (e.g. parents of preterm infants) can be handled as best as possible. A long recruitment period and collaboration with several NICU wards in Nordic countries can be a way to reach a higher volume of parents with preterm infants for longitudinal studies.

Another important consideration is to simplify the data collection in future studies and investigate sleep and health outcomes with fewer instruments than we used. It is also important to strengthen the general support of participation to avoid dropouts. We believe that attrition can be addressed with barrier-reducing efforts and the use of, for example, active methods to contact participants and avoid dropout. For parents with full-born infants, a focus on sufficient recruitment resources is important to handle the large number of eligible parents in longitudinal studies. We discovered that parents with extremely preterm infants were difficult to recruit to our study. An easier study design, such as qualitative interviews, could be useful for examining sleep and health outcomes in these vulnerable parents.

Overall, it is our opinion that our feasibility study has contributed with important knowledge of how to design robust longitudinal studies. Longitudinal studies can be valuable for expanding knowledge about sleep and HRQoL in parents in the postpartum phase. However, it is important that researchers are aware of recruitment barriers and attrition in designing robust studies. Knowledge of sleep and HRQoL is important to support a healthy parent population.

8 Possible implications for practice and further research

This study has highlighted that sleep is important for good parental HRQoL. Our findings have several implications for clinical practice and policy makers. Parents of preterm infants should be treated as vulnerable for sleep problems in the early postpartum phase, and mothers require particular concern. Nurses and midwives are often in unique positions to support mothers in the early postpartum period (Lean et al., 2018). Nurses can provide information and guidance about how mothers can achieve restorative sleep, reduce stress and increase coping with the situation (Redeker, 2020).

Postpartum parents are vulnerable to develop long-term sleep disorders such as insomnia in the postpartum phase (Sivertsen et al., 2017; Swanson et al., 2020). Insomnia prevention can help to promote good HRQoL in parents. It is important that health professionals focus on identifying the reasons why insomnia occurs in parents in the first weeks after birth and that we are aware of preventing and treating the condition (Swanson et al., 2020). We recommend that sleep screening be introduced as a standard clinical routine in maternity care so that parents with sleep disorders can be identified early and receive help.

More research is needed on predisposing factors for insomnia in the postpartum period (Redeker, 2020; Sivertsen et al., 2015; Swanson et al., 2020). It is crucial to expand existing knowledge of how sleep and HRQoL is linked in this period (Wyrwich & Gross, 2008). Longitudinal studies can contribute with valuable knowledge regarding sleep and HRQoL over time for postpartum parents. To successfully conduct longitudinal studies involving postpartum parent populations, recruitment procedures and attrition support need extra attention.

Sleep is a challenge for parents of premature infants. It is important that researchers also gain knowledge about sleep and HRQoL in parents of extremely premature children. This is a vulnerable group of parents that we failed to recruit as intended in our project. We also recommend that research on sleep and HRQoL in parents with a nonethnic Norwegian background and parents of multiples should be conducted.

9 Conclusions

This thesis provides new insights into sleep and HRQoL in parents of newborn children. Sleep and HRQoL were compared between mothers and fathers of preterm children and those of full-born children 2, 6 and 12 months after childbirth. There were no statistically significant differences in HRQoL between the groups, but the fathers in both groups had higher physical HRQoL compared to the mothers at all assessment points (2, 6 and 12 months). Parents of premature children had lower SE compared to parents in the term group 2 months after birth. Mothers in both groups had significantly lower SE and shorter TST compared to the fathers for the same period.

Insomnia was a frequently occurring sleep disorder among the parents. The incidence of insomnia was high in both groups 2 months after birth, and for mothers in both groups, the incidence remained high at 6 and 12 months after birth. Of the various sleep assessments investigated, insomnia was the only sleep component that had a significant negative impact on parents' HRQoL, and mental HRQoL was particularly negatively affected.

Our results indicated that parents' transition to the parenting role is demanding, with reduced sleep outcomes early postpartum that require increased attention from health professionals. The findings emphasize the importance of supporting sleep and preventing sleep disorders, especially for new mothers. Insomnia prevention can help to promote good HRQoL in parents. Sleep screening should be introduced as a standard clinical routine in maternity care for early identification and treatment of parents with sleep disorders.

Our results revealed that it is feasible to conduct a longitudinal study comparing sleep quality and HRQoL in parents of preterm and full-born infants, however on a much smaller scale than originally intended. It is important that the scope of the data collection does not become too burdensome for parents with premature children. It is also important to be active and supportive in the follow-up of included parents in longitudinal studies to prevent dropouts.

References

Aili, K., Astrom-Paulsson, S., Stoetzer, U., Svartengren, M., & Hillert, L. (2017). Reliability of Actigraphy and Subjective Sleep Measurements in Adults: The Design of Sleep Assessments. *Journal of Clinical Sleep Medicine*, *13*(1), 39-47. https://doi.org/10.5664/jcsm.6384

Al Maghaireh, D. F., Abdullah, K. L., Chong, M. C., Chua, Y. P., & Al Kawafha, M. M. (2017). Stress, Anxiety, Depression and Sleep Disturbance among Jordanian Mothers and Fathers of Infants Admitted to Neonatal Intensive Care Unit: A Preliminary Study. *Journal of Pediatric Nursing*, *36*, 132-140. https://doi.org/10.1016/j.pedn.2017.06.007

Al Rehaili, B. O., Al-Raddadi, R., Alenezi, N. K., & Alyami, A. H. (2023). Postpartum quality of life and associated factors: a cross-sectional study. *Quality of Life Research*, *32*(7), 2099-2106. https://doi.org/10.1007/s11136-023-03384-3

Alkozei, A., McMahon, E., & Lahav, A. (2014). Stress levels and depressive symptoms in NICU mothers in the early postpartum period. *Journal of Maternal-Fetal & Neonatal Medicine*, *27*(17), 1738-1743. https://doi.org/10.3109/14767058.2014.942626

Almalik, M. M. (2017). Understanding maternal postpartum needs: A descriptive survey of current maternal health services. *Journal of Clinical Nursing*, *26*(23-24), 4654-4663. https://doi.org/https://doi.org/10.1111/jocn.13812

Altman, D. G. (1990). *Practical statistics for medical research*. Chapmann& Hall/CRC.

Alvarez, G. G., & Ayas, N. T. (2004). The impact of daily sleep duration on health: a review of the literature. *Progress in Cardiovascular Nursing*, *19*(2), 56-59. https://doi.org/10.1111/j.0889-7204.2004.02422.x

American Psychiatric Association. (2000). *Diagnostic and statistical manual of mental disorders : DSM-IV-TR* (4th. ed.). American Psychiatric Association.

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders : DSM-5* (5th ed.). American Psychiatric Association.

Amorim, M., Silva, S., Kelly-Irving, M., & Alves, E. (2018). Quality of life among parents of preterm infants: a scoping review. *Quality of Life Research*, *27*(5), 1119-1131. https://doi.org/10.1007/s11136-017-1771-6

Arain, M., Campbell, M. J., Cooper, C. L., & Lancaster, G. A. (2010). What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Medical Research Methodology*, *10*, 67-67. https://doi.org/10.1186/1471-2288-10-67

Arksey, H., & O'Malley, L. (2005). Scoping Studies: Towards a Methodological Framework. *International Journal of Social Research Methodology*, *8*(1), 19-32. https://doi.org/10.1080/1364557032000119616

Arnau, J., Bendayan, R., Blanca, M. J., & Bono, R. (2013). The effect of skewness and kurtosis on the robustness of linear mixed models. *Behavior*

Research Methods, *45*(3), 873-879. https://doi.org/10.3758/s13428-012-0306-x

Aronsson, E., Holzmann, M., Bartocci, M., Hulthén Varli, I., & Saltvedt, S. (2023). Changes in perinatal management and outcomes of extremely preterm infants born below 26 weeks of gestation in a tertiary referral hospital in Sweden: Comparison between 2004–2007 and 2012–2016. *Acta Obstetricia et Gynecologica Scandinavica*, *102*(6), 716-727. https://doi.org/https://doi.org/10.1111/aogs.14576

Bagge, S. R., Westgate, B., Few, K., Clarke, P., Adlam, A., Walsh, J., & O'Brien, M. (2017). Acceptability and feasibility of collecting psychosocial data from fathers of very low birth weight infants. *Journal of Child Health Care*, *21*(3), 283-291. https://doi.org/10.1177/1367493517715147

Baglioni, C., Tang, N. K. Y., Johann, A. F., Altena, E., Bramante, A., Riemann, D., & Palagini, L. (2022). Insomnia and poor sleep quality during peripartum: a family issue with potential long term consequences on mental health. *Journal of Maternal-Fetal & Neonatal Medicine*, *35*(23), 4534-4542. https://doi.org/10.1080/14767058.2020.1854718

Bai, G., Korfage, I. J., Mautner, E., & Raat, H. (2019). Determinants of Maternal Health-Related Quality of Life after Childbirth: The Generation R Study. *International Journal of Environmental Research and Public Health*, *16*(18), 3231. https://www.mdpi.com/1660-4601/16/18/3231

Bakas, T., McLennon, S. M., Carpenter, J., Buelow, J., Otte, J., Hanna, K., Ellett, M., Hadler, K., & Welch, J. (2012). Systematic review of health-related quality of life models. *Health Qual. Life Outcomes*, *10:134*, 2-12. https://doi.org/10.1186/1477-7525-10-134

Baldwin, A., Herde, E., Hoehn, E., Kimble, R., Funk, H., Spink, D., Keevers, S., & Bor, W. (2022). Transition to Parenthood: Antenatal Education Promotes Perinatal Mental Health When Collaboratively Delivered by Midwives, Mental Health Peer Workers and Perinatal and Infant Mental Health Professionals. *J Perinat Educ*, *31*(2), 104-110. https://doi.org/10.1891/jpe-2021-0008

Bandura, A. (1982). Self-efficacy mechanism in human agency. *American Psychologist*, *37*(2), 122-147. https://doi.org/10.1037/0003-066X.37.2.122

Banks, D. J., Basnes M, Dinges D.F. (2017). Sleep deprivation. In M. R. Kryger, T. C Dement W. (Ed.), *Principles and practice of sleep medicine* (6 ed., pp. 49-62). Elsevier.

Baraldi, E., Allodi, M. W., Smedler, A. C., Westrup, B., Lowing, K., & Aden, U. (2020). Parents' Experiences of the First Year at Home with an Infant Born Extremely Preterm with and without Post-Discharge Intervention: Ambivalence, Loneliness, and Relationship Impact. *International Journal of Environmental Research and Public Health*, *17*(24), 1-26. https://doi.org/10.3390/ijerph17249326

Barandon, S., Castel, L., Galera, C., van der Waerden, J., & Sutter-Dallay, A. L. (2023). Women's quality of life and mental health in the first year after birth: Associated factors and effects of antenatal preventive measures

among mothers in the ELFE cohort. *Journal of Affective Disorders*, *321*, 16-27. https://doi.org/10.1016/j.jad.2022.10.012

Baumgartel, K., & Facco, F. (2018). An Integrative Review of the Sleep Experiences of Mothers of Hospitalized Preterm Infants. *Nursing for Women's Health*, *22*(4), 310-326. https://doi.org/10.1016/j.nwh.2018.05.003

Bhati, S., & Richards, K. (2015). A Systematic Review of the Relationship Between Postpartum Sleep Disturbance and Postpartum Depression. *JOGNN - Journal of Obstetric, Gynecologic, and Neonatal Nursing*, *44*(3), 350-357. https://doi.org/10.1111/1552-6909.12562

Bjorvatn, B. (2012). *Sleep disorders: modern evaluation and treatment* (1 ed.). Fagbokforlaget.

Bjorvatn, B., Berge, T., Lehmann, S., Pallesen, S., & Saxvig, I. W. (2018). No Effect of a Self-Help Book for Insomnia in Patients With Obstructive Sleep Apnea and Comorbid Chronic Insomnia - A Randomized Controlled Trial. *Frontiers in Psychology*, *9*, 1-8. https://doi.org/10.3389/fpsyg.2018.02413

Bjorvatn, B., Waage, S., & Pallesen, S. (2018). The association between insomnia and bedroom habits and bedroom characteristics: an exploratory cross-sectional study of a representative sample of adults. *Sleep Health*, *4*(2), 188-193. https://doi.org/10.1016/j.sleh.2017.12.002

Blomqvist, Y. T., Nyqvist, K. H., Rubertsson, C., & Funkquist, E. L. (2017). Parents need support to find ways to optimise their own sleep without seeing their preterm infant's sleeping patterns as a problem. *Acta Paediatrica*, *106*(2), 223-228. https://doi.org/10.1111/apa.13660

Boisgontier, M. P., & Cheval, B. (2016). The anova to mixed model transition. *Neuroscience and Biobehavioral Reviews*, *68*, 1004-1005. https://doi.org/https://doi.org/10.1016/j.neubiorev.2016.05.034

Booth, A., Sutton, A., & Papaioannou, D. (2016). *Systematic approaches to a successful literature review* (2nd ed.). Sage.

Bowen, D. J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., Bakken, S., Kaplan, C. P., Squiers, L., Fabrizio, C., & Fernandez, M. (2009). How we design feasibility studies. *American Journal of Preventive Medicine*, *36*(5), 452-457. https://doi.org/10.1016/j.amepre.2009.02.002

Bracken-Roche, D., Bell, E., Macdonald, M. E., & Racine, E. (2017). The concept of 'vulnerability' in research ethics: an in-depth analysis of policies and guidelines. *Health Research Policy and Systems*, *15*(1), 8-8. https://doi.org/10.1186/s12961-016-0164-6

Broadhead, W. E., Gehlbach, S. H., de Gruy, F. V., & Kaplan, B. H. (1988). The Duke-UNC Functional Social Support Questionnaire. Measurement of social support in family medicine patients. *Medical Care*, *26*(7), 709-723. https://www.ncbi.nlm.nih.gov/pubmed/3393031

Brumbaugh, J. E., Hansen, N. I., Bell, E. F., Sridhar, A., Carlo, W. A., Hintz, S. R., Vohr, B. R., Colaizy, T. T., Duncan, A. F., Wyckoff, M. H., Baack, M. L., Rysavy, M. A., DeMauro, S. B., Stoll, B. J., Das, A., & Higgins, R. D.

(2019). Outcomes of Extremely Preterm Infants With Birth Weight Less Than 400 g. *JAMA Pediatr*, *173*(5), 434-445. https://doi.org/10.1001/jamapediatrics.2019.0180

Bugge, C., Williams, B., Hagen, S., Logan, J., Glazener, C., Pringle, S., & Sinclair, L. (2013). A process for Decision-making after Pilot and feasibility Trials (ADePT): development following a feasibility study of a complex intervention for pelvic organ prolapse. *Trials*, *14*, 1-13. https://doi.org/10.1186/1745-6215-14-353

Busse, M., Stromgren, K., Thorngate, L., & Thomas, K. A. (2013). Parents responses to stress in the neonatal intensive care unit. *Critical Care Nurse*, *33*(4), 52-60. https://doi.org/10.4037/ccn2013715

Cappuccio, F., Miller, M., Lockley, S., Rajaratnam, S., D'Elia, L., Strazzullo, P., & Miller, M. (2010). Sleep Duration and All-Cause Mortality: A Systematic Review and Meta-Analysis of Prospective Studies. *Sleep*, *33*(5), 585-592. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2864873/

Carlander, A. K., Andolf, E., Edman, G., & Wiklund, I. (2015). Health-related quality of life five years after birth of the first child. *Sex Reprod Healthc*, *6*(2), 101-107. https://doi.org/10.1016/j.srhc.2015.01.005

Carney, C. E., Buysse, D. J., Ancoli-Israel, S., Edinger, J. D., Krystal, A. D., Lichstein, K. L., & Morin, C. M. (2012). The consensus sleep diary: standardizing prospective sleep self-monitoring. *Sleep*, *35*(2), 287-302. https://doi.org/10.5665/sleep.1642

Carscadon, M., & Dement, W. (2017). Normal human sleep: an overview. In M. Kryger, Roth T, Dement, WC (Ed.), *Principles and practice of sleep medicine* (6 ed., pp. 15-23). Elsevier.

Caruana, E. J., Roman, M., Hernández-Sánchez, J., & Solli, P. (2015). Longitudinal studies. *Journal of Thoracic Disease*, *7*(11), E537-E540. https://doi.org/10.3978/j.issn.2072-1439.2015.10.63

Chalder, T., Berelowitz, G., Pawlikowska, T., Watts, L., Wessely, S., Wright, D., & Wallace, E. P. (1993). Development of a fatigue scale. *Journal of Psychosomatic Research*, *37*(2), 147-153. https://www.ncbi.nlm.nih.gov/pubmed/8463991

Cheong, J. L. Y., Olsen, J. E., Lee, K. J., Spittle, A. J., Opie, G. F., Clark, M., Boland, R. A., Roberts, G., Josev, E. K., Davis, N., Hickey, L. M., Anderson, P. J., & Doyle, L. W. (2021). Temporal Trends in Neurodevelopmental Outcomes to 2 Years After Extremely Preterm Birth. *JAMA Pediatr*, *175*(10), 1035-1042. https://doi.org/10.1001/jamapediatrics.2021.2052

Cirelli, Benca, R., & Eichler, A. F. (2019, Jun 07, 2021). *Insufficient sleep: Definition, epidemiology, and adverse outcomes*. UpToDate. Retrieved Nov 22, 2021 from https://www.uptodate.com/contents/insufficient-sleep-definition-epidemiology-and-adverse-outcomes?search=insufficient%20sleep&source=search_result&selectedTitle=2~48&usage_type=default&display_rank=2

Cox, J. L., Holden, J. M., & Sagovsky, R. (1987). Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression

Scale. *British Journal of Psychiatry*, *150*, 782-786. https://doi.org/10.1192/bjp.150.6.782

Da Costa, D., Lai, J. K., & Zelkowitz, P. (2021). A prospective study on the course of sleep disturbances in first-time fathers during the transition to parenthood. *Infant Ment Health J*, *42*(2), 222-232. https://doi.org/10.1002/imhj.21911

Davis, L., Edwards, H., Mohay, H., & Wollin, J. (2003). The impact of very premature birth on the psychological health of mothers. *Early Human Development*, *73*(1), 61-70. https://doi.org/https://doi.org/10.1016/S0378-3782(03)00073-2

de Zambotti, M., Goldstone, A., Colrain, I. M., & Baker, F. C. (2018). Insomnia disorder in adolescence: Diagnosis, impact, and treatment. *Sleep Medicine Reviews*, *39*, 12-24. https://doi.org/10.1016/j.smrv.2017.06.009

Detry, M. A., & Ma, Y. (2016). Analyzing Repeated Measurements Using Mixed Models. *JAMA*, *315*(4), 407-408. https://doi.org/10.1001/jama.2015.19394

Donald, G. (2018). A brief summary of pilot and feasibility studies: Exploring terminology, aims, and methods. *European Journal of Integrative Medicine*, *24*, 65-70. https://doi.org/https://doi.org/10.1016/j.eujim.2018.10.017

Donohue, P. K., Maurin, E., Kimzey, L., Allen, M. C., & Strobino, D. (2008). Quality of life of caregivers of very low-birthweight infants. *Birth*, *35*(3), 212-219. https://doi.org/10.1111/j.1523-536X.2008.00242.x

Dorheim, S. K., Bjorvatn, B., & Eberhard-Gran, M. (2014). Can insomnia in pregnancy predict postpartum depression? A longitudinal, population-based study. *PloS One*, *9*(4), 1-10. https://doi.org/10.1371/journal.pone.0094674

Duangchan, C., & Matthews, A. K. (2021). Application of Ferrans et al.'s conceptual model of health-related quality of life: A systematic review. *Research in Nursing and Health*, *44*(3), 490-512. https://doi.org/10.1002/nur.22120

Dumville, J. C., Torgerson, D. J., & Hewitt, C. E. (2006). Reporting attrition in randomised controlled trials. *BMJ (Clinical research ed.)*, *332*(7547), 969-971. https://doi.org/10.1136/bmj.332.7547.969

Dørheim, S., Bondevik, G., Eberhard-Gran, M., & Bjorvatn, B. (2009). Sleep and depression in postpartum women: a population-based study. *Sleep*, *32*(7), 847-855. https://www.ncbi.nlm.nih.gov/pubmed/19639747

Dørheim, S., Bondevik, G., Eberhard-Gran, M., & Bjorvatn, B. (2009). Subjective and objective sleep among depressed and non-depressed postnatal women. *Acta Psychiatrica Scandinavica*, *119*(2), 128-136. https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1600-0447.2008.01272.x

Eberhard-Gran, M., Eskild, A., Tambs, K., Schei, B., & Opjordsmoen, S. (2001). The Edinburgh Postnatal Depression Scale: validation in a Norwegian community sample. *Nord J Psychiatry*, *55*(2), 113-117. https://doi.org/10.1080/08039480151108525

Edell-Gustafsson, U., Angelhoff, C., Johnsson, E., Karlsson, J., & Morelius, E. (2015). Hindering and buffering factors for parental sleep in neonatal care. A phenomenographic study. *Journal of Clinical Nursing*, *24*(5-6), 717-727. https://doi.org/10.1111/jocn.12654

Eiser, C., Eiser, J. R., Mayhew, A. G., & Gibson, A. T. (2005). Parenting the premature infant: balancing vulnerability and quality of life. *Journal of Child Psychology and Psychiatry and Allied Disciplines*, *46*(11), 1169-1177. https://doi.org/10.1111/j.1469-7610.2005.00415.x

El-Sherbeeny, N., El Tantawy, A., Ibrahim, O., Elsayed, M., El-Okda, N., & Hassan, H. (2022). Insomnia and sleep quality among women during the perinatal period. *Middle East Current Psychiatry-Mecpsych*, *29*(1), 2-9. https://doi.org/DOI10.1186/s43045-022-00209-w

Eldridge, S. M., Lancaster, G. A., Campbell, M. J., Thabane, L., Hopewell, S., Coleman, C. L., & Bond, C. M. (2016). Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework. *PloS One*, *11*(3), 1-22. https://doi.org/10.1371/journal.pone.0150205

Epifanio, M. S., Genna, V., De Luca, C., Roccella, M., & La Grutta, S. (2015). Paternal and Maternal Transition to Parenthood: The Risk of Postpartum Depression and Parenting Stress. *Pediatric Reports*, *7*(2), 38-44. https://doi.org/10.4081/pr.2015.5872

Erhart, M., & Ravens-Sieberer, U. (2006). Health-related quality of life instruments and individual diagnosis - a new area of application. *Psycho-Social Medicine*, *3*, 1-11. https://www.ncbi.nlm.nih.gov/pubmed/19742074

Faber, J., & Fonseca, L. M. (2014). How sample size influences research outcomes. *Dental Press Journal of Orthodontics*, *19*(4), 27-29. https://doi.org/10.1590/2176-9451.19.4.027-029.ebo

Fayers, P. M., & Machin, D. (2016). *Quality of life : the assessment, analysis and interpretation of patient-reported outcomes* (3rd ed.). John Wiley.

Feeley, C. A., Turner-Henson, A., Christian, B. J., Avis, K. T., Heaton, K., Lozano, D., & Su, X. (2014). Sleep quality, stress, caregiver burden, and quality of life in maternal caregivers of young children with bronchopulmonary dysplasia. *Journal of Pediatric Nursing*, *29*(1), 29-38. https://doi.org/10.1016/j.pedn.2013.08.001

Fekedulegn, D., Andrew, M. E., Shi, M., Violanti, J. M., Knox, S., & Innes, K. E. (2020). Actigraphy-Based Assessment of Sleep Parameters. *Ann Work Expo Health*, *64*(4), 350-367. https://doi.org/10.1093/annweh/wxaa007

Ferrans, C. E., Zerwic, J. J., Wilbur, J. E., & Larson, J. L. (2005). Conceptual model of health-related quality of life. *Journal of Nursing Scholarship*, *37*(4), 336-342. https://doi.org/10.1111/j.1547-5069.2005.00058.x

Fliege, H., Rose, M., Arck, P., Walter, O. B., Kocalevent, R. D., Weber, C., & Klapp, B. F. (2005). The Perceived Stress Questionnaire (PSQ) reconsidered: validation and reference values from different clinical and healthy adult samples. *Psychosomatic Medicine*, *67*(1), 78-88. https://doi.org/10.1097/01.psy.0000151491.80178.78

Fowler, C., Green, J., Elliott, D., Petty, J., & Whiting, L. (2019). The forgotten mothers of extremely preterm babies: A qualitative study. *Journal of Clinical Nursing*, *28*(11-12), 2124-2134. https://doi.org/https://doi.org/10.1111/jocn.14820

Gallicchio, L., & Kalesan, B. (2009). Sleep duration and mortality: a systematic review and meta-analysis. *Journal of Sleep Research*, *18*(2), 148-158. https://doi.org/10.1111/j.1365-2869.2008.00732.x

Garratt, A. M., & Stavem, K. (2017). Measurement properties and normative data for the Norwegian SF-36: results from a general population survey. *Health Qual Life Outcomes*, *15*(1), 1-10. https://doi.org/10.1186/s12955-017-0625-9

Gay, C. L., Lee, K. A., & Lee, S.-Y. (2004). Sleep patterns and fatigue in new mothers and fathers. *Biological Research for Nursing*, *5*(4), 311-318. https://doi.org/10.1177/1099800403262142

Gellerstedt, L., Medin, J., Kumlin, M., & Rydell Karlsson, M. (2015). Nurses' experiences of hospitalised patients' sleep in Sweden: a qualitative study. *Journal of Clinical Nursing*, *24*(23-24), 3664-3673. https://doi.org/10.1111/jocn.12985

Gellerstedt, L., Medin, J., Kumlin, M., & Rydell Karlsson, M. (2019). Nursing care and management of patients' sleep during hospitalisation: A cross-sectional study. *Journal of Clinical Nursing*, *28*(19-20), 3400-3407. https://doi.org/https://doi.org/10.1111/jocn.14915

Gennaro, S., & Fehder, W. (2000). Health Behaviors in Postpartum Women. *Family and Community Health*, *22*(4), 16-26. https://doi.org/10.1097/00003727-200001000-00004

Goyal, D., Gay, C. L., & Lee, K. A. (2007). Patterns of sleep disruption and depressive symptoms in new mothers. *Journal of Perinatal and Neonatal Nursing*, *21*(2), 123-129. https://doi.org/10.1097/01.JPN.0000270629.58746.96

Gul, R. B., & Ali, P. A. (2010). Clinical trials: the challenge of recruitment and retention of participants. *Journal of Clinical Nursing*, *19*(1-2), 227-233. https://doi.org/https://doi.org/10.1111/j.1365-2702.2009.03041.x

Haddad, S., Dennis, C. L., Shah, P. S., & Stremler, R. (2019). Sleep in parents of preterm infants: a systematic review. *Midwifery*, *73*, 35-48. https://doi.org/10.1016/j.midw.2019.01.009

Hall, M. H. (2013). Sleep. In M. D. Gellman & J. R. Turner (Eds.), *Encyclopedia of Behavioral Medicine* (pp. 1795-1799). Springer New York. https://doi.org/10.1007/978-1-4419-1005-9_839

Haraldstad, K., Kvarme, L. G., Christophersen, K.-A., & Helseth, S. (2019). Associations between self-efficacy, bullying and health-related quality of life in a school sample of adolescents: a cross-sectional study. *BMC Public Health*, *19*(1), 757-757. https://doi.org/10.1186/s12889-019-7115-4

Harrison, M. S., & Goldenberg, R. L. (2016). Global burden of prematurity. *Seminars in Fetal and Neonatal Medicine*, *21*(2), 74-79. https://doi.org/https://doi.org/10.1016/j.siny.2015.12.007

Hartzell, G., Shaw, R. J., & Givrad, S. (2023). Preterm infant mental health in the neonatal intensive care unit: A review of research on NICU parent-infant interactions and maternal sensitivity. *Infant Mental Health Journal*, *44*(6), 837-856. https://doi.org/https://doi.org/10.1002/imhj.22086

Hatzmann, J., Heymans, H. S., Ferrer-i-Carbonell, A., van Praag, B. M., & Grootenhuis, M. A. (2008). Hidden consequences of success in pediatrics: parental health-related quality of life--results from the Care Project. *Pediatrics*, *122*(5), e1030-1038. https://doi.org/10.1542/peds.2008-0582

Hays, R. D., & Morales, L. S. (2001). The RAND-36 measure of health-related quality of life. *Annals of Medicine*, *33*(5), 350-357. https://doi.org/10.3109/07853890109002089

Heale, R., & Twycross, A. (2015). Validity and reliability in quantitative studies. *Evidence Based Nursing*, *18*(3), 66. https://doi.org/10.1136/eb-2015-102129

Heidari, H., Hasanpour, M., & Fooladi, M. (2013). The experiences of parents with infants in Neonatal Intensive Care Unit. *Iranian Journal of Nursing and Midwifery Research*, *18*(3), 208-213. https://www.ncbi.nlm.nih.gov/pubmed/23983756

Hirshkowitz, M., Whiton, K., Albert, S. M., Alessi, C., Bruni, O., Doncarlos, L., Hazen, N., Herman, J., Katz, E. S., Kheirandish-Gozal, L., Neubauer, D. N., O'donnell, A. E., Ohayon, M., Peever, J., Rawding, R., Sachdeva, R. C., Setters, B., Vitiello, M. V., Ware, J. C., & Adams Hillard, P. J. (2015). National Sleep Foundation's sleep time duration recommendations: methodology and results summary. *Sleep Health*, *1*(1), 40-43. https://doi.org/10.1016/j.sleh.2014.12.010

Holditch-Davis, D., Robin Bartlett, T., Blickman, A. L., & Miles, M. S. (2003). Posttraumatic Stress Symptoms in Mothers of Premature Infants. *Journal of Obstetric, Gynecologic & Neonatal Nursing*, *32*(2), 161-171. https://doi.org/10.1177/0884217503252035

Holditch-Davis, D., Santos, H., Levy, J., White-Traut, R., O'Shea, T. M., Geraldo, V., & David, R. (2015). Patterns of psychological distress in mothers of preterm infants. *Infant Behavior and Development*, *41*, 154-163. https://doi.org/https://doi.org/10.1016/j.infbeh.2015.10.004

Horwitz, A., Bar-Shachar, Y., Ran-Peled, D., Finkelstein, O., Ben-Zion, H., Bar-Kalifa, E., Meiri, G., & Tikotzky, L. (2023). Sleep of mothers, fathers, and infants: a longitudinal study from pregnancy through 12 months. *Sleep*, *46*(9). https://doi.org/10.1093/sleep/zsad029

Huhtala, M., Korja, R., Lehtonen, L., Haataja, L., Lapinleimu, H., Munck, P., & Rautava, P. (2011). Parental psychological well-being and cognitive development of very low birth weight infants at 2 years. *Acta Paediatrica*, *100*(12), 1555-1560. https://doi.org/10.1111/j.1651-2227.2011.02428.x

Hunter, L. P., Rychnovsky, J. D., & Yount, S. M. (2009). A selective review of maternal sleep characteristics in the postpartum period. *Journal of Obstetric, Gynecologic, and Neonatal Nursing*, *38*(1), 60-68. https://doi.org/10.1111/j.1552-6909.2008.00309.x

Haas, J. S., Jackson, R. A., Fuentes-Afflick, E., Stewart, A. L., Dean, M. L., Brawarsky, P., & Escobar, G. J. (2005). Changes in the health status of women during and after pregnancy. *Journal of General Internal Medicine*, *20*(1), 45-51. https://doi.org/10.1111/j.1525-1497.2004.40097.x

Ibanez, V., Silva, J., & Cauli, O. (2018). A survey on sleep assessment methods. *PeerJ*, *6*, e4849. https://doi.org/10.7717/peerj.4849

Insana, S. P., Garfield, C. F., & Montgomery-Downs, H. E. (2014). A mixed-method examination of maternal and paternal nocturnal caregiving. *Journal of Pediatric Health Care*, *28*(4), 313-321. https://doi.org/10.1016/j.pedhc.2013.07.016

Insana, S. P., & Montgomery-Downs, H. E. (2013). Sleep and sleepiness among first-time postpartum parents: a field- and laboratory-based multimethod assessment. *Developmental Psychobiology*, *55*(4), 361-372. https://doi.org/10.1002/dev.21040

Ionio, C., Colombo, C., Brazzoduro, V., Mascheroni, E., Confalonieri, E., Castoldi, F., & Lista, G. (2016). Mothers and Fathers in NICU: The Impact of Preterm Birth on Parental Distress. *Europe's journal of psychology*, *12*(4), 604-621. https://doi.org/10.5964/ejop.v12i4.1093

Isaacs, K. B., & A. Hall, L. (2011). A Psychometric Analysis of the Functional Social Support Questionnaire in Low-Income Pregnant Women. *Issues in Mental Health Nursing*, *32*(12), 766-773. https://doi.org/10.3109/01612840.2011.610561

Iwata, H., Mori, E., Sakajo, A., Aoki, K., Maehara, K., & Tamakoshi, K. (2018). Course of maternal fatigue and its associated factors during the first 6 months postpartum: a prospective cohort study. *Nursing open*, *5*(2), 186-196. https://doi.org/10.1002/nop2.130

Jike, M., Itani, O., Watanabe, N., Buysse, D. J., & Kaneita, Y. (2018). Long sleep duration and health outcomes: A systematic review, meta-analysis and meta-regression. *Sleep Medicine Reviews*, *39*, 25-36. https://doi.org/10.1016/j.smrv.2017.06.011

Karimi, M., & Brazier, J. (2016). Health, Health-Related Quality of Life, and Quality of Life: What is the Difference? *Pharmacoeconomics*, *34*(7), 645-649. https://doi.org/10.1007/s40273-016-0389-9

Khan, H., Kella, D., Kunutsor, S. K., Savonen, K., & Laukkanen, J. A. (2018). Sleep Duration and Risk of Fatal Coronary Heart Disease, Sudden Cardiac Death, Cancer Death, and All-Cause Mortality. *The American Journal of Medicine*, *131*(12), 1499-1505. https://doi.org/https://doi.org/10.1016/j.amjmed.2018.07.010

Khandelwal, D., Dutta, D., Chittawar, S., & Kalra, S. (2017). Sleep Disorders in Type 2 Diabetes. *Indian Journal of Endocrinology and Metabolism*, *21*(5), 758-761. https://doi.org/10.4103/ijem.IJEM_156_17

King, L. S., Rangel, E., Simpson, N., Tikotzky, L., & Manber, R. (2020). Mothers' postpartum sleep disturbance is associated with the ability to sustain sensitivity toward infants. *Sleep Medicine*, *65*, 74-83. https://doi.org/10.1016/j.sleep.2019.07.017

Kissling, A. (2020). Partnership and Insomnia Status Among Mothers. *Family Relations*, *70*(4), 1253-1264. https://doi.org/10.1111/fare.12455

Klassen, A. F., Lee, S. K., Raina, P., Chan, H. W., Matthew, D., & Brabyn, D. (2004). Health status and health-related quality of life in a population-based sample of neonatal intensive care unit graduates. *Pediatrics*, *113*, 594-600. https://doi.org/10.1542/peds.113.3.594

Klopstad Wahl, A., & Rokne Hanestad, B. (2004). Livskvalitet i en helsefaglig sammenheng. In R. H. B. Klopstad Wahl A (Ed.), *Måling av livskvalitet i klinisk praksis [Measuring quality of life in clinical practice: An introduction]* (pp. 17-33). Fagbokforlaget.

Kocalevent, R. D., Levenstein, S., Fliege, H., Schmid, G., Hinz, A., Brähler, E., & Klapp, B. F. (2007). Contribution to the construct validity of the Perceived Stress Questionnaire from a population-based survey. *Journal of Psychosomatic Research*, *63*(1), 71-81. https://doi.org/10.1016/j.jpsychores.2007.02.010

Kong, L. P., Cui, Y., Qiu, Y. F., Han, S. P., Yu, Z. B., & Guo, X. R. (2013). Anxiety and depression in parents of sick neonates: a hospital-based study. *Journal of Clinical Nursing*, *22*(7-8), 1163-1172. https://doi.org/10.1111/jocn.12090

Kvien, T. K., Kaasa, S., & Smedstad, L. M. (1998). Performance of the Norwegian SF-36 Health Survey in patients with rheumatoid arthritis. II. A comparison of the SF-36 with disease-specific measures. *Journal of Clinical Epidemiology*, *51*(11), 1077-1086. https://doi.org/10.1016/s0895-4356(98)00099-7

Landis, C. (2011). Physiological and behavioural aspects of sleep. In N. S. Redeker, McEnany Geoffry Phillips (Ed.), *Sleep disorders and sleep promotion in nursing practice* (pp. 1-17). Springer publishing company.

Lappalainen, P., Pakkala, I., Strömmer, J., Sairanen, E., Kaipainen, K., & Lappalainen, R. (2021). Supporting parents of children with chronic conditions: A randomized controlled trial of web-based and self-help ACT interventions. *Internet Interv*, *24*, 100382. https://doi.org/10.1016/j.invent.2021.100382

Launes, J., Hokkanen, L., Laasonen, M., Tuulio-Henriksson, A., Virta, M., Lipsanen, J., Tienari, P. J., & Michelsson, K. (2014). Attrition in a 30-year follow-up of a perinatal birth risk cohort: factors change with age. *PeerJ*, *2*, 1-19. https://doi.org/10.7717/peerj.480

Lawson, A., Murphy, K. E., Sloan, E., Uleryk, E., & Dalfen, A. (2015). The relationship between sleep and postpartum mental disorders: A systematic review. *Journal of Affective Disorders*, *176*, 65-77. https://doi.org/10.1016/j.jad.2015.01.017

Lean, R. E., Rogers, C. E., Paul, R. A., & Gerstein, E. D. (2018). NICU Hospitalization: Long-Term Implications on Parenting and Child Behaviors. *Current treatment options in pediatrics*, *4*(1), 49-69. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5986282/pdf/nihms937105.pdf

LeBlanc, M., Beaulieu-Bonneau, S., Merette, C., Savard, J., Ivers, H., & Morin, C. M. (2007). Psychological and health-related quality of life factors associated with insomnia in a population-based sample. *Journal of Psychosomatic Research*, *63*(2), 157-166. https://doi.org/10.1016/j.jpsychores.2007.03.004

Lee, K. A. (2011). Sleep promotion in the Childbearing Family. In N. Redeker, Mcenany G.P (Ed.), *Sleep disorders and sleep promotion in nursing practice* (pp. 261-273). Springer Publishing Company.

Lee, S.-Y., & Hsu, H.-C. (2016). Genetic Susceptibility and Sleep Disturbance in Black Mothers of Preterm Infants: An Exploratory Study. *SAGE Open Nursing*, *2*. https://doi.org/10.1177/2377960816643326

Lee, S. K., Beltempo, M., McMillan, D. D., Seshia, M., Singhal, N., Dow, K., Aziz, K., Piedboeuf, B., & Shah, P. S. (2020). Outcomes and care practices for preterm infants born at less than 33 weeks' gestation: a quality-improvement study. *CMAJ: Canadian Medical Association Journal*, *192*(4), E81-e91. https://doi.org/10.1503/cmaj.190940

Lee, S. Y., Aycock, D. M., & Moloney, M. F. (2013). Bright Light Therapy to Promote Sleep in Mothers of Low-Birth-Weight Infants: A Pilot Study. *Biological Research for Nursing*, *15*(4), 398-406. https://doi.org/10.1177/1099800412445612

Lee, S. Y., Grantham, C. H., Shelton, S., & Meaney-Delman, D. (2012b). Does activity matter: an exploratory study among mothers with preterm infants? *Arch Womens Ment Health*, *15*(3), 185-192. https://doi.org/10.1007/s00737-012-0275-1

Lee, S. Y., & Hsu, H. C. (2012a). Stress and health-related well-being among mothers with a low birth weight infant: the role of sleep. *Social Science and Medicine*, *74*(7), 958-965. https://doi.org/10.1016/j.socscimed.2011.12.030

Lee, S. Y., & Kimble, L. P. (2009). Impaired sleep and well-being in mothers with low-birth-weight infants. *Journal of Obstetric, Gynecologic, and Neonatal Nursing*, *38*(6), 676-685. https://doi.org/10.1111/j.1552-6909.2009.01064.x

Leganger, A., Kraft, P., & Roysamb, E. (2000). Perceived self-efficacy in health behaviour research: Conceptualisation, measurement and correlates. *Psychology & Health*, *15*(1), 51-69. https://doi.org/Doi 10.1080/08870440008400288

Letourneau, N. L., Dennis, C. L., Benzies, K., Duffett-Leger, L., Stewart, M., Tryphonopoulos, P. D., Este, D., & Watson, W. (2012). Postpartum depression is a family affair: addressing the impact on mothers, fathers, and children. *Issues in Mental Health Nursing*, *33*(7), 445-457. https://doi.org/10.3109/01612840.2012.673054

Levac, D., Colquhoun, H., & O'Brien, K. K. (2010). Scoping studies: advancing the methodology. *Implement Sci*, *5*, 1-9. https://doi.org/10.1186/1748-5908-5-69

Levenstein, S., Prantera, C., Varvo, V., Scribano, M. L., Berto, E., Luzi, C., & Andreoli, A. (1993). Development of the perceived stress questionnaire: A

new tool for psychosomatic research. *Journal of Psychosomatic Research*, *37*(1), 19-32. https://doi.org/https://doi.org/10.1016/0022-3999(93)90120-5

Loge, J. H., Ekeberg, O., & Kaasa, S. (1998). Fatigue in the general Norwegian population: normative data and associations. *Journal of Psychosomatic Research*, *45*(1), 53-65. https://doi.org/10.1016/s0022-3999(97)00291-2

Manber, R., Bei, B., Suh, S., Simpson, N., Rangel, E., Sit, A., & Lyell, D. J. (2023). Randomized controlled trial of cognitive behavioral therapy for perinatal insomnia: postpartum outcomes. *Journal of Clinical Sleep Medicine*, *19*(8), 1411-1419. https://doi.org/10.5664/jcsm.10572

Marino, M., Li, Y., Rueschman, M. N., Winkelman, J. W., Ellenbogen, J. M., Solet, J. M., Dulin, H., Berkman, L. F., & Buxton, O. M. (2013). Measuring sleep: accuracy, sensitivity, and specificity of wrist actigraphy compared to polysomnography. *Sleep*, *36*(11), 1747-1755. https://doi.org/10.5665/sleep.3142

Marthinsen, G. N., Helseth, S., & Fegran, L. (2018). Sleep and its relationship to health in parents of preterm infants: a scoping review. *BMC Pediatrics*, *18*(1), 352. https://doi.org/10.1186/s12887-018-1320-7

Marthinsen, G. N., Helseth, S., Småstuen, M., Bjorvatn, B., Bandlien, S. M., & Fegran, L. (2022). Sleep patterns and psychosocial health of parents of preterm and full-born infants: a prospective, comparative, longitudinal feasibility study. *BMC Pregnancy and Childbirth*, *22*(1), 546. https://doi.org/10.1186/s12884-022-04862-1

Martin, J. L., & Hakim, A. D. (2011). Wrist actigraphy. *Chest*, *139*(6), 1514-1527. https://doi.org/10.1378/chest.10-1872

Matricardi, S., Agostino, R., Fedeli, C., & Montirosso, R. (2013). Mothers are not fathers: differences between parents in the reduction of stress levels after a parental intervention in a NICU. *Acta Paediatrica*, *102*(1), 8-14. https://doi.org/10.1111/apa.12058

Mazza, S., Bastuji, H., & Rey, A. E. (2020). Objective and Subjective Assessments of Sleep in Children: Comparison of Actigraphy, Sleep Diary Completed by Children and Parents' Estimation. *Front Psychiatry*, *11*, 1-11. https://doi.org/10.3389/fpsyt.2020.00495

McAndrew, S., Acharya, K., Westerdahl, J., Brousseau, D. C., Panepinto, J. A., Simpson, P., Leuthner, J., & Lagatta, J. M. (2019). A Prospective Study of Parent Health-Related Quality of Life before and after Discharge from the Neonatal Intensive Care Unit. *Journal of Pediatrics*, *213*, 38-45 https://doi.org/10.1016/j.jpeds.2019.05.067

McBean, A. L., & Montgomery-Downs, H. E. (2015). Diurnal Fatigue Patterns, Sleep Timing, and Mental Health Outcomes Among Healthy Postpartum Women. *Biological Research for Nursing*, *17*(1), 29-39. https://doi.org/10.1177/1099800414528278

McGraw, D., Greene, S. M., Miner, C. S., Staman, K. L., Welch, M. J., & Rubel, A. (2015). Privacy and confidentiality in pragmatic clinical trials. *Clinical Trials*, *12*(5), 520-529. https://doi.org/10.1177/1740774515597677

McMillen, I. C., Mulvogue, H. M., Kok, J. S., Deayton, J. M., Nowak, R., & Adamson, T. M. (1993). Circadian rhythms in sleep and wakefulness and in salivary melatonin and cortisol concentrations in mothers of term and preterm infants. *Sleep*, *16*(7), 624-631. https://doi.org/10.1093/sleep/16.7.624

Medic, G., Wille, M., & Hemels, M. E. H. (2017). Short- and long-term health consequences of sleep disruption. *Nature and Science of Sleep*, *9*, 151-161. https://doi.org/10.2147/NSS.S134864

Medina, A. M., Lederhos, C. L., & Lillis, T. A. (2009). Sleep disruption and decline in marital satisfaction across the transition to parenthood. *Families, systems & health : the journal of collaborative family healthcare*, *27*(2), 153. https://doi.org/10.1037/a0015762

Meisinger, C., Heier, M., Löwel, H., Schneider, A., & Döring, A. (2007). Sleep duration and sleep complaints and risk of myocardial infarction in middle-aged men and women from the general population: the MONICA/KORA Augsburg cohort study. *Sleep*, *30*(9), 1121-1127. https://doi.org/10.1093/sleep/30.9.1121

Milner, C., & Cote, K. (2009). Benefits of napping in healthy adults: impact of nap length, time of day, age, and experience with napping. *Journal of Sleep Research*, *18*(2), 272-281. https://doi.org/https://doi.org/10.1111/j.1365-2869.2008.00718.x

Montgomery-Downs, H. E., Insana, S. P., Clegg-Kraynok, M. M., & Mancini, L. M. (2010). Normative longitudinal maternal sleep: the first 4 postpartum months. *American Journal of Obstetrics and Gynecology*, *203*(5), 1-7. https://doi.org/10.1016/j.ajog.2010.06.057

Mullington, J. M., Haack, M., Toth, M., Serrador, J. M., & Meier-Ewert, H. K. (2009). Cardiovascular, inflammatory, and metabolic consequences of sleep deprivation. *Progress in Cardiovascular Diseases*, *51*(4), 294-302. https://doi.org/10.1016/j.pcad.2008.10.003

Myrhaug, H. T., Brurberg, K. G., Hov, L., & Markestad, T. (2019). Survival and Impairment of Extremely Premature Infants: A Meta-analysis. *Pediatrics*, *143*(2), 1-12. https://doi.org/10.1542/peds.2018-0933

Mörelius, E., Olsson, E., Sahlén Helmer, C., Thernström Blomqvist, Y., & Angelhoff, C. (2020). External barriers for including parents of preterm infants in a randomised clinical trial in the neonatal intensive care unit in Sweden: a descriptive study. *BMJ Open*, *10*(12), 1-5. https://doi.org/10.1136/bmjopen-2020-040991

Nishihara, K., Horiuchi, S., Eto, H., & Uchida, S. (2000). Mothers' wakefulness at night in the post-partum period is related to their infants' circadian sleep-wake rhythm. *Psychiatry and Clinical Neurosciences*, *54*, 305-306. https://doi.org/10.1046/j.1440-1819.2000.00689.x

Norman, M., Hallberg, B., Abrahamsson, T., Björklund, L. J., Domellöf, M., Farooqi, A., Foyn Bruun, C., Gadsbøll, C., Hellström-Westas, L., Ingemansson, F., Källén, K., Ley, D., Maršál, K., Normann, E., Serenius, F., Stephansson, O., Stigson, L., Um-Bergström, P., & Håkansson, S. (2019). Association Between Year of Birth and 1-Year Survival Among

Extremely Preterm Infants in Sweden During 2004-2007 and 2014-2016. *JAMA*, *321*(12), 1188-1199. https://doi.org/10.1001/jama.2019.2021

Oakley, L. L., Örtqvist, A. K., Kinge, J., Hansen, A. V., Petersen, T. G., Söderling, J., Telle, K. E., Magnus, M. C., Mortensen, L. H., Nybo Andersen, A.-M., Stephansson, O., & Håberg, S. E. (2022). Preterm birth after the introduction of COVID-19 mitigation measures in Norway, Sweden, and Denmark: a registry-based difference-in-differences study. *American Journal of Obstetrics and Gynecology*, *226*(4), 550.e552-550e552. https://doi.org/https://doi.org/10.1016/j.ajog.2021.11.034

Obregon, E., Litt, J. S., Patel, P., Ziyeh, T., & McCormick, M. C. (2019). Health related quality of life (HRQoL) in mothers of premature infants at NICU discharge. *Journal of Perinatology*, *39*(10), 1356-1361. https://doi.org/10.1038/s41372-019-0463-1

Ojelabi, A., Graham, Y., Haighto, C., & Ling J. (2017). A systematic review of the application of Wilson and Cleary health-related quality of life model in chronic diseases. *Health and Quality of Life Outcomes*, *15*(1), 241-241. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5725920/

Okun, M. L. (2015). Sleep and postpartum depression. *Current Opinion in Psychiatry*, *28*(6), 490-496. https://doi.org/10.1097/YCO.0000000000000206

Pallant, J. (2020). *SPSS survival manual : a step by step guide to data analysis using IBM SPSS* (7th edition. ed.). Open University Press.

Pallesen, S., Bjorvatn, B., Nordhus, I. H., Sivertsen, B., Hjornevik, M., & Morin, C. M. (2008). A new scale for measuring insomnia: the Bergen Insomnia Scale. *Perceptual and Motor Skills*, *107*(3), 691-706. https://doi.org/10.2466/pms.107.3.691-706

Peters, M. D., Godfrey, C. M., Khalil, H., McInerney, P., Parker, D., & Soares, C. B. (2015). Guidance for conducting systematic scoping reviews. *Int J Evid Based Healthc*, *13*(3), 141-146. https://doi.org/10.1097/xeb.0000000000000050

Polit, D. F., Beck, C. T., & Polit, D. F. (2021). *Essentials of nursing research : appraising evidence for nursing practice* (Tenth edition. ed.). Wolters Kluwer.

Post, M. W. (2014). Definitions of quality of life: what has happened and how to move on. *Top Spinal Cord Inj Rehabil*, *20*(3), 167-180. https://doi.org/10.1310/sci2003-167

Redeker, & McEnany. (2011). The nature of Sleep disorders and theoir impact In N. Redeker, Mcenany G.P (Ed.), *Sleep disorders and sleep promotion in nursing practice* (pp. 43-52). Springer publishing company.

Redeker, N. S. (2020). Sleep Health in Women of Childbearing Age. *J Womens Health (Larchmt)*, *29*(3), 430-434. https://doi.org/10.1089/jwh.2020.8349

Richter, D., Kramer, M. D., Tang, N. K. Y., Montgomery-Downs, H. E., & Lemola, S. (2019). Long-term effects of pregnancy and childbirth on sleep satisfaction and duration of first-time and experienced mothers and fathers. *Sleep*, *42*(4), 1-10. https://doi.org/10.1093/sleep/zsz015

Romano, M., Cacciatore, A., Giordano, R., & La Rosa, B. (2010). Postpartum period: three distinct but continuous phases. *J Prenat Med*, *4*(2), 22-25. https://www.ncbi.nlm.nih.gov/pubmed/22439056

Roque, A. T. F., Lasiuk, G. C., Radunz, V., & Hegadoren, K. (2017). Scoping Review of the Mental Health of Parents of Infants in the NICU. *Journal of Obstetric, Gynecologic, and Neonatal Nursing*, *46*(4), 576-587. https://doi.org/10.1016/j.jogn.2017.02.005

Ross, L. E., Murray, B. J., & Steiner, M. (2005). Sleep and perinatal mood disorders: A critical review. *Journal of Psychiatry and Neuroscience*, *30*(4), 247-256. https://www.jpn.ca/content/jpn/30/4/247.full.pdf

Sadeh, A. (2011). The role and validity of actigraphy in sleep medicine: an update. *Sleep Medicine Reviews*, *15*(4), 259-267. https://doi.org/10.1016/j.smrv.2010.10.001

Saletin, J. M., Hilditch, C. J., Dement, W. C., & Carskadon, M. A. (2017). Short Daytime Naps Briefly Attenuate Objectively Measured Sleepiness Under Chronic Sleep Restriction. *Sleep*, *40*(9), 1-9. https://doi.org/10.1093/sleep/zsx118

Schaffer, L., Jallo, N., Howland, L., James, K., Glaser, D., & Arnell, K. (2013). Guided imagery: an innovative approach to improving maternal sleep quality. *Journal of Perinatal and Neonatal Nursing*, *27*(2), 151-159. https://doi.org/10.1097/JPN.0b013e3182870426

Schobinger, E., Vanetti, M., Ramelet, A. S., & Horsch, A. (2022). Social support needs of first-time parents in the early-postpartum period: A qualitative study. *Front Psychiatry*, *13*, 1-13. https://doi.org/10.3389/fpsyt.2022.1043990

Shadish, W. R., & Luellen, J. K. (2005). Attrition. In *Encyclopedia of Statistics in Behavioral Science*. https://doi.org/10.1002/0470013192.bsa031

Shanyinde, M., Pickering, R. M., & Weatherall, M. (2011). Questions asked and answered in pilot and feasibility randomized controlled trials. *BMC Medical Research Methodology*, *11*(1), 117. https://doi.org/10.1186/1471-2288-11-117

Shaw, R. J., Bernard, R. S., Deblois, T., Ikuta, L. M., Ginzburg, K., & Koopman, C. (2009). The Relationship Between Acute Stress Disorder and Posttraumatic Stress Disorder in the Neonatal Intensive Care Unit. *Psychosomatics*, *50*(2), 131-137. https://doi.org/10.1176/appi.psy.50.2.131

Shelton, S. L., Meaney-Delman, D. M., Hunter, M., & Lee, S.-Y. (2014). Depressive symptoms and the relationship of stress, sleep, and well-being among NICU mothers. *Journal of Nursing Education and Practice*, *4*(8), 1-10. https://doi.org/10.5430/jnep.v4n8p70

Shields, L. (2015). What is family-centred care? European Journal of Person Centered Healthcare. 2015;3(2):139-144. *European Journal of Person Centered Health Care*, *3*, 139-144.

Shiely, F., Murphy, D., & Millar, S. R. (2023). Clinical research nurse predictions of trial failure, recruitment and retention: a case for their early

inclusion in trial design. *Trials*, *24*(1), 458. https://doi.org/10.1186/s13063-023-07504-9

Shin, M., Swan, P., & Chow, C. M. (2015). The validity of Actiwatch2 and SenseWear armband compared against polysomnography at different ambient temperature conditions. *Sleep Science*, *8*(1), 9-15. https://doi.org/https://doi.org/10.1016/j.slsci.2015.02.003

Short, M. A., Arora, T., Gradisar, M., Taheri, S., & Carskadon, M. A. (2017). How Many Sleep Diary Entries Are Needed to Reliably Estimate Adolescent Sleep? *Sleep*, *40*(3), 1-10. https://doi.org/10.1093/sleep/zsx006

Signal, T. L., Gander, P. H., Sangalli, M. R., Travier, N., Firestone, R. T., & Tuohy, J. F. (2007). Sleep duration and quality in healthy nulliparous and multiparous women across pregnancy and post-partum. *Australian and New Zealand Journal of Obstetrics and Gynaecology*, *47*(1), 16-22. https://doi.org/10.1111/j.1479-828X.2006.00672.x

Simard, V., Pilon, M., & Blouin, M.-M. (2021). Maternal lack of sleep in the first two years after childbirth: Perceived impacts and help-seeking behaviors. *Infant Mental Health Journal*, *42*(3), 346-361. https://doi.org/https://doi.org/10.1002/imhj.21918

Sivertsen, B., Hysing, M., Dorheim, S. K., & Eberhard-Gran, M. (2015). Trajectories of maternal sleep problems before and after childbirth: a longitudinal population-based study. *BMC Pregnancy and Childbirth*, *15*, 2-8. https://doi.org/10.1186/s12884-015-0577-1

Sivertsen, B., Hysing, M., Harvey, A. G., & Petrie, K. J. (2021). The Epidemiology of Insomnia and Sleep Duration Across Mental and Physical Health: The SHoT Study. *Frontiers in Psychology*, *12*, 1-8. https://doi.org/10.3389/fpsyg.2021.662572

Sivertsen, B., Lallukka, T., Salo, P., Pallesen, S., Hysing, M., Krokstad, S., & Simon, O. (2014). Insomnia as a risk factor for ill health: results from the large population-based prospective HUNT Study in Norway. *Journal of Sleep Research*, *23*(2), 124-132. https://doi.org/10.1111/jsr.12102

Sivertsen, B., Petrie, K. J., Skogen, J. C., Hysing, M., & Eberhard-Gran, M. (2017). Insomnia before and after childbirth: The risk of developing postpartum pain-a longitudinal population-based study. *European Journal of Obstetrics, Gynecology, and Reproductive Biology*, *210*(C), 348-354. https://doi.org/10.1016/j.ejogrb.2017.01.020

Smith, A. M., & Saleh, L. (2021). A Narrative Review of Maternal Sleep Issues with a Focus on Mental Health in the Postpartum Period. *SN Comprehensive Clinical Medicine*, *3*(5), 1165-1176. https://doi.org/10.1007/s42399-021-00840-4

Spilker, B. (1996). *Quality of life and pharmacoeconomics in clinial trials*. Lippincott-Raven.

Starke, V., Diderholm, B., Heyman, M., & Blomqvist, Y. T. (2023). Being parents of extremely preterm children, from a long-term perspective: A qualitative study of parents' experiences. *Early Human Development*, *183*, 105819. https://doi.org/https://doi.org/10.1016/j.earlhumdev.2023.105819

Stone, K. L., Ancoli-Israel, Sonia. (2017). Actigraphy. In M. Kryger, Roth, T., Dement W.C, (Ed.), *Principles and practice of sleep medicine* (6 ed., pp. 1671-1678). Elsevier.

Stranges, S., Cappuccio, F. P., Kandala, N. B., Miller, M. A., Taggart, F. M., Kumari, M., Ferrie, J. E., Shipley, M. J., Brunner, E. J., & Marmot, M. G. (2008). Cross-sectional versus prospective associations of sleep duration with changes in relative weight and body fat distribution: the Whitehall II Study. *American Journal of Epidemiology*, *167*(3), 321-329. https://doi.org/10.1093/aje/kwm302

Stremler, R., Dhukai, Z., Pullenayegum, E., Weston, J., Wong, L., & Parshuram, C. (2014). Sleep, sleepiness, and fatigue outcomes for parents of critically ill children. *Pediatric Critical Care Medicine*, *15*(2), e56-65. https://doi.org/10.1097/01.pcc.0000436198.15337.15

Stremler, R., McMurray, J., & Brennenstuhl, S. (2020). Self-Reported Sleep Quality and Actigraphic Measures of Sleep in New Mothers and the Relationship to Postpartum Depressive Symptoms. *Behavioral Sleep Medicine*, *18*(3), 396-405. https://doi.org/10.1080/15402002.2019.1601629

Stremler, R., Sharkey, K. M., & Wolfson, A. R. (2017). Postpartum Period and Early motherhood. In M. Kryger, Roth T. C., Dement W.C, (Ed.), *Principles and practice of sleep medicine* (6 ed., pp. 1547-1552). Elsevier.

Sultan, P., Guo, N., Kawai, M., Barwick, F. H., Carvalho, B., Mackey, S., Kallen, M. A., Gould, C. E., & Butwick, A. J. (2023). Prevalence and predictors for postpartum sleep disorders: a nationwide analysis. *The Journal of Maternal-Fetal & Neonatal Medicine*, *36*(1), 2170749. https://doi.org/10.1080/14767058.2023.2170749

Suonpera, E., Lanceley, A., Ni, Y., & Marlow, N. (2023). Parenting stress and health-related quality of life among parents of extremely preterm born early adolescents in England: a cross-sectional study. *Archives of Disease in Childhood: Fetal and Neonatal Edition*, F1-F8. https://doi.org/10.1136/archdischild-2023-325429

Swanson, L. M., Flynn, H., Adams-Mundy, J. D., Armitage, R., & Arnedt, J. T. (2013). An open pilot of cognitive-behavioral therapy for insomnia in women with postpartum depression. *Behavioral Sleep Medicine*, *11*(4), 297-307. https://doi.org/10.1080/15402002.2012.683902

Swanson, L. M., Kalmbach, D. A., Raglan, G. B., & O'Brien, L. M. (2020). Perinatal Insomnia and Mental Health: a Review of Recent Literature. *Curr Psychiatry Rep*, *22*(12), 2-15. https://doi.org/10.1007/s11920-020-01198-5

Teague, S., Youssef, G. J., Macdonald, J. A., Sciberras, E., Shatte, A., Fuller-Tyszkiewicz, M., Greenwood, C., McIntosh, J., Olsson, C. A., Hutchinson, D., Bant, S., Barker, S., Booth, A., Capic, T., Di Manno, L., Gulenc, A., Le Bas, G., Letcher, P., Lubotzky, C. A., . . . Williams, J. (2018). Retention strategies in longitudinal cohort studies: a systematic review and meta-analysis. *BMC Medical Research Methodology*, *18*(1), 1-22. https://doi.org/10.1186/s12874-018-0586-7

The Norwegian Directorate of Health. (2007). *Guidance for maternity care*. https://helsedirektoratet.no/Lists/Publikasjoner/Attachments/274/Nasjonale-faglige-retningslinjer-for-oppfolging-av-for-tidlig-fodte-barn-IS-1419.pdf

The World Health Organization. (2012). *The World Health Organization Quality of Life (WHOQOL)*. Retrieved 0712 2021 from https://www.who.int/publications/i/item/WHO-HIS-HSI-Rev.2012.03

Thivierge, E., Luu, T. M., Bourque, C. J., Duquette, L. A., Pearce, R., Jaworski, M., Barrington, K. J., Synnes, A., & Janvier, A. (2023). Guilt and Regret Experienced by Parents of Children Born Extremely Preterm. *Journal of Pediatrics*, *257*, 113268. https://doi.org/10.1016/j.jpeds.2022.10.042

Thomas, K. A., & Spieker, S. (2016). Sleep, Depression, and Fatigue in Late Postpartum. *MCN. The American journal of maternal child nursing*, *41*(2), 104-109. https://doi.org/10.1097/NMC.0000000000000213

Treyvaud, K., Anderson, V. A., Howard, K., Bear, M., Hunt, R. W., Doyle, L. W., Inder, T. E., Woodward, L., & Anderson, P. J. (2009). Parenting behavior is associated with the early neurobehavioral development of very preterm children. *Pediatrics*, *123*(2), 555-561. https://doi.org/10.1542/peds.2008-0477

Treyvaud, K., Anderson, V. A., Lee, K. J., Woodward, L. J., Newnham, C., Inder, T. E., Doyle, L. W., & Anderson, P. J. (2010). Parental mental health and early social-emotional development of children born very preterm. *Journal of Pediatric Psychology*, *35*(7), 768-777. https://doi.org/10.1093/jpepsy/jsp109

Treyvaud, K., Doyle, L. W., Lee, K. J., Roberts, G., Cheong, J. L., Inder, T. E., & Anderson, P. J. (2011). Family functioning, burden and parenting stress 2 years after very preterm birth. *Early Human Development*, *87*(6), 427-431. https://doi.org/10.1016/j.earlhumdev.2011.03.008

Valla, L., Helseth, S., Småstuen, M. C., Misvær, N., & Andenæs, R. (2022). Factors associated with maternal overall quality of life six months postpartum: a cross sectional study from The Norwegian Mother, Father and Child Cohort Study. *BMC Pregnancy and Childbirth*, *22*(1), 4. https://doi.org/10.1186/s12884-021-04303-5

Van de Water, A. T., Holmes, A., & Hurley, D. A. (2011). Objective measurements of sleep for non-laboratory settings as alternatives to polysomnography--a systematic review. *Journal of Sleep Research*, *20*, 183-200. https://doi.org/10.1111/j.1365-2869.2009.00814.x

Vargas-Garrido, H., Moyano-Díaz, E., & Andrades, K. (2021). Sleep problems are related to commuting accidents rather than to workplace accidents. *BMC Public Health*, *21*(1), 652. https://doi.org/10.1186/s12889-021-10737-5

Wahl, A. K. (2004). *Måling av livskvalitet i klinisk praksis : en innføring [Measuring life quality in clinical practice: An introduction]*. Fagbokforl.

Wallace, L. S., Okito, O., Herrera, N., & Soghier, L. (2020). Parental Engagement, Social Support, and Stress in the Neonatal Intensive Care Unit. *Pediatrics*, *146*, 374-375. https://doi.org/10.1542/peds.146.1

Ware, J. E., Jr., & Sherbourne, C. D. (1992). The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical Care*, *30*(6), 473-483. https://doi.org/10.1097/00005650-199206000-00002

Watson, N. F., Badr, M. S., Belenky, G., Bliwise, D. L., Buxton, O. M., Buysse, D., Dinges, D. F., Gangwisch, J., Grandner, M. A., Kushida, C., Malhotra, R. K., Martin, J. L., Patel, S. R., Quan, S. F., & Tasali, E. (2015). Recommended Amount of Sleep for a Healthy Adult: A Joint Consensus Statement of the American Academy of Sleep Medicine and Sleep Research Society. *Sleep*, *38*(6), 843-844. https://doi.org/10.5665/sleep.4716

Weiss, A. R., Johnson, N. L., Berger, N. A., & Redline, S. (2010). Validity of activity-based devices to estimate sleep. *Journal of Clinical Sleep Medicine*, *6*(4), 336-342. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2919663/pdf/jcsm.6.4.336.pdf

West, B. T., Gillespie, B. W., Welch, K. B., & Galecki, A. T. (2015). *Linear mixed models : a practical guide using statistical software* (2nd ed.). CRC Press.

WHO. (1995). The World Health Organization quality of life assessment (WHOQOL): Position paper from the World Health Organization. *Social Science and Medicine*, *41*(10), 1403-1409. https://doi.org/https://doi.org/10.1016/0277-9536(95)00112-K

Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A., & Erikson, P. (2005). Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: Report of the ISPOR Task Force for Translation and Cultural Adaptation. *Value in Health*, *8*(2), 94-104. https://doi.org/https://doi.org/10.1111/j.1524-4733.2005.04054.x

Wilman, E., Megone, C., Oliver, S., Duley, L., Gyte, G., & Wright, J. M. (2015). The ethical issues regarding consent to clinical trials with pre-term or sick neonates: a systematic review (framework synthesis) of the empirical research. *Trials*, *16*(1), 1-13. https://doi.org/10.1186/s13063-015-0957-x

Wilson, I. B., & Cleary, P. D. (1995). Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. *JAMA*, *273*(1), 59-65. https://jamanetwork.com/journals/jama/article-abstract/385444

Witt, W. P., Litzelman, K., Spear, H. A., Wisk, L. E., Levin, N., McManus, B. M., & Palta, M. (2012). Health-related quality of life of mothers of very low birth weight children at the age of five: results from the Newborn Lung Project Statewide Cohort Study. *Quality of Life Research*, *21*(9), 1565-1576. https://doi.org/10.1007/s11136-011-0069-3

Wold health organization. (2019/2021). *World health organization International Classification of Diseases, Eleventh Revision (ICD-11)* (2 ed.). World Health Organization (WHO).

World Health Organization. (2014). *Basic documents* (48th ed ed.). World Health Organization. https://apps.who.int/iris/handle/10665/151605

World health organization. (2023, 10 May 2023). *Preterm birth*. World Health Organization. http://www.who.int/news-room/fact-sheets/detail/preterm-birth

World medical association. (2009, 01/24). *Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects*. World Medical Association. Retrieved 23.11.2021 from https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Wyrwich, K. W., & Gross, C. R. (2008). Quality of Life in Clinical Medicine. In J. C. Verster, S. R. Pandi-Perumal, & D. L. Streiner (Eds.), *Sleep and Quality of Life in Clinical Medicine* (pp. 1-9). Humana Press. https://doi.org/10.1007/978-1-60327-343-5_1

Østerås, B., Sigmundsson, H., & Haga, M. (2018). Psychometric Properties of the Perceived Stress Questionnaire (PSQ) in 15–16 Years Old Norwegian Adolescents. *Frontiers in Psychology*, *9*(1850), 1-10. https://doi.org/10.3389/fpsyg.2018.01850

Åkerstedt, T., Orsini, N., Petersen, H., Axelsson, J., Lekander, M., & Kecklund, G. (2012). Predicting sleep quality from stress and prior sleep – A study of day-to-day covariation across sixweeks. *Sleep Medicine*, *13*(6), 674-679. https://doi.org/https://doi.org/10.1016/j.sleep.2011.12.013

Appendix 1

Pilot study

Søvn og helserelatert livskvalitet hos foreldre til premature og terminfødte barn. En pilotstudie.

Til avdelingsleder ved

Dato: 6.2.2019

Søknad om å gjennomføre en pilotstudie

Dette er en forespørsel om at avdelingen deres deltar i en pilotstudie tilknyttet et forskningsprosjekt. Prosjektet har til hensikt å kartlegge søvn, og se på relasjonen mellom søvn og livskvalitet hos foreldre til premature og terminfødte barn og inngår i en doktorgradsavhandling som gjennomføres av prosjektkoordinator Gunhild Nordbø Marthinsen ved Universitetet i Agder (UIA).

Bakgrunnen for studien er behov for mer kunnskap om foreldres søvn og helse etter en fødsel. Søvn er viktig for alle, og nødvendig for å opprettholde helse og velvære. Tidligere studier har vist at foreldre til premature barn sover lite og dårlig de første to ukene etter fødselen, og at dette kan være forbundet med redusert livskvalitet, utmattelse, angst, og stress. Per i dag har vi lite forskningsbasert kunnskap om hva som skjer med søvn etter denne perioden, og om lite søvn kan påvirke foreldres helse og livskvalitet negativt over tid.

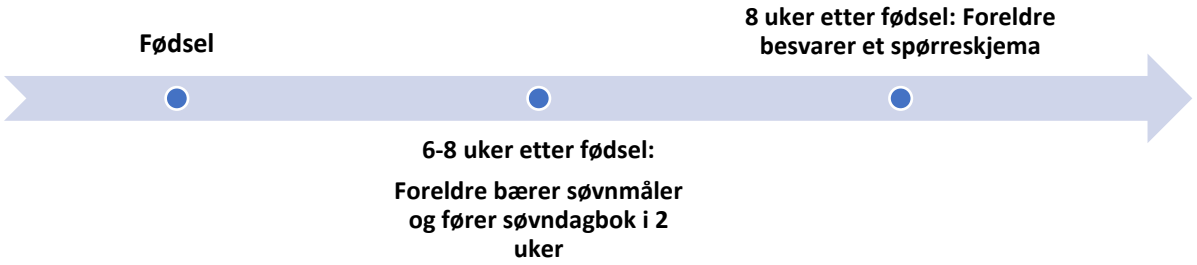
Målet med prosjektet er å kartlegge og beskrive søvn hos foreldre til premature og terminfødte barn, og studere sammenhengen mellom søvn og helserelatert livskvalitet (HRQoL). For å undersøke om foreldre til premature barn er mer utsatt for søvnforstyrrelser enn foreldre til fullbårne barn, vil vi sammenligne de to gruppene.

I forkant av hovedstudien vil det gjennomføres en pilotstudie ved barsel og nyfødtavdelingen ved [redacted] fra 1 februar til og med mars 2019. Vi ønsker å få erfaring med hvordan rekruttering og praktisk gjennomføring av datasamling fungerer. Ansattes deltakelse i pilotprosjektet innebære å formidle muntlig og skriftlig informasjon om studien til foreldre. Foreldre som vil delta, melder seg på selv via prosjektets nettside: foreldresovn.uia.no

Registreringen må foretas innen foreldrene har blitt utskrevet fra avdelingen/ og innen barnet har fylt fire uker. Vi ønsker å rekruttere tilsammen 6 foreldrepar (3 par på barsel og 3 på nyfødt). Det vil bli holdt et informasjonsmøte for alle sykepleiere i avdelingen i forkant av pilotstudien.

Informasjon om gjennomføring av prosjektet

Foreldres deltakelse innebærer å bære søvnmåler (aktigraf), føre søvndagbok og besvare et spørreskjema om søvnvansker, tro på egen mestring, opplevd helse og livskvalitet.



Frivillig deltakelse

All deltakelse i pilotprosjektet er basert på frivillighet. Foreldre kan når som helst og uten å oppgi noen grunn trekke sitt samtykke. Dersom de trekker seg fra prosjektet, kan de kreve å få slettet innsamlede prøver og opplysninger. Norsk senter for forskningsdata (NSD) og Regional komité for medisinsk og helsefaglig forskningsetikk, Sør-Øst, har godkjent studien (saks.nr 2018/1025).

Med vennlig hilsen fra

Liv Fegran

Professor, prosjektleder

Universitetet i Agder

Sølvi Helseth

Professor, prosjektmedarbeider

OsloMet-storbyuniversitet/Universitetet i Agder

Gunhild Nordbø Marthinsen

Doktorgradsstipendiat,

Prosjektkoordinator

Universitetet i Agder

Søvn og helserelatert livskvalitet hos foreldre til premature og terminfødte barn. En pilotstudie.

Til sykepleiere ved [redacted]

Dato: 7.3.2019

Kjære ansatte.

Din leder har takket ja til at avdelingen din deltar i en pilotstudie tilknyttet et forskningsprosjekt. Prosjektet har til hensikt å kartlegge søvn, og se på relasjonen mellom søvn og livskvalitet hos foreldre til premature og terminfødte barn, og inngår i en doktorgradsavhandling som gjennomføres av stipendiat Gunhild Nordbø Marthinsen ved Universitetet i Agder (UIA).

Bakgrunnen for studien er behov for mer kunnskap om foreldres søvn og helse etter fødsel. Søvn er viktig for mennesker, og bidrar til å opprettholde helse og velvære. Tidligere forskning har vist at mødre til premature barn sover lite og dårlig de første to ukene etter fødselen, og at dette kan være forbundet med redusert livskvalitet, utmattelse, angst, og stress. Per i dag har vi lite forskningsbasert kunnskap om hva som skjer med søvn etter denne perioden, og om lite søvn kan påvirke foreldres helse og livskvalitet negativt over tid.

Målet med prosjektet er å kartlegge og beskrive søvn hos foreldre til premature og terminfødte barn, og få kunnskap om sammenhengen mellom søvn og helserelatert livskvalitet (HRQoL). For å undersøke om foreldre til premature barn er mer utsatt for søvnforstyrrelser enn foreldre til fullbårne barn, vil vi sammenligne de to gruppene.

I forkant av hovedstudien vil det gjennomføres en pilotstudie ved barsel og nyfødtavdelingen ved [redacted]. Vi starter rekruttering av foreldre til pilotstudien i mars 2019. Hensikten med å gjennomføre pilot er å teste og få erfaring med rekruttering og praktisk gjennomføring av datainnsamling.

Til piloten vil vi rekruttere 3 foreldrepar til to grupper:

- Foreldre til premature barn (født før svangerskapsuke 37) rekrutteres til **gruppe 1.**
- Foreldre til terminfødte barn (født etter svangerskapsuke 37) rekrutteres til **gruppe 2**.

Inklusjonskriterier for begge gruppene er:

- Foreldre rekrutteres som par og bor sammen.
- Foreldrene behersker et nordisk språk (skriftlig og muntlig).
- Begge foreldre er over 16 år.

Eksklusjonskriterier i begge grupper er:

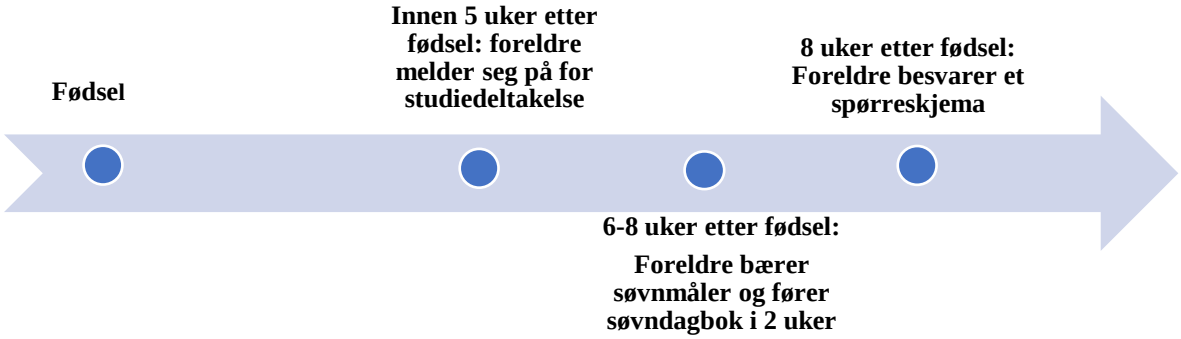
- Foreldre som har et alvorlig rusmiddelmisbruk (journalført jamfør ICD-10 eller DSM-IV).
- Det nyfødte barnet har alvorlig misdannelse/ eller livstruende tilstand som kan påvirke leveutsiktene.
- Mor har tilstand/ eller diagnose som gjør at prosjektdeltakelse er etisk utilrådelig, (eksempelvis alvorlig, livsinngripende helsetilstand).
- Foreldre til flerlinger.

Hva innebærer pilotstudien for deg?

En kontaktperson i din avdeling vil bistå med å formidle muntlig og skriftlig informasjon om studien til aktuelle foreldre. Foreldre som ønsker å delta, registrerer seg selv via prosjektets nettside: foreldresovn.uia.no senest innen fem uker etter fødsel. Gjennomføringen av pilotstudien vil i liten grad påvirke deg. All datainnsamling i prosjektet besørges av stipendiat Gunhild Nordbø Marthinsen.

Hva innebærer pilotstudien for foreldrene?

Foreldres deltakelse i pilotstudien innebærer å bære søvnmåler, og føre søvndagbok i to uker fra barnet er 6-8 uker gammelt. Utstyr til søvnregistrering blir sendt til foreldrenes private postadresse. Etter endt måling returneres utstyret i en ferdigfrankert svarkonvolutt til Universitetet i Agder. Når barnet er 8 uker gammelt mottar foreldrene mail med en lenke til spørreskjema. De blir spurt om søvnvansker, tro på egen mestring, opplevd helse og livskvalitet etter fødselen. All innsamling og bearbeidelse av data skjer anonymt og oppfyller alle lovkrav til personvern og sikkerhet.



Frivillig deltakelse i studien

All deltakelse i pilotprosjektet er basert på frivillighet. Foreldre kan når som helst og uten å oppgi noen grunn trekke sitt samtykke. Dersom de trekker seg fra prosjektet, kan de kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller er brukt i vitenskapelige publikasjoner. NSD og Regional komité for medisinsk og helsefaglig forskningsetikk, Sør-Øst, har godkjent studien (saks.nr 2018/1025).

Med vennlig hilsen fra

Liv Fegran

Professor, prosjektleder

Universitetet i Agder

Sølvi Helseth

Professor, prosjektmedarbeider

OsloMet-storbyuniversitet/Universitetet i Agder

Gunhild Nordbø Marthinsen

Doktorgradsstipendiat,

Prosjektkoordinator

Universitetet i Agder

Dersom du har spørsmål til studien kan du kontakte stipendiat og prosjektkoordinator:

Gunhild Nordbø Marthinsen: gunhild.n.marthinsen@uia.no Tlf: 38141738

UNIVERSITETET I AGDER

OSLOMET

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET:

Søvn og helserelatert livskvalitet hos foreldre til premature og terminfødte barn- en pilotstudie

Dette er et spørsmål til deg om å delta i en pilotstudie. Pilotstudien gjennomføres for å få mer kunnskap om søvn og helserelatert livskvalitet hos foreldre til premature og terminfødte barn. Til sammen ønsker vi å rekruttere 6 foreldrepar til to grupper. Studien gjennomføres ved barsel og nyfødtavdelingen ved [redacted]

Pilotstudien er del av et prosjekt som inngår i en doktorgradsavhandling. Avhandlingen gjennomføres av stipendiat Gunhild Nordbø Marthinsen ved Universitetet i Agder. Du blir forespurt om å delta fordi du har blitt forelder til et:

1) Prematurt født barn (født før svangerskapsuke 37) eller
2) Et terminfødt barn (født etter svangerskapsuke 37).

Hensikten med å gjennomføre pilotstudien er å få erfaring med hvordan rekruttering og praktisk gjennomføring av datainnsamling fungerer, i forkant av hovedstudien.

HVA INNEBÆRER PROSJEKTET?

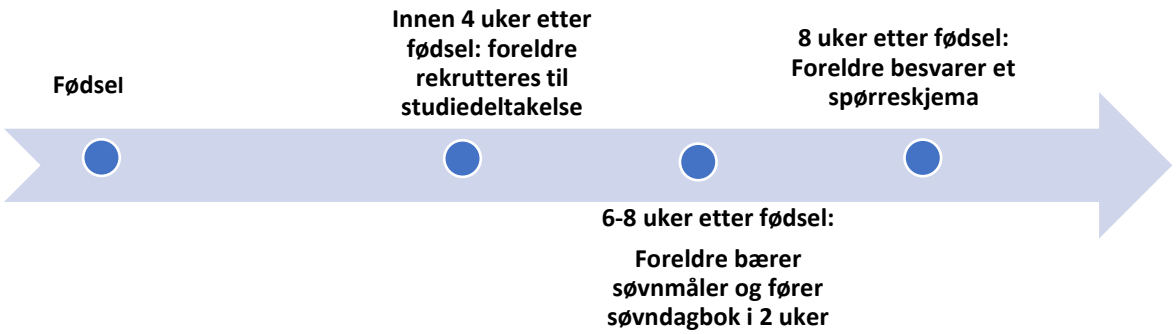
Bakgrunn og hensikt

Bakgrunnen for prosjektet er behov for mer kunnskap om foreldres søvn og helse etter en fødsel. Søvn er viktig for mennesker, og nødvendig for å opprettholde helse og velvære. Tidligere studier har vist at mødre til premature barn sover lite og dårlig de første to ukene etter fødselen, og at dette kan være forbundet med redusert livskvalitet, utmattelse, angst, og stress. Per i dag har vi lite forskningsbasert kunnskap om hva som skjer med søvn etter denne perioden, og om lite søvn kan påvirke foreldres helse og livskvalitet negativt over tid. Målet med prosjektet er å kartlegge og beskrive søvn hos foreldre til premature og terminfødte barn, og studere sammenhengen mellom søvn og helserelatert

livskvalitet (HRQoL). For å undersøke om foreldre til premature barn er mer utsatt for søvnforstyrrelser enn foreldre til fullbårne barn, vil vi sammenligne de to gruppene.

I pilotprosjektet ønsker vi at du deltar ved å:

- registrere deg for deltakelse ved å signere et samtykkeskjema. Du finner påmelding og samtykkeerklæring på https://foreldresovn.uia.no/
- I påmeldingen registrerer du opplysninger om deg selv og din partner, og vil motta en postsending med et spørreskjema, en søvnmåler og en søvndagbok.
- 6-8 uker etter fødselen bærer du søvnmåler og fører søvndagbok. Søvnmåleren er et lettvektig plastarmbånd (veier 16 g), laget av allergivennlig materiale. Den kan lett skjules under klær, tåler vann, og behøver ikke lading. Søvndagboken ser ut som et spørreskjema med 10 avkrysningsrubrikker. To rubrikker fylles ut før sengetid, resten neste morgen. Det tar ca. 8 minutter å fylle ut søvndagboken hver dag.
- 8 uker etter fødselen besvarer du et spørreskjema som du får tilsendt på mail. Hver forelder vil bli spurt om søvn og søvnforhold, sosial støtte, livskvalitet, mestring, humør og energi. Ved første datainnsamling etterspørres også foreldrenes vekt, alder, utdanning, yrke, inntekt, og etnisitet. Det tar ca. 25 minutter å svare på spørreskjemaet.
- Du returnerer søvnmåler, søvndagbok og spørreskjema anonymisert i en ferdigfrankert konvolutt per post. Utstyret er kun påført et id nummer.
- Vi ønsker å kontakte deg per telefon innen utgangen av mai 2019 for å høre hvor lang tid du brukte på å fylle ut søvndagbok og besvare spørreskjema, og vil gjerne stille deg noen spørsmål knyttet til den praktiske gjennomføringen av datainnsamlingen.



MULIGE FORDELER OG ULEMPER

Deltakelse i prosjektet innebærer at du bidrar til økt kunnskap om søvn og helse hos foreldre etter fødsel. Kunnskapen angår og er viktig for mange mennesker. På sikt kan resultatene benyttes til å utvikle tiltak for å bedre søvn hos foreldre. Deltakelse i prosjektet innebærer at du må bruke noe tid på å besvare spørreskjemaet. Du må også beregne noe tid på å føre søvndagbok og ha på søvnmåler i 2 uker. Utover dette har prosjektet få personlige ulemper for deg.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta i pilotstudien, undertegner du samtykkeerklæringen digitalt. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke, med mindre opplysningene allerede er inngått i analyser eller er brukt i vitenskapelige publikasjoner.

Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede prøver og opplysninger. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte prosjektkoordinator Gunhild Nordbø Marthinsen på e-post: gunhild.n.marthinsen@uia.no, eller telefon 38141738.

HVA SKJER MED INFORMASJONEN OM DEG?

Opplysningene som registreres om deg skal kun brukes slik som beskrevet i hensikten med prosjektet. Du har rett til innsyn i hvilke opplysninger som er registrert om deg, og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene.

Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun prosjektkoordinator som har adgang til denne listen.

Opplysningene om deg vil bli anonymisert og slettet etter prosjektslutt (1.8.2027)

GODKJENNING

Regional etisk komite for medisinsk og helsefaglig forskningsetikk har vurdert prosjektet, og har gitt forhåndsgodkjenning, (saksnr. 2018/1025).

Etter ny personopplysningslov har behandlingsansvarlig Universitetet i Agder og prosjektleder professor Liv Fegran ved UIA et selvstendig ansvar for å sikre at behandlingen av dine opplysninger har et lovlig grunnlag. Dette prosjektet har rettslig grunnlag i EUs personvernforordning. Du har rett til å klage på behandlingen av dine opplysninger til Datatilsynet.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet kan du ta kontakt med stipendiat og prosjektkoordinator Gunhild Nordbø Marthinsen e-post: gunhild.n.marthinsen@uia.no , telefon 38141738.
Personvernombud ved UIA er, Ina Danielsen tlf 45254401, e-post: ina.danielsen@uia.no

SAMTYKKE TIL DELTAKELSE I PROSJEKTET

JEG ER VILLIG TIL Å DELTA I PROSJEKTET

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

Deltakers kontaktopplysninger: (bruk blokkbokstaver- alle detaljer må fylles ut:)

Fullt navn:……

Privat postadresse:……

Telefonnummer/Mobil:…….

Epost adresse: ……..

Din relasjon til barnet: Er du fødende eller far/partner?

- ☐ Fødende
- ☐ Partner

Din partners navn (fornavn og etternavn) For å kunne koble dere som foreldrepar, og sende ut søvnmåler og spørreskjema, trenger vi denne opplysninger

Partners navn:……

Ditt barns fødselsdato: (for å kunne sende ut søvnmålere, søvndagbok og spørreskjema til riktig tid trenger vi denne opplysningen

Jeg bekrefter å ha gitt informasjon om prosjektet

Sted og dato

Signatur

Rolle i prosjektet

Appendix 2

Pilot study evaluation

Pilot- evalueringsskjema

Vi ønsker å få din erfaring og tilbakemelding på hvordan det har vært å være med i pilotstudien i foreldre & søvn prosjektet, og vil gjerne at du besvarer noen spørsmål.

1. **Informasjon i forkant av pilotstudien:** Vi vil gjerne høre din opplevelse av informasjonen du fikk i forkant av pilotstudien:

   «Jeg fikk god og tilstrekkelig med informasjon om pilotstudien i forkant»:

- ☐ Det stemmer svært godt
- ☐ Det stemmer nokså godt
- ☐ Det stemmer nokså dårlig
- ☐ Det stemmer svært dårlig

   Oppfølgingsspørsmål:

- Kan du utdype hva som var bra ved informasjonen du fikk?
- Er det noe du ville hatt mere informasjon om?

2. **Påmelding og samtykke til deltakelse:** Vi vil gjerne høre din opplevelse med påmeldingen og digitalt samtykke til deltakelse.

   «Det gikk fint å melde seg på/ og samtykke til deltakelse via prosjektets nettside»:

- ☐ Det stemmer svært godt
- ☐ Det stemmer nokså godt
- ☐ Det stemmer nokså dårlig
- ☐ Det stemmer svært dårlig

   Oppfølgingsspørsmål:

- Kan du utdype hva syns fungerte bra ved påmeldingen/samtykket?
- Er det noe du gjerne ville endret på ved påmeldingen/samtykket?

3. **Prosjektets nettside:** Vi vil gjerne høre din tilbakemelding på utformingen og informasjonen du fikk om prosjektet via nettsiden:

   «Nettsiden var informativ og ga god informasjon om prosjektets innhold og utforming»

- ☐ Det stemmer svært godt
- ☐ Det stemmer nokså godt
- ☐ Det stemmer nokså dårlig
- ☐ Det stemmer svært dårlig

Oppfølgingsspørsmål:

- Hva syns du fungerte bra informasjonen du fikk via nettsiden?
- Er det noe ved nettsiden du ikke syns fungerte bra/ ville endret på?

4. **Mottak og retur av utstyr til søvnregistrering:** Vi vil gjerne høre din opplevelse av å motta og returnere postsending med søvnmåler og søvndagbok.

   «Det gikk fint å motta og returnere postsending med utstyr til søvnregistrering»:

- Det stemmer svært godt
- Det stemmer nokså godt
- Det stemmer nokså dårlig
- Det stemmer svært dårlig

Oppfølgingsspørsmål:

- Kan du utdype hva du syns fungerte mottak og retur av postsendingen?
- Er det noe du gjerne ville hatt annerledes ved sendingen?

5. **Søvnregistrering:** Vi vil gjerne høre din opplevelse av å bære søvnregistrator og føre søvndagbok i to ukers periode.

   «Det fungerte greit å bære søvnregistrator og føre søvndagbok i to uker»

- Det stemmer svært godt
- Det stemmer nokså godt
- Det stemmer nokså dårlig
- Det stemmer svært dårlig

Oppfølgingsspørsmål:

- Kan du utdype hva du syns fungerte greit ved søvnregistreringen?
- Er det noe du gjerne ville endret på ved søvnregistreringen?

6. **Spørreundersøkelsen:** Vi vil gjerne høre din opplevelse av å besvare spørreskjemaet

   «Spørreskjemaet inneholdt relevante spørsmål for å kartlegge hvordan jeg har det »

- Det stemmer svært godt
- Det stemmer nokså godt
- Det stemmer nokså dårlig

- Det stemmer svært dårlig

Oppfølgingsspørsmål:

- Kan du utdype hva du syns fungerte ved spørsmålene i spørreskjemaet?
- Er det noe du gjerne ville endret på ved spørreskjemaet?

«Spørreskjemaet var passelig i omfang»

- Det stemmer svært godt
- Det stemmer nokså godt
- Det stemmer nokså dårlig
- Det stemmer svært dårlig

Oppfølgingsspørsmål:

- Dersom ikke passelig: Hva ville du ha endret på ved størrelse/omfang på spørreskjemaet?

«Spørsmålene i spørreskjemaet var greie å besvare og forståelige»

- Det stemmer svært godt
- Det stemmer nokså godt
- Det stemmer nokså dårlig
- Det stemmer svært dårlig

- Er det noe du gjerne ville endret på ved spørsmålene, slik at de ville vært lettere å forstå?

Har du ellers andre tilbakemeldinger, både positivt og negativt om selve prosjektet og om deltakelsen i pilotstudien?

Tusen takk for at du deltok!

Appendix 3

Sample size

Estimated sample sizes for a two-sample means test

Satterthwaite's t test assuming unequal variances

Ho: m2 = m1 versus Ha: m2 != m1

Sett inn referanser:

Preterm : mean 6.3, SD=2

Norm: mean 7.2, SD=1

Study parameters:

alpha = 0.0500

power = 0.8000

delta = -0.9000

m1 = 7.2000

m2 = 6.3000

sd1 = 1.0000

sd2 = 2.0000

Estimated sample sizes:

N = 100

N per group = 50

Kontrollere for multiple testing; sig nivå =0.01

Estimated sample sizes for a two-sample means test

Satterthwaite's t test assuming unequal variances

Ho: m2 = m1 versus Ha: m2 != m1

Study parameters:

alpha = 0.0100

power = 0.8000

delta = -0.9000

m1 = 7.2000

m2 = 6.3000

sd1 = 1.0000

sd2 = 2.0000

Estimated sample sizes:

N = 150

N per group = 75

Appendix 4

Approvals from Regional Committees for Medical and Health Research Ethics

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Silje U. Lauvrak	22845520	25.06.2018	2018/1025 REK sør-øst D
			Deres dato:	**Deres referanse:**
			07.05.2018	

Vår referanse må oppgis ved alle henvendelser

Liv Fegran
Universitetet i Agder

2018/1025 Søvn og helserelatert livskvalitet hos foreldre til premature barn

Forskningsansvarlig: Universitetet i Agder
Prosjektleder: Liv Fegran

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst D) i møtet 13.06.2018. Vurderingen er gjort med hjemmel i helseforskningsloven § 10.

Prosjektleders prosjektbeskrivelse
Søvn er viktig for mennesker, lite søvn kan påvirke både helse og velvære. Studier viser at foreldre som får fortidligfødte (premature) barn kan oppleve følelsesmessige belastninger i barseltiden, dette kan gi dårlig søvn. Målet med prosjektet er å få mer kunnskap om søvn og helserelatert livskvalitet hos foreldre etter fødselen. Prosjektet består av to studier: 1. En scoping review for å kartlegge eksisterende kunnskap. 2 En kvantitativ, komparativ longitudinell studie, hvor man måler foreldres søvn og livskvalitet det første året etter fødselen. Her vil vi sammenlikne data fra premature barns foreldre med foreldre til terminfødte barn. Forskningsspørsmål: Er foreldre som fått premature barn mer utsatt for søvnproblemer enn andre foreldre? Hvilken sammenheng er det mellom lite søvn og livskvalitet? Resultatene fra prosjektet er relevante for helsepersonell og utøvere av barselomsorg, og kan gi grunnlag for å utvikle tiltak for å fremme god søvn. Søknaden gjelder studie 2 med pilot.

Vurdering
Prosjektets formål er å undersøke søvn og livskvalitet hos foreldre til premature barn. Deltagelse innebærer at foreldrene besvarer spørreskjemaer om søvn, depresjon, fatigue, mestringstro og helserelatert livskvalitet ved tre anledninger det første året etter fødsel, og at de går med søvnregistrator (armbånd) og fører søvndagbok (10 avkrysningsrubrikker) i to uker, ca. 10 min hver dag.

Foreldrene som skal inkluderes er i en sårbar og vanskelig sistuasjon, og for komiteen er det viktig at prosjektet har stor nytteverdi siden det er relativt krevende å delta med mange spørreskjemaer og en del tidsbruk. På bakgrunn av dette ønsker komiteen er nærmere redegjørelse for nytteverdien av prosjektet, og vedtak utsettes dermed i påvente av tilbakemelding fra prosjektleder på følgende spørsmål:

1) Det oppgis at: ”Resultatene fra prosjektet er relevante for helsepersonell og utøvere av barselomsorg, og kan gi grunnlag for å utvikle tiltak for å fremme god søvn”. Dersom resultatene viser at foreldre som har fått premature barn er mer utsatt for søvnproblemer enn andre foreldre, hvilke nye tiltak tenkes det da å kunne iversettes for å fremme bedre søvn for denne gruppen?

2) Det oppgis at: ”100 foreldrepar i hver gruppe vil gi et tilstrekkelig grunnlag for å gjennomføre studien”. Komiteen ber om en nærmere redegjørelse for styrkeberegningen som er gjort.

Hvor store forskjeller i søvn mellom de to gruppene anses å være klinisk signifikant, og hvor mange deltagere må inkluderes for å kunne vise en slik forskjell?

Vedtak
Vedtak utsettes i påvente av tilbakemelding fra prosjektleder. Tilbakemeldingen vil bli behandlet i full komité.

Vennligst benytt skjema for tilbakemelding som sendes inn via saksportalen til REK http://helseforskning.etikkom.no. Tilbakemeldingen må være oss i hende innen seks måneder.

Med vennlig hilsen

Finn Wisløff
Professor em. dr. med.
Leder

Silje U. Lauvrak
Rådgiver

Kopi til: *veslemoy.rabe@uia.no*
Universitetet i Agder ved øverste administrative ledelse: post@uia.no

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Silje U. Lauvrak	22845520	10.10.2018	2018/1025 REK sør-øst D
			Deres dato:	**Deres referanse:**
			11.09.2018	

Vår referanse må oppgis ved alle henvendelser

Liv Fegran
Universitetet i Agder

2018/1025 Søvn og helserelatert livskvalitet hos foreldre til premature barn

Forskningsansvarlig: Universitetet i Agder
Prosjektleder: Liv Fegran

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst D) i møtet 19.09.2018. Vurderingen er gjort med hjemmel i helseforskningsloven (hforsknl) § 10.

Prosjektleders prosjektbeskrivelse
Søvn er viktig for mennesker, lite søvn kan påvirke både helse og velvære. Studier viser at foreldre som får fortidligfødte (premature) barn kan oppleve følelsesmessige belastninger i barseltiden, dette kan gi dårlig søvn. Målet med prosjektet er å få mer kunnskap om søvn og helserelatert livskvalitet hos foreldre etter fødselen. Prosjektet består av to studier: 1. En scoping review for å kartlegge eksisterende kunnskap. 2 En kvantitativ, komparativ longitudinell studie, hvor man måler foreldres søvn og livskvalitet det første året etter fødselen. Her vil vi sammenlikne data fra premature barns foreldre med foreldre til terminfødte barn. Forskningsspørsmål: Er foreldre som fått premature barn mer utsatt for søvnproblemer enn andre foreldre? Hvilken sammenheng er det mellom lite søvn og livskvalitet? Resultatene fra prosjektet er relevante for helsepersonell og utøvere av barselomsorg, og kan gi grunnlag for å utvikle tiltak for å fremme god søvn. Søknaden gjelder studie 2 med pilot.

Saksgang
Søknaden ble første gang behandlet i møtet 25.04.2018, hvor komiteen utsatte å fatte vedtak i saken. Komiteen ba om en nærmere redegjørelse for hvilke nye tiltak som kan iverksettes for å fremme bedre søvn for denne gruppen, samt hvor store forskjeller i søvn mellom de to gruppene anses å være klinisk signifikant, og hvor mange deltagere det må inkluderes for å kunne vise en slik forskjell.

Vurdering
Prosjektleder har svart utfyllende og tilfredsstillende på komiteens spørsmål, og komiteen har ingen innvendinger til at studien gjennomføres som beskrevet i søknad, protokoll og tilbakemelding.

Komiteen setter imidlertid som vilkår for godkjenning at informasjonsskrivet knyttet til studien revideres i tråd med ny mal på REKs nettsider, slik at informasjonen som gis til deltakerne er forenlig med ny personopplysningslov.

Vedtak
REK har gjort en helhetlig forskningsetisk vurdering av alle prosjektets sider. Prosjektet godkjennes med hjemmel i helseforskningsloven § 10, under forutsetning av at ovennevnte vilkår er oppfylt.

Vi gjør samtidig oppmerksom på at etter ny personopplysningslov må det også foreligge et behandlingsgrunnlag etter personvernforordningen. Det må forankres i egen institusjon.

I tillegg til vilkår som fremgår av dette vedtaket, er godkjenningen gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad og protokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Tillatelsen gjelder til 01.08.2022. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 01.08.2027. Forskningsfilen skal oppbevares atskilt i en nøkkel- og en opplysningsfil. Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse og omsorgssektoren».

Dersom det skal gjøres vesentlige endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.

Prosjektet skal sende sluttmelding på eget skjema, senest et halvt år etter prosjektslutt.

Komiteens avgjørelse var enstemmig.

Klageadgang
REKs vedtak kan påklages, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst D. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst D, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Vi ber om at alle henvendelser sendes inn på korrekt skjema via vår saksportal: http://helseforskning.etikkom.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Finn Wisløff
Professor em. dr. med.
Leder

Silje U. Lauvrak
Rådgiver

Kopi til: veslemoy.rabe@uia.no
Universitetet i Agder ved øverste administrative ledelse: post@uia.no

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Silje U. Lauvrak	22845520	05.03.2019	2018/1025/REK sør-øst D
			Deres dato:	**Deres referanse:**
			13.02.2019	

Vår referanse må oppgis ved alle henvendelser

Liv Fegran
Universitetet i Agder

2018/1025 Søvn og helserelatert livskvalitet hos foreldre til premature barn

Forskningsansvarlig: Universitetet i Agder
Prosjektleder: Liv Fegran

Vi viser til søknad om prosjektendring datert 13.02.2019 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK sør-øst på fullmakt, med hjemmel i helseforskningsloven § 11.

Endringene innebærer:
- Det skal legges til 2 nye spørreskjemaer om sosial støtte og stress: "The Duke- UNC Functional Social Support questionaire" (FSSQ) og "Perceived stress questionaire" (PSQ).
- Istedenfor å bruke opprinnelig spørreskjema for mestringstro (GSE), skal kortversjonen av dette skjemaet benyttes. Kortversjonen er godt validert, og det gjør at foreldrene ikke må besvare så mange spørsmål (nå ca. 30 totalt).
- Det skal ikke lenger registreres eventuelle medisinske diagnoser for barna eller foreldrene. Det er mer relevant å kartlegge om foreldre har hatt en søvndiagnose, og det er derfor lagt til et spørsmål om de tidligere har fått en av følgende søvndiagnoser: "Søvnrelatert respirasjonslidelse (blant annet obstruktiv søvnapne), sentral hypersomnilidelse (blant annet narkolepsi), insomnilidelse, søvnrelatert bevegleseforstyrrelse (restless legs), parasomni, eller døgnrytmelidelse, eller ingen av disse diagnosene". Det er også lagt til et spørsmål om medikamentbruk for å kartlegge om foreldrene bruker medikamenter som kan påvirke søvn.
- Det er gjort endringer i inklusjons- og eksklusjonskriteriene: foreldre med søvndiagnoser skal ikke lenger ekskluderes (jf. ovennevnte punkt), og det er lagt til følgende eksklusjonskriterier: foreldre til flerlinger, foreldrene har et alvorlig rusmiddelmisbruk, barnet har alvorlige misdannelser eller livstruende tilstand, mor har tilstand eller diagnose som gjør deltagelse utilrådelig. Det er lagt til følgende inklusjonskriterier: foreldrene må bo sammen, de må beherske et nordisk språk og de må være over 16 år.
- Protokoll og informasjonsskriv er oppdatert i henhold til endringene.

Vurdering
Komiteens leder har vurdert søknaden og har ingen forskningsetiske innvendinger mot endringen av prosjektet.

Vedtak
REK har gjort en forskningsetisk vurdering av endringene i prosjektet, og godkjenner prosjektet slik det nå foreligger, jf. helseforskningsloven § 11.

Vi gjør samtidig oppmerksom på at etter ny personopplysningslov må det også foreligge et behandlingsgrunnlag etter personvernforordningen. Det må forankres i egen institusjon.

Tillatelsen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden, endringssøknad, oppdatert protokoll og de bestemmelser som følger av helseforskningsloven med forskrifter.

REKs vedtak kan påklages, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Vi ber om at alle henvendelser sendes inn med korrekt skjema via vår saksportal: http://helseforskning.etikkom.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Finn Wisløff
Professor em. dr. med.
Leder

Silje U. Lauvrak
Seniorrådgiver

Kopi til: veslemoy.rabe@uia.no
Universitetet i Agder ved øverste administrative ledelse: post@uia.no

Appendix 5

Approvals from the Norwegian Centre for Research Data

NSD NORSK SENTER FOR FORSKNINGSDATA

NSD sin vurdering

Prosjekttittel

Søvn og helserelatert livskvalitet hos foreldre til premature barn

Referansenummer

242170

Registrert

12.11.2018 av Liv Fegran - liv.fegran@uia.no

Behandlingsansvarlig institusjon

Universitetet i Agder / Fakultet for helse- og idrettsvitenskap / Institutt for helse- og sykepleievitenskap

Prosjektansvarlig

Liv Fegran, Liv.fegran@uia.no, tlf: 4799248832

Type prosjekt

Forskerprosjekt

Prosjektperiode

01.12.2018 - 01.07.2022

Status

08.01.2019 - Vurdert

Vurdering (1)

08.01.2019 - Vurdert

Prosjektet er vurdert og godkjent av REK sør-øst D etter helseforskningsloven § 10, deres referanse 2018/1025.

Det er vår vurdering at behandlingen også vil være i samsvar med personvernlovgivningen, så fremt den gjennomføres i tråd med det som er dokumentert i meldeskjema med vedlegg 8.1.2019. Behandlingen kan starte.

MELD ENDRINGER
Dersom behandlingen av personopplysninger endrer seg, kan det være nødvendig å melde dette til NSD ved å oppdatere meldeskjemaet. På våre nettsider informerer vi om hvilke endringer som må meldes. Vent på svar før endringen gjennomføres.

TYPE OPPLYSNINGER OG VARIGHET
Prosjektet vil behandle alminnelige personopplysninger samt særlige kategorier av personopplysninger om

helseforhold frem til 1.7.2022. Etter dette vil personopplysningene oppbevares for dokumentasjonshensyn i fem år.

LOVLIG GRUNNLAG
Prosjektet vil innhente samtykke fra de registrerte til behandlingen av personopplysninger. Vår vurdering er at prosjektet legger opp til et samtykke i samsvar med kravene i art. 4 nr. 11 og art. 7, ved at det er en frivillig, spesifikk, informert og utvetydig bekreftelse som kan dokumenteres og som den registrerte kan trekke tilbake.

Lovlig grunnlag for behandlingen vil dermed være den registrertes uttrykkelige samtykke, jf. personvernforordningen art. 6 nr. 1 a), jf. art. 9 nr. 2 bokstav a, jf. personopplysningsloven § 10, jf. § 9 (2).

PERSONVERNPRINSIPPER
NSD vurderer at den planlagte behandlingen av personopplysninger vil følge prinsippene i personvernforordningen om
- lovlighet, rettferdighet og åpenhet (art. 5.1 a), ved at de registrerte får tilfredsstillende informasjon om og samtykker til behandlingen
- formålsbegrensning (art. 5.1 b), ved at personopplysninger samles inn for spesifikke, uttrykkelig angitte og berettigede formål, og ikke viderebehandles til nye uforenlige formål
- dataminimering (art. 5.1 c), ved at det kun behandles opplysninger som er adekvate, relevante og nødvendige for formålet med prosjektet
- lagringsbegrensning (art. 5.1 e), ved at personopplysningene ikke lagres lengre enn nødvendig for å oppfylle formålet

DE REGISTRERTES RETTIGHETER
Så lenge de registrerte kan identifiseres i datamaterialet vil de ha følgende rettigheter: åpenhet (art. 12), informasjon (art. 13), innsyn (art. 15), retting (art. 16), sletting (art. 17), begrensning (art. 18), underretning (art. 19), dataportabilitet (art. 20).

NSD vurderer at informasjonen som de registrerte vil motta oppfyller lovens krav til form og innhold, jf. art. 12.1 og art. 13.

Vi minner om at hvis en registrert tar kontakt om sine rettigheter, har behandlingsansvarlig institusjon plikt til å svare innen en måned.

FØLG DIN INSTITUSJONS RETNINGSLINJER
NSD legger til grunn at behandlingen oppfyller kravene i personvernforordningen om riktighet (art. 5.1 d), integritet og konfidensialitet (art. 5.1. f) og sikkerhet (art. 32).

For å forsikre dere om at kravene oppfylles, må dere følge interne retningslinjer og eventuelt rådføre dere med behandlingsansvarlig institusjon.

OPPFØLGING AV PROSJEKTET
NSD vil følge opp underveis og ved planlagt avslutning for å avklare status for behandlingen av personopplysninger.

Lykke til med prosjektet!

Kontaktperson hos NSD: Lasse Raa
Tlf. personverntjenester: 55 58 21 17 (tast 1)

Appendix 6

The Faculty of Health and Sports Sciences' Research Ethics Committee

UNIVERSITETET I AGDER

Gunhild Nordbø
Marthinsen

Besøksadresse:
Universitetsveien 25
Kristiansand

Ref: 19/07028

Tidspunkt for godkjenning: : 26/09/2019

Søknad om etisk godkjenning av forskningsprosjekt - Søvn og helserelatert livskvalitet hos foreldre til premature barn

Vi informerer om at din søknad er ferdig behandlet og godkjent.

Kommentar fra godkjenner:
FEK tar søknaden til orientering og arkivering.

Hilsen
Forskningsetisk komite
Fakultet for helse - og idrettsvitenskap
Universitetet i Agder

Appendix 7

Invitation to leaders

Søvn og helserelatert livskvalitet hos foreldre til premature og terminfødte barn.

Til leder ved nyfødtavdelingen Sykehus:

Dato: 26.09.2019

Søknad om å gjennomføre et forskningsprosjekt.

Dette er en forespørsel om å få rekruttere og gi informasjon til foreldre i et forskningsprosjekt som omhandler søvn og helserelatert livskvalitet hos foreldre etter fødsel. Prosjektet inngår i en doktorgradsavhandling som gjennomføres av stipendiat Gunhild Nordbø Marthinsen ved Universitetet i Agder. En forskergruppe ved Universitetet i Agder (UIA), fakultet for helse og idrettsvitenskap, og ved OsloMet- storbyuniversitet, fakultet for helsefag, gjennomfører og er ansvarlig for prosjektet. Regional komité for medisinsk og helsefaglig forskningsetikk, Sør-Øst, har godkjent studien (Ref. nr. 2018/1025).

Bakgrunn og hensikt

Bakgrunnen for studien er behov for mer kunnskap om foreldres søvn og helse etter en fødsel. Tidligere studier har vist at foreldre til premature barn sover lite og dårlig de første to ukene etter fødselen, dette kan være forbundet med redusert livskvalitet, utmattelse, angst, og stress. Per i dag har vi lite forskningsbasert kunnskap om hva som skjer med søvn etter denne perioden, og om lite søvn kan påvirke foreldres helse og livskvalitet negativt over tid.

Målet med prosjektet er å kartlegge og beskrive søvn hos foreldre til premature og terminfødte barn, og se på sammenhengen mellom søvn og helserelatert livskvalitet (HRQoL). For å undersøke om foreldre til premature barn er mer utsatt for søvnforstyrrelser enn foreldre til fullbårne barn, vil vi sammenligne de to gruppene.

I forkant av hovedstudien ble det gjennomført en pilotstudie ved barsel og nyfødtavdelingen ved Sørlandet sykehus HF (januar til mars 2019). Selve hovedstudien ble startet i juni 2019.

Hvilke foreldre kan delta i søvnprosjektet?

Foreldre rekrutteres fra barsel og nyfødtavdelinger til to grupper:

- Foreldre til premature barn (født før svangerskapsuke 37) rekrutteres til **gruppe 1.**
- Foreldre til terminfødte barn (født etter svangerskapsuke 37) rekrutteres til **gruppe 2**.

Inklusjonskriterier i begge grupper er:

- Foreldre rekrutteres som par og bor sammen.
- Foreldrene behersker et nordisk språk (skriftlig og muntlig).
- Begge foreldre er over 16 år.

Eksklusjonskriterier i begge grupper er:

- Foreldre som har et alvorlig rusmiddelmisbruk (journalført jamfør ICD-10 eller DSM-IV).
- Det nyfødte barnet har alvorlig misdannelse/ eller livstruende tilstand som kan påvirke leveutsiktene.
- Mor har tilstand/ eller diagnose som gjør at prosjektdeltakelse er etisk utilrådelig, (eksempelvis alvorlig, livsinngripende helsetilstand).
- Foreldre til flerlinger.

Til sammen ønsker vi å rekruttere ca. 100 foreldrepar til hver av de to gruppene.

Hva innebærer deltakelse for foreldre?

Data samles inn ved tre anledninger i barnets første leveår. Ved hver anledning fyller foreldre ut spørreskjema om søvn og helse, bærer søvnmåler og fører søvndagbok.

- **Spørreskjema:**

Hver forelder vil få tilsendt et spørreskjema via en link på mail når barnet er 2, 6 og 12 måneder gammelt. Det tar ca. 20 minutter å svare på skjemaet. De vil bli spurt om søvnvansker, opplevd livskvalitet, utmattelse, tro på egen mestring og nedstemthet/depresjon. Ved første datainnsamling etterspørres også foreldrenes vekt, høyde, alder, utdanning, yrke, inntekt, og etnisitet, og antall barn. Foreldrene fyller også inn det nyfødte barnets fødselsvekt og gestasjonsalder ved fødsel.

- **Registrering av søvn:**

Foreldre bærer små søvnregistratorer (armbånd) i 2 uker ved hvert av de tre måletidspunktene. Aktigrafene er små, lettvektige plastarmbånd (veier ca. 16 g), og laget av allergivennlig materiale. Søvnregistratoren skal sitte på kontinuerlig i måleperioden, og behøver ikke lading.

- **Føre søvndagbok:**

For å supplere dataene fra søvnmålerne, fører foreldrene samtidig søvndagbok. Søvndagboken har form som et spørreskjema med 10 avkrysningsrubrikker. To av rubrikkene fylles ut før sengetid, de resterende fylles ut om morgenen. Det vil ta foreldrene ca. 10 minutter å fylle ut søvndagboken hver dag.

Innsamling og lagring av data:

Foreldrene mottar søvnmålere og søvndagbøker på sin oppgitte hjemme- postadresse. Etter endt måling returneres utstyret avidentifisert per post til prosjektkoordinator i ferdigfrankert svarkonvolutt. Spørreskjemaet besvares digitalt. I prosjektet har vi har valgt en sikker digital løsning tilknyttet TSD (Tjenester for sensitive data). TSD er et fullt sett med tjenester, fra innsamling av data, til analyse, behandling og lagring i sikrede omgivelser. All bearbeidelse foregår i en lukket verden som oppfyller alle lovkrav til personvern og sikkerhet. Prosjektet er tenkt publisert som to vitenskapelige artikler i internasjonale, vitenskapelige tidsskrift.

Hvorfor er prosjektet viktig?

Søvn er viktig for mennesker, og bidrar til å opprettholde god helse og velvære. I den generelle befolkningen har søvnmangel blitt assosiert med en rekke negative effekter på helsen, blant annet redusert livskvalitet, dårligere mestringsstrategier og risiko for psykiske og somatiske plager. Tilstrekkelig og god søvn er viktig for at foreldre skal kunne fungere i hverdagen og være omsorgspersoner for sine barn. Resultatene fra dette prosjektet vil være relevante for både fagfolk og forskere innen nyfødt og barselomsorg, og kan gi grunnlag til å utvikle nye og helsefremmende tiltak som kan sikre god søvn.

Frivillig deltakelse

All deltakelse i prosjektet er basert på frivillighet. Foreldre kan når som helst og uten å oppgi noen grunn trekke sitt samtykke. Dersom de trekker seg fra prosjektet, kan de kreve å få slettet innsamlede prøver og opplysninger.

Med vennlig hilsen fra

Liv Fegran

Professor, prosjektleder

Universitetet i Agder

Sølvi Helseth

Professor, prosjektmedarbeider

OsloMet-storbyuniversitet/Universitetet i Agder

Gunhild Nordbø Marthinsen

Doktorgradsstipendiat,

Prosjektkoordinator

Universitetet i Agder

Spørsmål om studien kan rettes til stipendiat og prosjektkoordinator:

Gunhild Nordbø Marthinsen: gunhild.n.marthinsen@uia.no Tlf: 48065577/38141738

Appendix 8

Permission from research committees, hospitals

[redacted]

Fagavdelingen
Forskningsenheten

Vår dato
31.01.2019
Deres dato
18.01.2019

Vår referanse
19/00729-2 - 522
Deres referanse

Gunhild Nordbø Marthinsen

Søknadsskjema for godkjenning av forskningsprosjekt - Søvn og helserelatert livskvalitet hos foreldre med premature barn

Det vises til søknad om datainnsamling til prosjektet «Søvn og helserelatert livskvalitet hos foreldre med premature barn.»

Prosjektet er forskningsfaglig godkjent 31.01.2019.

Med vennlig hilsen

Kirsten Andersen

Kirsten Andersen
Konsulent

elektronisk godkjent

Kopi: Fagavdeling, Frode Gallefoss; Forskning, Sandrine Schuhler Slotten

Appendix 9

Information to nurses

Søvn og helserelatert livskvalitet hos foreldre til premature og terminfødte barn.

Kjære sykepleier!

Avdelingsleder har takket ja til at din avdeling deltar i et forskningsprosjekt om søvn og helserelatert livskvalitet hos foreldre til premature og terminfødte barn. Studien har til hensikt å kartlegge søvn, og se på forholdet mellom søvn og livskvalitet i de to foreldregruppene. Prosjektet starter våren 2019 og inngår i en doktorgradsavhandling som gjennomføres av stipendiat Gunhild Nordbø Marthinsen ved Universitetet i Agder. En forskergruppe ved Universitetet i Agder (UIA), fakultet for helse og idrettsvitenskap, og ved OsloMet- storbyuniversitet, fakultet for helsefag, gjennomfører og er ansvarlig for prosjektet. Forskningsprosjektet vil foregå ved barsel og nyfødtavdelinger ved 3 sykehus i sørøst Norge. Regional komité for medisinsk og helsefaglig forskningsetikk, Sør-Øst, har godkjent studien.

En sykepleier i din avdeling, [redacted] vil være behjelpelig med å rekruttere foreldre til prosjektet. Hun vil bistå oss med å identifisere foreldre som er aktuelle for deltakelse i prosjektet, og informere dem med muntlig og skriftlig informasjon (informasjonsbrosjyre).

Bakgrunn og hensikt

Bakgrunnen for prosjektet er et behov for mer kunnskap om foreldres søvn og helse etter en fødsel. Tidligere forskning har vist at foreldre til premature barn sover lite og dårlig de første to ukene etter fødselen. Dette kan være forbundet med redusert livskvalitet, utmattelse, angst, og stress. Per i dag har vi lite forskningsbasert kunnskap om hva som skjer med søvn etter denne perioden, og om lite søvn kan påvirke foreldres helse og livskvalitet negativt over tid. Målet er å få gode data om søvn, helse og livskvalitet hos foreldre til premature og terminfødte barn i tiden etter fødselen. For å undersøke om foreldre til premature barn er mer utsatt for søvnforstyrrelser enn foreldre til fullbårne barn, vil vi sammenligne de to gruppene.

Hvilke foreldre kan delta i søvnprosjektet?

Foreldre rekrutteres til to grupper:

- Foreldre til premature barn (født før svangerskapsuke 37) rekrutteres til **gruppe A.**
- Foreldre til terminfødte barn (født etter svangerskapsuke 37) rekrutteres til **gruppe B**.

Inklusjonskriterier i begge grupper er:

- Foreldre rekrutteres som par og bor sammen.
- Foreldrene behersker et nordisk språk (skriftlig og muntlig).
- Begge foreldre er over 16 år.

Eksklusjonskriterier i begge grupper er:

- Foreldre som har et alvorlig rusmiddelmisbruk (journalført jamfør ICD-10 eller DSM-IV).
- Det nyfødte barnet har alvorlig misdannelse/ eller livstruende tilstand som kan påvirke leveutsiktene.
- Mor har tilstand/ eller diagnose som gjør at prosjektdeltakelse er etisk utilrådelig, (eksempelvis alvorlig, livsinngripende helsetilstand).
- Foreldre til flerlinger.

Til sammen vil vi rekruttere ca. 100 foreldrepar til hver av de to gruppene.

Hva innebærer deltakelse for foreldre?

Data samles inn ved tre anledninger i barnets første leveår (2,6 og 12 måneder). Ved hver anledning bærer foreldre søvnmåler og fører søvndagbok, samt besvarer et spørreskjema.

- **Spørreskjema:**

Foreldrene vil få tilsendt et spørreskjema via en link på mail når barnet er 2, 6 og 12 måneder gammelt. Det tar ca. 20 minutter å svare på skjemaet. De vil bli spurt om søvnvansker, opplevd livskvalitet, utmattelse, tro på egen mestring og nedstemthet/depresjon. Ved første datainnsamling etterspørres også foreldrenes vekt, høyde, alder, utdanning, yrke, inntekt, og etnisitet, og antall barn. Foreldrene fyller inn det nyfødte barnets fødselsvekt og gestasjonsalder ved fødsel.

- **Registrering av søvn:**

Foreldre bærer små søvnregistratorer (armbånd) i 2 uker ved hvert måletidspunkt. Aktigrafene er små, lettvektige plastarmbånd (veier ca. 16 g), og laget av allergivennlig materiale. Registratoren skal sitte på kontinuerlig i måleperioden, og behøver ikke lading.

- **Føre søvndagbok:**

For å supplere dataene fra søvnmålerne, fører foreldrene samtidig søvndagbok. Søvndagboken har form som et spørreskjema med 10 avkrysningsrubrikker. To av rubrikkene fylles ut før sengetid, de resterende fylles ut om morgenen. Det vil ta foreldrene ca. 10 minutter å fylle ut søvndagboken hver dag.

Innsamling og lagring av data:

Foreldre som vil delta signerer på en skriftlig samtykkeerklæring. De vil deretter motta utstyr til første søvnmåling på sin private adresse når barnet er 2 mnd. gammelt. Etter endt måling returnerer de utstyret avidentifisert per post til prosjektkoordinator i en ferdigfrankert svarkonvolutt. Spørreskjemaet besvares digitalt. Prosjektkoordinator Gunhild Nordbø Marthinsen vil ha ansvar for all datainnsamling. I prosjektet har vi valgt en sikker digital løsning tilknyttet TSD (Tjenester for sensitive data). TSD er et fullt sett med tjenester, fra innsamling av data, til analyse, behandling og lagring i sikrede omgivelser. All bearbeidelse foregår i en lukket verden som oppfyller alle lovkrav til personvern og sikkerhet.

Hva innebærer studien for avdelingen?

Kontaktpersonen i avdelingen vil samarbeide med prosjektkoordinator om å rekruttere foreldre til prosjektet. Prosjektet vil ellers i liten grad affisere deg i arbeidet som sykepleier.

Hvorfor er prosjektet viktig?

Søvn er viktig for mennesker, og bidrar til å opprettholde god helse og velvære. I den generelle befolkningen har søvnmangel blitt assosiert med en rekke negative effekter på helsen, blant annet redusert livskvalitet, dårligere mestringsstrategier og risiko for psykiske og somatiske plager. Tilstrekkelig og god søvn er viktig for at foreldre skal kunne fungere i hverdagen og være omsorgspersoner for sine barn. Resultatene fra dette prosjektet vil være relevante for både fagfolk og forskere innen nyfødt og barselomsorg, og kan gi grunnlag til å utvikle nye og helsefremmende tiltak som kan sikre god søvn.

Frivillig deltakelse

All deltakelse i prosjektet er basert på frivillighet. Foreldre kan når som helst og uten å oppgi noen grunn trekke sitt samtykke. Dersom de trekker seg fra prosjektet, kan de kreve å få slettet innsamlede prøver og opplysninger.

Med vennlig hilsen fra

Liv Fegran

Professor, prosjektleder

Universitetet i Agder

Sølvi Helseth

Professor, prosjektmedarbeider

OsloMet-storbyuniversitet/Universitetet i Agder

Gunhild Nordbø Marthinsen

Doktorgradsstipendiat,

Prosjektkoordinator

Universitetet i Agder

Spørsmål om studien kan rettes til stipendiat/ prosjektkoordinator:

Gunhild Nordbø Marthinsen: gunhild.n.marthinsen@uia.no Tlf: 48065577/38141738

Appendix 10

Brochure


& foreldre søvn
Søvn, helse og livskvalitet
hos foreldre etter fødsel
FORSKNINGSPROSJEKTET
ØNSKER
DELTAKERE!

Vi ønsker deltakere til et forskningsprosjekt som skal undersøke søvn, helse og livskvalitet hos foreldre til terminfødte og premature barn etter fødsel.

HVEM KAN VÆRE MED?

Foreldrepar til premature (født før svangerskapsuke 37), eller terminfødte barn (født etter svangerskapsuke 37).

OM PROSJEKTET

Søvn er viktig for mennesker, lite søvn kan påvirke både helse og velvære. Etter en fødsel kan foreldre oppleve at søvnmønsteret endrer seg, sammenliknet med tidligere. I dette prosjektet ønsker vi å få mer kunnskap om søvn og søvnmønster hos foreldre til premature og terminfødte barn, og se på sammenhengen mellom søvn, helse og livskvalitet etter fødsel hos foreldre. Ved å sammenlikne data fra de to foreldregruppene vil vi kunne se etter forskjeller i søvn og helseforhold i tiden etter fødselen. Du finner mer informasjon om forskningsprosjektet på **foreldresovn.uia.no**

HVA INNEBÆRER DELTAKELSE?

- Foreldre deltar som par og besvarer internettbaserte spørreundersøkelser når barnet er 2, 6 og 12 måneder gammelt
- Dere bærer søvnmåler (armbånd), og fører søvndagbok i 2 uker før hver spørreundersøkelse.
- I spørreskjemaet blir det stilt spørsmål om søvn, livskvalitet, mestring, humør og energi.
- Ingen vil kunne gjenkjenne deg eller svarene dine.
- All deltakelse i forskningsprosjektet er frivillig.

Ønsker du og din partner å delta i forskningsprosjektet?

Påmelding: foreldresovn.uia.no

(senest innen 5 uker etter fødsel)

KONTAKTPERSON

Gunhild Nordbø Marthinsen,
doktorgradsstipendiat
gunhild.n.marthinsen@uia.no
tlf. 38141738

PROSJEKTLEDER

Liv Fegran, professor
liv.fegran@uia.no
tlf. 38141894

Prosjektet er et samarbeid mellom

UNIVERSITETET I AGDER

UNIVERSITETET I BERGEN

SOVno
Nasjonal kompetansetjeneste for søvnsykdommer

Oslo universitetssykehus

SØRLANDET SYKEHUS

OSLOMET

Appendix 11

Informed consent form, parents

UNIVERSITETET I AGDER

OSLOMET

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET:

” SØVN OG HELSERELATERT LIVSKVALITET HOS FORELDRE TIL PREMATURE OG TERMINFØDTE BARN”

Dette er et spørsmål til deg om å delta i et forskningsprosjekt om søvn og helserelatert livskvalitet hos foreldre etter fødsel. Prosjektet skal gjennomføres blant foreldre som har fått fortidligfødte (premature) og terminfødte barn. Til sammen ønsker vi å rekruttere ca. 100 foreldrepar i hver gruppe. Studien retter seg mot norske forhold, og foreldre vil bli rekruttert fra barsel og nyfødtavdelinger ved flere sykehus i sørøst Norge. Prosjektet inngår i en doktorgradsavhandling, og gjennomføres av stipendiat Gunhild Nordbø Marthinsen ved Universitetet i Agder. En forskergruppe ved Universitetet i Agder (UIA), fakultet for helse og idrettsvitenskap, og ved OsloMet- storbyuniversitet, fakultet for helsefag, gjennomfører og er ansvarlig for prosjektet. Du blir herved forespurt om å delta i studien fordi du i den senere tid har blitt forelder til et:

A) Prematurt født barn (født *før* svangerskapsuke 37) eller

B) Et terminfødt barn (født *etter* svangerskapsuke 37).

Bakgrunn og hensikt

Bakgrunnen for prosjektet er behov for kunnskap om foreldres søvn og helse etter fødsel. Lite søvn er svært vanlig og utbredt hos foreldre i småbarnsperioden. Forskning viser at foreldre som får et fortidligfødt barn kan oppleve følelsesmessige utfordringer i barseltiden som påvirker søvnen negativt. Om de derfor er mer utsatt for søvnforstyrrelser sammenliknet med terminfødtes foreldre, vites ikke. I prosjektet vil vi se på hvordan søvn og søvnmønster utvikler seg over tid etter fødselen, på sammenhengen mellom søvn og helserelatert livskvalitet i de to foreldregruppene. I dag vet vi ikke nok om hva som skjer med foreldres søvnmønster over tid, og om sammenhengen mellom søvn og helse. God søvn er viktig for at foreldre skal kunne fungere i hverdagen og være omsorgspersoner for sine barn. Kunnskapen fra studien vil være relevant og nyttig for både fagfolk og forskere innen nyfødt og barselomsorg. Resultatene vil også kunne brukes som et grunnlag for å utvikle nye tiltak som kan fremme god søvn hos foreldre.

HVA INNEBÆRER PROSJEKTET?

I prosjektet vil vi innhente og registrere opplysninger om deg. Data samles ved tre anledninger i barnets første leveår. Et spørreskjema blir tilsendt deg via en lenke på mail når barnet er 2, 6 og 12 måneder gammelt. Det tar ca. 25 minutter å svare på skjemaet. Du vil bli spurt om søvn og søvnforhold, sosial støtte, livskvalitet, mestring, humør og energi. Ved første datainnsamling etterspørres også din vekt, alder, utdanning, yrke, inntekt, og etnisitet. Vi ønsker å vite antall barn fra før, og det nyfødte barnets fødselsvekt og gestasjonsalder ved fødsel.

Du skal bære søvnregistrator (armbånd), som suppleres med at det føres søvndagbok i 2 uker ved de tre måletidspunktene. Søvnregistreringene gjennomføres i forkant av at spørreskjemaet utfylles. Aktigrafene er små, lettvektige plastarmbånd (veier ca. 16 g), og laget av allergivennlig materiale. De kan lett skjules under klær. Søvnregistratoren skal sitte på kontinuerlig i måleperioden, og behøver ikke lading.

Søvndagboken har form som et spørreskjema med 10 avkrysningsrubrikker. To av rubrikkene fylles ut før sengetid, de resterende fylles ut om morgenen. Det vil ta deg ca. 8 minutter å fylle ut søvndagboken hver dag. Dagboken er et viktig supplement når data fra aktigrafen skal tolkes.

Ved hvert måletidspunkt vil du motta en aktigraf og søvndagbok på postadressen du oppgav da du registrerte dg for deltakelse. Måler og søvndagbok returneres avidentifisert til stipendiaten per post i ferdigfrankert konvolutt. Spørreskjemaet besvares digitalt via en lenke på mail i slutten av hver måleperiode.

MULIGE FORDELER OG ULEMPER

Deltakelse i prosjektet innebærer at du bidrar til økt kunnskap om søvn og helse hos foreldre etter en fødsel. Kunnskapen angår og er viktig for mange mennesker. Deltakelse i prosjektet innebærer at du må bruke noe tid på å besvare spørreundersøkelsen ved tre anledninger. Du må også beregne noe tid på å føre søvndagbok og ha på søvnmåler i 2 uker ved hvert måletidspunkt. Utover dette har prosjektet få personlige ulemper for deg. I spørreundersøkelsen blir du bedt om å besvare spørsmål om egen søvn og helse. Dersom spørsmålene skulle oppleves sensitive eller vekke negative følelser hos deg, vil du til enhver tid kunne trekke deg fra deltakelse i studien. Dersom du skulle oppleve at du har helseutfordringer som krever medisinsk oppfølging, ber vi deg kontakte egen fastlege eller helsestasjon.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, signerer du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller er brukt i vitenskapelige publikasjoner. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte stipendiaten i prosjektet, Gunhild Nordbø Marthinsen på e-post: gunhild.n.marthinsen@uia.no , telefon 38141738.

HVA SKJER MED INFORMASJONEN OM DEG?

Opplysningene som registreres om deg skal kun brukes slik som beskrevet i hensikten med prosjektet. Du har rett til innsyn i hvilke opplysninger som er registrert om deg, og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Du har også rett til å få innsyn i sikkerhetstiltakene ved behandling av opplysningene. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun stipendiat Gunhild Nordbø Marthinsen som har adgang til denne listen.

I prosjektet har vi har valgt en sikker digital løsning tilknyttet TSD (Service for sensitive data) sine tjenester for behandling av sensitive data. TSD er et fullt sett med tjenester, fra innsamling av data, til analyse, behandling og lagring i sikrede omgivelser. All bearbeidelse foregår i en lukket verden som oppfyller alle lovkrav til personvern og sikkerhet. Opplysningene om deg vil bli anonymisert eller slettet senest fem år etter prosjektslutt.

GODKJENNING

Regional etisk komite for medisinsk og helsefaglig forskningsetikk har vurdert prosjektet, og har gitt forhåndsgodkjenning, saksnr (2018/1025). Etter ny personopplysningslov har behandlingsansvarlig Universitetet i Agder og prosjektleder professor Liv Fegran ved UIA et selvstendig ansvar for å sikre at behandlingen av dine opplysninger har et lovlig grunnlag. Dette prosjektet har rettslig grunnlag i EUs personvernforordning. Du har rett til å klage på behandlingen av dine opplysninger til Datatilsynet.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål til prosjektet kan du ta kontakt med stipendiat Gunhild Nordbø Marthinsen e-post: gunhild.n.marthinsen@uia.notelefon 38141738. Du kan ta kontakt med institusjonens personvernombud dersom du har spørsmål om behandlingen av dine personopplysninger i prosjektet; Personvernombud ved UIA, Ina Danielsen tlf 45254401, e-post: ina.danielsen@uia.no

SAMTYKKE TIL DELTAKELSE I PROSJEKTET

JEG ER VILLIG TIL Å DELTA I PROSJEKTET

Sted og dato	Deltakers signatur

A.

Deltakers kontaktopplysninger: (bruk blokkbokstaver og tydelig skrift)

Fullt navn:……

Privat postadresse:……

Telefonnummer/Mobil:…….

Epost adresse: ……..

Din relasjon til barnet: Er du fødende eller far/partner?

- ☐ Fødende
- ☐ Far/Partner

Din partners navn (fornavn og etternavn) For å kunne koble dere som foreldrepar, og sende ut søvnmåler og spørreskjema, trenger vi denne opplysningen

Partners navn:……

Partners epost adresse:

……..

Ditt barns fødselsdato (dd.mm.åååå) For å kunne sende ut søvnmåler og spørreskjema til riktig tid, trenger vi denne opplysningen

Barnets fødselsdato:……

Appendix 12

Information to parents (actigraphy, sleep diary)

Kjære foreldre!

Tusen takk for at dere deltar i foreldre & søvnprosjektet! Dere mottar nå en postsending med utstyr til søvnregistrering. Registreringen foregår i to uker, f.o.m …….t.o.m……. …….
På registreringens første dag tar dere på søvnmåler, og begynner med å føre søvndagbok.

- Utstyret er merket med mor eller far/partner. Det er viktig at riktig person benytter utstyret merket for seg. Søvnmålerne er forhåndsprogrammert, og vil starte automatisk.
- Søvndagboken fylles ut morgen og kveld. En instruksjon om utfyllingen finnes på baksiden av dagboken.
- Dere vil motta hver deres mail med lenke til et spørreskjema:……., når søvnregistreringen er ferdig.
- De utfylte søvndagbøkene og søvnmålerne returneres via post i den vedlagte, ferdigfrankerte konvolutten. Fint om dere kan returnere utstyret så snart som mulig, da vi har behov for søvnmålerne i den videre fremdriften av prosjektet.

Litt om bruk av søvnmåler:

Måleren kan måle armbevegelse og lysnivå, og på den måten si noe om ditt søvnmønster. Den plasseres rundt håndleddet på den ikke- dominante armen (oftest den venstre). Det er viktig at den sitter godt inntil huden. Søvnmåleren skal sitte på kontinuerlig i to uker, og behøver ikke lading. Den tåler vann, og kan dusjes og bades med. På dens venstre side, finner du en hendelsesmarkør. Du trykker på markøren når du skal sove, og når du står opp (dersom du glemmer det, fortsetter du bare som vanlig.)

Lykke til, og tusen takk for at dere deltar!

Med vennlig hilsen fra

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Appendix 13

Questionnaire

SPØRRESKJEMA FOR KARTLEGGING AV FORELDRES SØVN, HELSE OG LIVSKVALITET ETTER FØDSEL.

Du har tidligere samtykket til å delta i forskningsprosjektet «Foreldre & Søvn. Du mottar nå et spørreskjema. Svar med ett kryss (X) for hvert spørsmål. Bruk sort eller blå kulepenn når du svarer.

A. BAKGRUNNSOPPLYSNINGER OM DEG

1. Oppgi dag, måned og år for utfyllingen av skjemaet

(Dag- måned- år).

2. Er du kvinne eller mann?
   - ☐ Kvinne
   - ☐ Mann

3. Hva er din fødselsdato?

(Dag- måned- år)

4. I hvilket land er du født?.....

5. Hvor mange barn har du (<u>inkludert</u> ditt nyfødte barn)

6. Hvilken utdannelse har du? Sett kun ett kryss for den høyeste utdannelsen du har fullført)
   - ☐ 9 årig grunnskole
   - ☐ 1-2 årig videregående
   - ☐ Videregående yrkesfaglig
   - ☐ 3 årig videregående allmennfaglig, gymnas
   - ☐ Distriktshøgskole, universitet inntil 4 år (cand.mag, sykepleier, lærer, ingeniør)
   - ☐ Universitet, høyskole mer enn 4 år (hovedfag, embetseksamen)
   - ☐ Annet

7. Hva var din brutto årsinntekt (før skatt) det siste året? (inkl. barnebidrag, arbeidsledighetstrygd, kontantstøtte, osv.)
   - ☐ Ingen inntekt
   - ☐ Under 150.000 kr
   - ☐ 150 – 199.999 kr
   - ☐ 200- 299 999 kr
   - ☐ 300 –399 000 kr
   - ☐ 400 – 499 000 kr
   - ☐ Over 500.000 kr

8. Hva var din arbeidssituasjon før siste svangerskap? (hvis far- før din partners svangerskap)
   1. Skolelev/student
   2. Hjemmeværende
   3. Yrkespraksis/lærling
   4. Militærtjeneste
   5. Arbeidssøkende/permittert
   6. Attføring/ufør
   7. Ansatt i offentlig virksomhet
   8. Ansatt i privat virksomhet
   9. Selvstendig næringsdrivende
   10. Familiemedlem uten fast lønn i familiebedrift /for eksempel. Gårdsbruk, forretning)
   11. Annet

9. Har du fått en av følgende diagnoser hos din lege?
   - ☐ Søvnrelatert respirasjonslidelse (blant annet obstruktiv søvnapne)
   - ☐ Sentral hypersomnilidelse (blant annet narkolepsi)
   - ☐ Insomnilidelse
   - ☐ Søvnrelatert bevegelsesforstyrrelse (blant annet restless legs syndrom)
   - ☐ Parasomni (blant annet søvngjengeri)
   - ☐ Døgnrytmelidelse
   - ☐ Nei, jeg har ingen av disse diagnosene

10. Bruker du medisiner jevnlig? (Dette gjelder alle typer medisiner, også naturmedisiner.)

    ☐ Nei

    ☐ Ja

11. Hvis ja, oppgi navn på medisinene og hvor ofte du bruker dem. (Ta med alle typer medisiner, også naturmedisiner.)

    Navn på medisinen (for eksempel APOCILLIN, PARACET)

	Hvor ofte bruker du dem?		
	Hver dag	Daglig i perioder	Av og til
……...			
……..			
…….			

12. Hva er din høyde (cm),

13. Hva er din vekt (kg)

B. BAKGRUNNSOPPLYSNINGER OM BARNET DITT

14. Er du forelder til et:

    ☐ Prematurt barn (født før svangerskapsuke 37)

    ☐ Terminfødt barn (født etter svangerskapsuke 37

15.Når er barnet ditt født?

(Dato- måned- år)

16.Hvor stort var barnet ved fødselen?

Fødselsvekt: ☐☐☐☐ (g)

Lengde: ☐☐ cm

17. Ved hvilket sykehus ble barnet ditt født?

- ☐ Oslo Universitetssykehus (OUS)
- ☐ Sørlandet sykehus (SSHF)
- ☐ Ingen av delene, (oppgi sykehus:)…….

18. Hva slags drikke har barnet fått de første 6 levemånedene? (Sett kryss for hver måned barnet har fått den aktuelle drikken)

		Barnets alder i måneder	0	1	2	3	4	5	6
Brystmelk									
Collett vanlig									
Collett med Omega 3									
Nan vanlig									
Nan HA1									
Annen melk, beskriv…..									
Vann									
Saft/juice									

C. DINE SØVNVANER

19. De siste to ukene - hvor har du sovet om natten?

- ☐ Hjemme
- ☐ På sykehuset
- ☐ Begge stedene
- ☐ Ingen av stedene

20. Har du og din partner sovet på samme rom?

- ☐ Ja
- ☐ Nei

21. Har du sovet i samme rom som ditt nyfødte barn?

- ☐ Ja
- ☐ Nei

22. Har du de siste to ukene hatt jobbrelatert nattarbeid?

- ☐ Ja
- ☐ Nei

D. DIN SØVN (Bergen insomnia scale-BIS)

Instruksjon: På spørreskjemaet under er det 6 spørsmål knyttet til søvn og tretthet. Vær vennlig å sett ring rundt det alternativet (antall dager per uke) som passer best for deg. 0 er ingen dager i løpet av en uke, 7 er alle dager i løpet av en uke. **Eksempel:** hvis du 3 dager i løpet av en uke har brukt mer enn 30 minutter på å sovne etter at du har slukket lyset, setter du ring rundt alternativ 3.

1. I løpet av de siste tre månedene, hvor mange dager per uke har du brukt mer enn 30 minutter for å sovne inn etter at lyset ble slukket?

   0 1 2 3 4 5 6 7

2. I løpet av de siste tre månedene, hvor mange dager per uke har du vært våken mer enn 30 minutter innimellom søvnen?

0 1 2 3 4 5 6 7

3. I løpet av de siste tre månedene, hvor mange dager per uke har du våknet mer enn 30 minutter tidligere enn du har ønsket uten å sove igjen?

   0 1 2 3 4 5 6 7

4. I løpet av de siste tre månedene, hvor mange dager per uke har du følt deg for lite uthvilt etter å ha sovet?

   0 1 2 3 4 5 6 7

5. I løpet av de siste tre månedene, hvor mange dager per uke har du vært så trøtt at det har gått ut over skole/jobb eller privatlivet?

   0 1 2 3 4 5 6 7

6. I løpet av de siste tre månedene, hvor mange dager per uke har du vært misfornøyd med søvnen din?

   0 1 2 3 4 5 6 7

E. DIN ENERGI (FATIGUE) (Chalder Fatigue scale- CFS)

Vi vil gjerne vite om du har følt deg sliten, svak eller i mangel av overskudd den siste måneden. Vennligst besvar alle spørsmålene ved å krysse av for det svaret du syns passer best for deg. Vi ønsker at du besvarer alle spørsmålene selv om du ikke har hatt slike problemer. Vi spør deg om hvordan du har følt deg i det siste og ikke om hvordan du følte deg for lenge siden. Hvis du har følt deg sliten lenge, ber vi deg om at du sammenlikner deg med hvordan du følte deg sist du var bra (ett kryss for hver linje).

1. Har du problemer med at du føler deg sliten?
   - ☐ Mindre enn vanlig
   - ☐ Ikke mer enn vanlig
   - ☐ Mer enn vanlig

- Mye mer enn vanlig

2. Trenger du mer hvile?
   - Nei, mindre enn vanlig
   - Ikke mer enn vanlig
   - Mer enn vanlig
   - Mye mer enn vanlig

3. Føler du deg søvnig eller døsig?
   - Mindre enn vanlig
   - Ikke mer enn vanlig
   - Mer enn vanlig
   - Mye mer enn vanlig

4. Har du problemer med å komme i gang med ting?
   - Mindre enn vanlig
   - Ikke mer enn vanlig
   - Mer enn vanlig
   - Mye mer enn vanlig

5. Mangler du overskudd?
   - Ikke i det hele tatt
   - Ikke mer enn vanlig
   - Mer enn vanlig
   - Mye mer enn vanlig

6. Har du redusert styrke i musklene dine?
   - Ikke i det hele tatt
   - Ikke mer enn vanlig
   - Mer enn vanlig
   - Mye mer enn vanlig

7. Føler du deg svak?
   - Mindre enn vanlig
   - Som vanlig
   - Mer enn vanlig

- ☐ Mye mer enn vanlig

8. Har du vansker med å konsentrere deg?
   - ☐ Mindre enn vanlig
   - ☐ Som vanlig
   - ☐ Mer enn vanlig
   - ☐ Mye mer enn vanlig

9. Forsnakker du deg i samtaler?
   - ☐ Mindre enn vanlig
   - ☐ Ikke mer enn vanlig
   - ☐ Mer enn vanlig
   - ☐ Mye mer enn vanlig

10. Er det vanskeligere å finne det rette ordet?
    - ☐ Mindre enn vanlig
    - ☐ Ikke mer enn vanlig
    - ☐ Mer enn vanlig
    - ☐ Mye mer enn vanlig

11. Hvordan er hukommelsen din?
    - ☐ Bedre enn vanlig
    - ☐ Ikke verre enn vanlig
    - ☐ Verre enn vanlig
    - ☐ Mye verre enn vanlig

12. Hvis du føler deg sliten for tiden, omtrent hvor lenge har det vart? (Ett kryss)
    - ☐ Mindre enn en uke
    - ☐ Mindre enn tre måneder
    - ☐ Mellom tre og seks måneder
    - ☐ Seks måneder eller mer

13. Hvis du føler deg sliten for tiden, omtrent hvor mye av tiden kjenner du det? (Ett kryss)¨

- 25% av tiden
- 50% av tiden
- 75% av tiden
- Hele tiden

F. PSYKISK HELSE (Edinburgh postnatal depresjonsskår- EPDS)

De neste spørsmålene gjelder de siste 7 dagene

1. Har du siste 7 dager kunnet le og se det komiske i en situasjon?
   - Like mye som vanlig
   - Ikke riktig så mye som jeg pleier
   - Klart mindre enn jeg pleier
   - Ikke i det hele tatt

2. Har du siste 7 dager gledet deg til ting som skulle skje?
   - Like mye som vanlig
   - Noe mindre enn jeg pleier
   - Klart mindre enn jeg pleier
   - Nesten ikke i det hele tatt

3. Har du siste 7 dager bebreidet deg selv uten grunn når noe gikk galt?
   - Ja, nesten hele tiden
   - Ja, av og til
   - Ikke særlig ofte
   - Nei, aldri

4. Har du siste 7 dager vært nervøs eller bekymret uten grunn?
   - Nei, slett ikke
   - Nesten aldri
   - Ja, iblant
   - Ja, veldig ofte

5. Har du siste 7 dager vært redd eller fått panikk uten grunn?
    - Ja, svært ofte
    - Ja, noen ganger
    - Sjelden
    - Nei, aldri

6. Har du siste 7 dager følt at det har blitt for mye for deg?
    - Ja, jeg har stort sett ikke fungert i det hele tatt
    - Ja, iblant har jeg ikke klart å fungere som jeg pleier
    - Nei, for det meste har jeg klart meg bra
    - Nei, jeg har klart meg like bra som vanlig

7. Har du siste 7 dager vært så ulykkelig at du har hatt vanskeligheter med å sove?
    - Ja, for det meste
    - Ja, iblant
    - Ikke særlig ofte
    - Nei, ikke i det hele tatt

8. Har du siste 7 dager følt deg nedfor eller ulykkelig?
    - Ja, det meste av tiden
    - Ja, ganske ofte
    - Ikke særlig ofte
    - Nei, ikke i det hele tatt

9. Har du siste 7 dager vært så ulykkelig at du har grått?
    - Ja, nesten hele tiden
    - Ja, veldig ofte
    - Ja, det har skjedd iblant
    - Nei, aldri

10. Har tanken på å skade deg streifet deg, de siste 7 dagene?
    - Ja, nokså ofte

- Ja, av og til
- Ja, såvidt
- Aldri

G. DIN MESTRINGSEVNE (Mestringstro, Self efficacy- GSE)

1. Jeg klarer alltid å løse vanskelige problemer hvis jeg prøver hardt nok
   - Ikke riktig
   - Litt riktig
   - Nesten riktig
   - Helt riktig

2. Hvis noen motarbeider meg, så finner jeg måter å oppnå det jeg vil på
   - Ikke riktig
   - Litt riktig
   - Nesten riktig
   - Helt riktig

3. Jeg føler meg trygg på at jeg ville kunne takle uventede hendelser på en effektiv måte
   - Ikke riktig
   - Litt riktig
   - Nesten riktig
   - Helt riktig

4. Jeg beholder roen når jeg møter vanskeligheter fordi jeg stoler på mestringsevnen min
   - Ikke riktig
   - Litt riktig
   - Nesten riktig
   - Helt riktig

5. Hvis jeg er i en knipe, så finner jeg vanligvis en vei ut.
    - □ Ikke riktig
    - □ Litt riktig
    - □ Nesten riktig
    - □ Helt riktig

H. DIN HELSE OG LIVSKVALITET (RAND- 36)

Spørsmålene under handler om hvordan du oppfatter helsen din. Disse opplysningene vil hjelpe oss til å forstå hvordan du føler deg og hvor godt du er i stand til å utføre dine vanlige aktiviteter.

1. Stort sett, vil du si at helsen din er:
    - □ Utmerket
    - □ Veldig godt
    - □ God
    - □ Nokså god
    - □ Dårlig

2. Sammenliknet <u>med for ett år siden</u>, hvordan vil du si at helsen din stort sett er nå?
    - □ Mye bedre nå enn for ett år siden
    - □ Litt bedre nå enn for ett år siden
    - □ Omtrent som for ett år siden
    - □ Litt dårligere enn for ett år siden
    - □ Mye dårligere enn for ett år siden

3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er helsen din slik at den begrenser deg i utførelsen av disse aktivitetene nå? Hvis ja- hvor mye (Kryss X en boks på hver linje):
4.
    A. Anstrengende aktiviteter som å løpe, løfte tunge gjenstander, delta i anstrengende idrett
        - □ Ja, begrenser meg mye
        - □ Ja, begrenser meg litt
        - □ Nei, begrenser meg ikke i det hele tatt

B. Moderate aktiviteter som å flytte et bord, støvsuge, gå en spasertur eller drive hagearbeid
   - □ Ja, begrenser meg mye
   - □ Ja, begrenser meg litt
   - □ Nei, begrenser meg ikke i det hele tatt

C. Løfte eller bære poser med dagligvarer
   - □ Ja, begrenser meg mye
   - □ Ja, begrenser meg litt
   - □ Nei, begrenser meg ikke i det hele tatt

D. Gå opp trappen flere etasjer
   - □ Ja, begrenser meg mye
   - □ Ja, begrenser meg litt
   - □ Nei, begrenser meg ikke i det hele tatt

E. Gå opp trappen en etasje
   - □ Ja, begrenser meg mye
   - □ Ja, begrenser meg litt
   - □ Nei, begrenser meg ikke i det hele tatt

F. Bøye deg eller gå ned på kne
   - □ Ja, begrenser meg mye
   - □ Ja, begrenser meg litt
   - □ Nei, begrenser meg ikke i det hele tatt

G. Gå mer enn to kilometer
   - □ Ja, begrenser meg mye
   - □ Ja, begrenser meg litt
   - □ Nei, begrenser meg ikke i det hele tatt

H. Gå flere hundre meter
   - □ Ja, begrenser meg mye
   - □ Ja, begrenser meg litt
   - □ Nei, begrenser meg ikke i det hele tatt

I. Gå hundre meter

- Ja, begrenser meg mye
- Ja, begrenser meg litt
- Nei, begrenser meg ikke i det hele tatt

J. Dusje eller kle på deg

- Ja, begrenser meg mye
- Ja, begrenser meg litt
- Nei, begrenser meg ikke i det hele tatt

5. I løpet av de siste fire ukene, har du hatt noen av de følgende problemene i arbeidslivet ditt eller i andre aktiviteter på grunn av din fysiske helse?
   a. Kuttet ned på hvor mye tid du brukte på arbeid eller andre aktiviteter

      - Ja
      - Nei

   b. Fått gjort mindre enn du ønsket

      - Ja
      - Nei

   c. Vært begrenset i type arbeidsoppgaver eller andre aktiviteter

      - Ja
      - Nei

   d. Hatt problemer med å utføre arbeidet eller andre aktiviteter (for eksempel at det krevde en ekstra innsats av deg)

      - Ja
      - Nei

6. I løpet av de siste fire ukene, har du hatt noen av de følgende problemene i arbeidslivet dit eller i andre daglige aktiviteter på grunn av følelsesmessige problemer (som å føle seg engstelig eller deprimert)?
   a. Kuttet ned på hvor mye tid du brukte på arbeid eller andre aktiviteter

- Ja
- Nei

b. Fått gjort mindre enn du ønsket
   - Ja
   - Nei

c. Utført arbeid eller andre aktiviteter **mindre grundig** enn vanlig
   - Ja
   - Nei

7. I løpet av de siste fire ukene, i hvilken grad har den fysiske helsen din eller følelsesmessige problemer påvirket dine vanlige sosiale aktiviteter med familie, venner, naboer, eller andre grupper mennesker?
   - Ikke i det hele tatt
   - Litt
   - Moderat
   - Ganske mye
   - Ekstremt mye

8. Hvor mye kroppslig smerter har du hatt i løpet av de siste fire ukene?
   - Ingen
   - Veldig svake
   - Svake
   - Moderate
   - Sterke
   - Veldig sterke

9. I løpet av de siste fire ukene, hvor mye har smerter påvirket det vanlige arbeidet ditt (gjelder både arbeid utenfor hjemmet og husarbeid)
   - Ikke i det hele tatt
   - Litt
   - Moderat
   - Ganske mye

- □ Ekstremt mye

10. De neste spørsmålene handler om hvordan du føler deg og hvordan du har hatt det i løpet av de siste fire ukene. For hvert spørsmål, ber vi deg velge det svaret som best beskriver hvordan du har følt deg. Hvor ofte i løpet av de siste fire ukene:

a. Har du følt deg full av liv?
   - □ Hele tiden
   - □ Mesteparten av tiden
   - □ En god del av tiden
   - □ Noe av tiden
   - □ Litt av tiden
   - □ Aldri

b. Har du vært veldig nervøs?
   - □ Hele tiden
   - □ Mesteparten av tiden
   - □ En god del av tiden
   - □ Noe av tiden
   - □ Litt av tiden
   - □ Aldri

c. Har du følt deg så langt nede at ingenting kunne gjøre deg glad?
   - □ Hele tiden
   - □ Mesteparten av tiden
   - □ En god del av tiden
   - □ Noe av tiden
   - □ Litt av tiden
   - □ Aldri

d. Har du følt deg rolig og avslappet?
   - □ Hele tiden
   - □ Mesteparten av tiden
   - □ En god del av tiden
   - □ Noe av tiden
   - □ Litt av tiden

- Aldri

e. Har du hatt mye overskudd?
   - Hele tiden
   - Mesteparten av tiden
   - En god del av tiden
   - Noe av tiden
   - Litt av tiden
   - Aldri

f. Har du følt deg nedfor og deprimert?
   - Hele tiden
   - Mesteparten av tiden
   - En god del av tiden
   - Noe av tiden
   - Litt av tiden
   - Aldri

g. Har du følt deg utslitt?
   - Hele tiden
   - Mesteparten av tiden
   - En god del av tiden
   - Noe av tiden
   - Litt av tiden
   - Aldri

h. Har du følt deg glad?
   - Hele tiden
   - Mesteparten av tiden
   - En god del av tiden
   - Noe av tiden
   - Litt av tiden
   - Aldri

i. Har du følt deg sliten?

- Hele tiden
- Mesteparten av tiden
- En god del av tiden
- Noe av tiden
- Litt av tiden
- Aldri

11. I løpet av de siste fire ukene, hvor mye av tiden har den fysiske helsen din eller følelsesmessige problemer påvirket dine sosiale aktiviteter (som å besøke venner, slektninger, osv.?)

- Hele tiden
- Mesteparten av tiden
- En del av tiden
- Litt av tiden
- Aldri

12. Hvor RIKTIG eller GAL er hver av de følgende påstandene for deg ?

a. Det virker som om jeg blir syk lettere enn andre

- Helt riktig
- Stort sett riktig
- Vet ikke
- Stort sett galt
- Helt galt

b. Jeg er like frisk som de fleste jeg kjenner

- Helt riktig
- Stort sett riktig
- Vet ikke
- Stort sett galt
- Helt galt

c. Jeg regner med at helsen min blir dårligere

- Helt riktig
- Stort sett riktig

- Vet ikke
- Stort sett galt
- Helt galt

d. Helsen min er utmerket
   - Helt riktig
   - Stort sett riktig
   - Vet ikke
   - Stort sett galt
   - Helt galt

I. OPPLEVD STRESS (Perceived stress questionnaire- PSQ)

Sett ring rundt tallet som beskriver hvordan det er eller har vært for deg den siste måneden. Gjør dette raskt uten å sjekke svarene nøye og merk at det skal gjelde den siste måneden.

1. Du føler deg uthvilt
   - Nesten aldri
   - Av og til
   - Ofte
   - Vanligvis

2. Du føler at du får for mange krav stilt til deg
   - Nesten aldri
   - Av og til
   - Ofte
   - Vanligvis

3. Du er irritabel og gretten
   - Nesten aldri
   - Av og til
   - Ofte
   - Vanligvis

4. Du har for mye å gjøre
   - ☐ Nesten aldri
   - ☐ Av og til
   - ☐ Ofte
   - ☐ Vanligvis

5. Du føler deg ensom og isolert
   - ☐ Nesten aldri
   - ☐ Av og til
   - ☐ Ofte
   - ☐ Vanligvis

6. Du opplever å være i konfliktsituasjoner
   - ☐ Nesten aldri
   - ☐ Av og til
   - ☐ Ofte
   - ☐ Vanligvis

7. Du føler at du gjør ting som du virkelig liker
   - ☐ Nesten aldri
   - ☐ Av og til
   - ☐ Ofte
   - ☐ Vanligvis

8. Du kjenner deg trøtt
   - ☐ Nesten aldri
   - ☐ Av og til
   - ☐ Ofte
   - ☐ Vanligvis

9. Du frykter at du kanskje ikke klarer å nå målene dine
   - ☐ Nesten aldri
   - ☐ Av og til
   - ☐ Ofte
   - ☐ Vanligvis

10. Du føler deg rolig

- Nesten aldri
- Av og til
- Ofte
- Vanligvis

11. Du har for mange avgjørelser å ta
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

12. Du føler deg frustrert
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

13. Du er full av energi
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

14. Du føler deg anspent
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

15. Problemene dine virker å hope seg opp
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

16. Du føler du har det travelt
    - Nesten aldri

- Av og til
- Ofte
- Vanligvis

17. Du føler deg trygg og beskyttet
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

18. Du har for mange bekymringer
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

19. Du er under press fra andre mennesker
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

20. Du føler deg motløs
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

21. Du har det hyggelig
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

22. Du er redd for fremtiden
    - Nesten aldri
    - Av og til

- Ofte
- Vanligvis

23. Du føler at du gjør ting du må, ikke fordi du vil
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis
24. Du føler deg kritisert eller bedømt
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis
25. Du er munter
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis
26. Du føler deg mentalt utmattet
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis
27. Du har problemer med å slappe av
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis
28. Du føler deg tynget av ansvar
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

29. Du har nok tid til deg selv
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

30. Du føler deg presset av tidsfrister
    - Nesten aldri
    - Av og til
    - Ofte
    - Vanligvis

J. SOSIAL STØTTE

(Duke UNC Functional Social support questionnaire- FSSQ)

1. Jeg har mennesker som bryr seg om hva som skjer med meg
    - Så mye jeg ønsker
    - Nesten så mye jeg ønsker
    - Noe, men kunne ønske litt mer
    - Mindre enn jeg ønsket
    - Mye mindre enn jeg ønsket

2. Jeg får kjærlighet og hengivenhet.
    - Så mye jeg ønsker
    - Nesten så mye jeg ønsker
    - Noe, men kunne ønske litt mer
    - Mindre enn jeg ønsket
    - Mye mindre enn jeg ønsket

3. Jeg får mulighet til å snakke med noen om problemer på arbeidsplassen eller med husarbeidet
    - Så mye jeg ønsker
    - Nesten så mye jeg ønsker
    - Noe, men kunne ønske litt mer
    - Mindre enn jeg ønsket
    - Mye mindre enn jeg ønsket

4. Jeg får mulighet til å snakke med noen jeg stoler på om mine personlige problemer eller familieproblemer
    - Så mye jeg ønsker
    - Nesten så mye jeg ønsker
    - Noe, men kunne ønske litt mer
    - Mindre enn jeg ønsket
    - Mye mindre enn jeg ønsket

5. Jeg får mulighet til å snakke om økonomiske forhold.
    - Så mye jeg ønsker
    - Nesten så mye jeg ønsker
    - Noe, men kunne ønske litt mer
    - Mindre enn jeg ønsket
    - Mye mindre enn jeg ønsket

6. Jeg blir invitert ut for å gjøre ting sammen med andre mennesker
    - Så mye jeg ønsker
    - Nesten så mye jeg ønsker
    - Noe, men kunne ønske litt mer
    - Mindre enn jeg ønsket
    - Mye mindre enn jeg ønsket

7. Jeg får nyttige råd om viktige ting i livet.
    - Så mye jeg ønsker
    - Nesten så mye jeg ønsker
    - Noe, men kunne ønske litt mer
    - Mindre enn jeg ønsket
    - Mye mindre enn jeg ønsket

8. Jeg får hjelp når jeg er syk og sengeliggende
    - Så mye jeg ønsker
    - Nesten så mye jeg ønsker
    - Noe, men kunne ønske litt mer
    - Mindre enn jeg ønsket
    - Mye mindre enn jeg ønsket

Appendix 14

Sleep diary

SØVNDAGBOK

Navn: Spørsmål 1 og 2 fylles ut før sengetid, resten av skjemaet fylles ut om morgenen. Husk å notere dato.

	Eksempel 01.01.10	Mandag	Tirsdag	Onsdag	Torsdag	Fredag	Lørdag	Søndag
1. Hvordan har du fungert på dagtid? 1 = veldig bra, 2 = bra, 3 = middels, 4 = dårlig, 5 = veldig dårlig	4							
2. Har du tatt en eller flere blunder i løpet av dagen? Notér tidspunktene for alle blundene.	16-16.30 og 18.15-18.30							
3. Har du tatt sovemedisin og/eller alkohol som hjelp til å sove? Notér medikament og dose, samt evt alkoholinntak	5 mg Imovane 1 glass rødvin							
4. Når gikk du til sengs? Når skrudde du av lyset?	22.30 23.00							
5. Hvor lang tid tok det fra lyset var skrudd av til du sovnet?	45 min							
6. Hvor mange ganger våknet du i løpet av natten?	3							
7. Hvor lange var oppvåkningsperiodene (oppgi antall minutter for hver oppvåkning)?	15, 30, 80							
8. Når våknet du opp om morgenen uten å få sove igjen? Notér tidspunktet for din endelige oppvåkning.	06.15							
9. Når stod du opp?	06.40							
10. Hvordan var siste natts søvn totalt sett: 1 = veldig lett, 2 = lett, 3 = middels, 4 = dyp, 5 = veldig dyp.	1							

Kartlegg søvnen din med søvndagbok

Hvordan sover du?
Utfylling av søvndagbok i en til to uker er en god og enkel måte å kartlegge søvnen din på. I moderne behandling av søvnproblemer benyttes slike dagbøker som hjelp til å stille diagnose, og også til å følge respons på behandling.

Instruksjoner til bruk av søvndagbok:
De to første spørsmålene fylles ut om kvelden før sengetid, mens de andre spørsmålene besvares om morgenen rett etter at du har stått opp. Søvndagboken fylles ut hver dag.

Det er vanskelig å vite nøyaktig hvor lang tid det tar å sovne inn, og hvor lenge man er våken om natten. Når dagboken likevel inneholder slike spørsmål er det fordi man ønsker at du prøver å gi et anslag på disse tidene (ikke se på klokken). Hvis det har skjedd noe spesielt om nettene, notér ned hva det var (sykdom, telefonoppringing o.l.).

Her følger litt hjelp til å fylle ut hvert enkelt spørsmål. Et eksempel på utfylling er også gitt i selve dagboken.

1. *Kvalitet på dagen:* Bruk skalaen i søvndagboken til å angi hvordan du fungerte i løpet av dagen.
2. *Blund:* Alle søvnperioder utenom nattesøvnen noteres, også om blundene var ufrivillige. Hvis du for eksempel sovnet foran fjernsynet i 10 minutter, ønsker vi at du noterer dette.
3. *Hjelp til å sove:* Ta med alle former for sovemidler, også de uten resept. Alkohol-inntak spesielt brukt som sovemiddel noteres også.
4. *Sengetid:* Dette er tiden du går til sengs og faktisk skrur av lysene. Hvis du legger deg kl. 22.45, men skrur av lysene først kl. 23.15, skal begge tidspunktene noteres.
5. *Innsovningtid:* Gi ditt beste anslag over hvor lang tid du tok på å sovne etter at du hadde skrudd av lyset.
6. *Antall oppvåkninger:* Dette er antall nattlige oppvåkninger som du husker.
7. *Varigheten av oppvåkningene:* Angi så godt du kan hvor lenge du var våken i hver av de nattlige oppvåkningene. Hvis dette er umulig, angi cirka hvor lenge du tror du var våken totalt sett i løpet av natten. Ta ikke med tiden det tok fra du våknet til du stod opp, siden det går fram av deneste spørsmålene.
8. *Våkenhet om morgenen:* Her noteres tidspunktet du våknet opp om morgenen uten å få sove igjen. Hvis du våknet kl. 04.00 og ikke sovnet etterpå, noteres dette tidspunktet. Hvis du imidlertid våknet 04.00, men sov en kort periode (f.eks. fra 06.00 til 06.20), noteres 06.20.
9. *Tidspunkt du stod opp:* Her noteres det tidspunktet du stod opp for godt den morgenen.
10. *Søvnkvalitet:* Bruk skalaen i søvndagboken til å angi hvordan du opplevde kvaliteten på nattesøvnen.

Appendix 15

Translation of FSSQ

Duke- UNC Functional Social support questionnaire (FSSQ).

Her er en liste over ting som andre mennesker gjør for oss eller gir oss som kan være nyttige eller støttende. Vennligst les hver uttalelse nøye og skriv 'X' i kolonnen som passer best til din situasjon. Gi bare ett svar per rad.

	5	4	3	2	1
	Så mye jeg ønsker	**Nesten så mye jeg ønsker**	**Noe, men kunne ønske litt mer**	**Mindre enn jeg ønsket**	**Mye mindre enn jeg ønsket**
Jeg har mennesker som bryr seg om hva som skjer med meg					
Jeg får kjærlighet og hengivenhet					
Jeg får mulighet til å snakke med noen om problemer på arbeidsplassen eller med husarbeidet.					
Jeg får mulighet til å snakke med noen jeg stoler på om mine personlige problemer eller familieproblemer.					
Jeg får mulighet til å snakke om økonomiske forhold.					
Jeg blir invitert ut for å gjøre ting sammen med andre mennesker					
Jeg får nyttige råd om viktige ting i livet.					
Jeg får hjelp når jeg er syk og sengeliggende					

Paper 1

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RESEARCH ARTICLE Open Access

Sleep and its relationship to health in parents of preterm infants: a scoping review

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Abstract

Background: Sleep is essential for human health and functioning. Parents of preterm infants are susceptible to sleep disturbances because of stress related to the preterm birth. Poor sleep has the potential to affect parental health and well-being. The aim of this study was to identify and map evidence on sleep and its relationship to health in parents of preterm infants. No review has summarized the evidence on this topic.

Methods: A scoping review was conducted. Seven health and medical electronic research databases were searched for relevant quantitative and qualitative primary studies, including grey literature. The search was performed March 2–7, 2017.

Results: Ten American studies and one Australian study were included in the review. Most research was quantitative and focused on maternal sleep and mental health within the first two weeks after the childbirth. Both objective and subjective sleep measures were used to study sleep at the hospital; actigraphs were not used after discharge. Maternal sleep was poor early postpartum, and this was associated with negative health outcomes. Two cohort studies compared sleep in mothers of preterm and term infants, but the results were conflicting. In one qualitative study, fathers described their inability to catch up on sleep after homecoming with a preterm baby.

Conclusions: Quantitative studies reporting on maternal sleep early postpartum was most frequently occurring in the results. Qualitative research on the topic was identified as a knowledge gap. More cultural and geographical breadth, including research on fathers' sleep, is recommended in future research.

Keywords: Scoping review, Sleep, Health, Parents, Mother, Father, Preterm, Nursing

Background

Every year, approximately 15 million infants around the world are born before 37 completed weeks of gestation, and the rate of preterm birth is increasing [1]. Globally, preterm birth is the second highest direct cause of death in children younger than 5 years [2]. Depending on the degree of prematurity and severity of disease, the preterm infant requires hospitalization and technological care in a neonatal intensive care unit (NICU) [3]. The event of a preterm birth has been associated with maternal and parental distress [4–8]. Recent studies have reported negative effects on parental sleep because of feelings arising from the preterm birth experience [9, 10]. Sleep is important for parents' own physical and emotional health, as well as for their abilities to cope with illness, support their child and family members, participate in decision making and maintain relationships [11]. Sleep is also a critical determinant of physical and mental health [12]. Parents may benefit from postpartum nursing care that prioritizes sleep given that parents are experiencing a critical time for healing [13]. This literature review was a scoping review of the existing evidence on sleep and its relationship to health in parents of preterm infants. The findings are relevant to healthcare providers in NICUs. An understanding of parental sleep after the incidence of preterm birth might

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be the first step toward developing strategies and interventions to promote sleep and health in this parent population.

Sleep is a multidimensional, biobehavioural process that is essential for human health and functioning [14]. Although the functions and mechanisms of sleep are not yet fully understood, it is generally accepted that sleep entails restorative mechanisms and aids in the physiological and emotional regeneration of individuals [15, 16]. Sleep performs essential functions in restoring human energy, conserves energy and body metabolism, keeps physiological systems within proper homeostatic limits, maintains host defences, and restores physiological processes that have progressively degraded during wakefulness [16]. Sleep deprivation has been associated with deficits in function across a wide range of indicators of psychological, interpersonal, and somatic well-being [17]. Increasing evidence points to a bidirectional relationship between sleep and health; sleep disturbances contribute to the development of or increase the severity of various medical and psychiatric disorders. Such disorders also have a negative impact on sleep [18]. It is generally accepted that 7–8 h is the optimal amount of sleep needed per night for adequate daytime functioning and to reduce the risk of developing serious medical conditions [12].

During the postpartum period, sleep disturbances are common among new parents [19]. The postpartum (or postnatal) period begins immediately after birth; the initial or acute postpartum phase, refers to the first 6–12 h after childbirth, the subacute postpartum period, refers to 2–6 weeks after birth, and the delayed postpartum period refers to the period up to 6 months after birth [20]. In the subacute and delayed postpartum period, parents of preterm infants are reported to be susceptible to poor sleep because of stress [9, 10]. Parents are often subject to psychological distress related to the infant's health, treatment, survival and risk of disability [21]; the use of complex medical language and technology in the NICU [22]; and the loss of the parental role [21–23]. The emotional burden on parents can last for months [7, 24]; mothers have continued to report high levels of emotional stress [5, 7], and depression [5, 25] after their discharge from hospital. Prematurely born children are also likely to have more sleep problems than full term infants [26], and the sleep problems may last throughout the early years [27]. The role of sleep and its impact on health outcomes for these parents seems to be complex.

In healthy postpartum women, poor sleep has been associated with stress and adverse wellbeing [28], fatigue [29], and depression [10, 30, 31]. Poor parental sleep can negatively affect the parent-child relationship [32] and have a negative effect on parent and family relationships [33]. The mental health of parents with hospitalized neonates has been an increasing concern for clinical paediatric workers in recent years [34]. Parental mental health and parents' ability to be responsive and sensitive to the needs of the preterm infant have been found to be crucial factors in the long-term development of very preterm infants [35, 36]. Establishment of this early physical and emotional contact is important for both the infant and the parents [37]. Sleep-disrupted parents may have fewer opportunities for this important early contact with their child; parents have described negative effects on daily functioning, well-being, and parenting as a result of fatigue caused by sleep disruption [38]. Thus, adequate sleep for parents is crucial to their psychological functioning and ability to support and participate in care for their child [39]. To our knowledge, no review has summarized the existing knowledge of the sleep and health characteristics of parents of preterm infants in the NICU and studied the relationships between sleep and health in this population over time. Therefore, there was a need to summarize the existing evidence on this topic.

Methods

The objective of this scoping review was to identify and map information on sleep and its potential relationships to parental health among parents of preterm infants. More specifically, the review focused on the following questions:

1. What study designs have been used to investigate relationships between sleep and health in parents of preterm infants?
2. Which research instruments have been used to study relationships between sleep and health in parents of preterm infants?
3. What outcomes have been reported regarding sleep and its relation to health in parents of preterm infants?

This scoping review was based on the methodology and guidance for conducting systematic scoping reviews developed by Arksey and O'Malley [40] and further expanded by Levac and colleagues [41]. Levac et al.'s recommendations for refining the methodology included to clearly articulate the research question and link the aim and research questions (stage one); combine feasibility with range and extensiveness of the scoping process (stage two); using an iterative team- based approach in the study selection process (stage three); extracting data (stage four); integrating a numeric summary and qualitative thematic analysis, reporting outcomes, and considering the consequences of study results for policy practice or research (stage five); and finally, incorporating discussion with stakeholders as a compulsory knowledge translation part of the scoping process (stage six) [41]. In this

review, no consultation with stakeholders was performed. According to the recommendations, a suitable team, with content and methodological expertise, was established early in the process to ensure a successful completion of the review. The results are presented as a descriptive numerical summary and textually.

Search terms and search strategies

The search strategy aimed to trace both published and unpublished studies up to March 7, 2017. To prepare for the search process, an identification of the main concepts inherent in the research questions was guided by the elements of a PICOC structure (population, intervention/exposure, comparison, outcome, context) [42]. Three main concepts were identified for the development of search strategies. These concepts were population: parents of preterm infants; interest: sleep; and context: hospital or home settings. A three-step search strategy was performed. First, an initial limited search in Ovid Medline and Cinahl plus with full text (EBSCOhost) was undertaken, followed by an analysis of the text words contained in titles and abstracts, as well as an analysis of the index terms used to describe each article. A second search, using all identified keywords and index terms, was modified and adapted to each database: CINAHL Plus with Full Text (EBSCOhost), MEDLINE, Embase, PsycINFO (all via Ovid SP), Proquest, and Web of Science. The searches were performed based on a building block search strategy [43]. Each main word from PICO was represented by a block of keywords / single words / phrases or controlled nouns. Individual search terms in the same block were combined with OR. Each block was searched separately, and finally, the search boxes were combined with AND so that at least one word from each search block was to be included in the final search block. The proximity operator was used to ensure that words for sleep and parents would appear close to each other (Cinahl; N8 and Medline; adj 9). Truncation marks* were used to search word trunks. In CINAHL Plus with Full Text (EBSCOhost), the key search words included (Mesh headings) ("Parents" +) OR (maternal* OR paternal* OR parent* OR mother* OR father*) OR (Sleep +) OR ("Sleep disorders +") OR ("Wakefulness") OR sleep* OR (Infant, Premature) OR ("Infant, Low Birth Weight +") OR ("Childbirth, Premature") OR ("Intensive Care Units Neonatal"). Keywords used were neonat* OR NICU OR prematur* OR preterm* OR birth weight OR (sleep OR insomnia OR awake OR asleep OR wake OR wakeful* OR REM) N8 (parent* OR mother* OR father* OR caregiver* OR maternal*). After identifying studies, the reference lists of all included studies were searched for additional literature. Citation searches included searches in Google scholar, Scopus, Ovid SP, PubMed and Web of Science. The search for unpublished studies included Prospero and Proquest. The searches were conducted March 2–7, 2017. Figure 1 presents a PRISMA flow diagram from search to the final inclusion of the studies according to Moher et al. [44] (Figure 1).

Search outcome

After the searches in seven electronic databases, the identified papers were transferred to Endnote Reference Manager for removal of duplicates and further exported into a Microsoft Excel format for screening of titles and abstracts. Only studies meeting the inclusion and exclusion criteria were eligible for inclusion in the review. The inclusion criteria were the following: primary studies of quantitative or qualitative design published in English, reporting on sleep in parents (mothers or fathers) of preterm infants (infants born before gestational week 37), and parents' health issues up to one year after the birth of the preterm infant. Health aspects were understood according to the World health organization (WHO's) definition of health [45] and categorized as health concerns about social, physical, or psychological well-being. The exclusion criteria used in the review were the following: not primary studies, studies published in languages other than English, and studies not reporting on parental sleep and health. According to the requirements of the screening process, the team met to discuss decisions surrounding the inclusion and exclusion of studies. Studies were screened independently by two reviewers, and any disagreements were resolved during the screening process. Reviewers met at the beginning, midpoint and final stages to discuss challenges and uncertainties related to study selection, as recommended by Levac et al. [41].

Quality appraisal

Based on the current methodological guidelines for scoping studies [40, 41], no critical appraisal of the strength and quality of the included papers was performed.

Data abstraction

A data extraction sheet was developed to determine which variables to extract to answer the research questions. Each study was screened and extracted according to author, year of publication, country of origin, study design, purpose of study, population, and research instruments used to study sleep and health. A summary of the key findings was also extracted from each study. The results are presented in tables (Tables 1 and 2). Data were extracted by one reviewer and discussed with two other reviewers. Uncertainties and disagreements resulting from data abstraction were resolved through discussion.

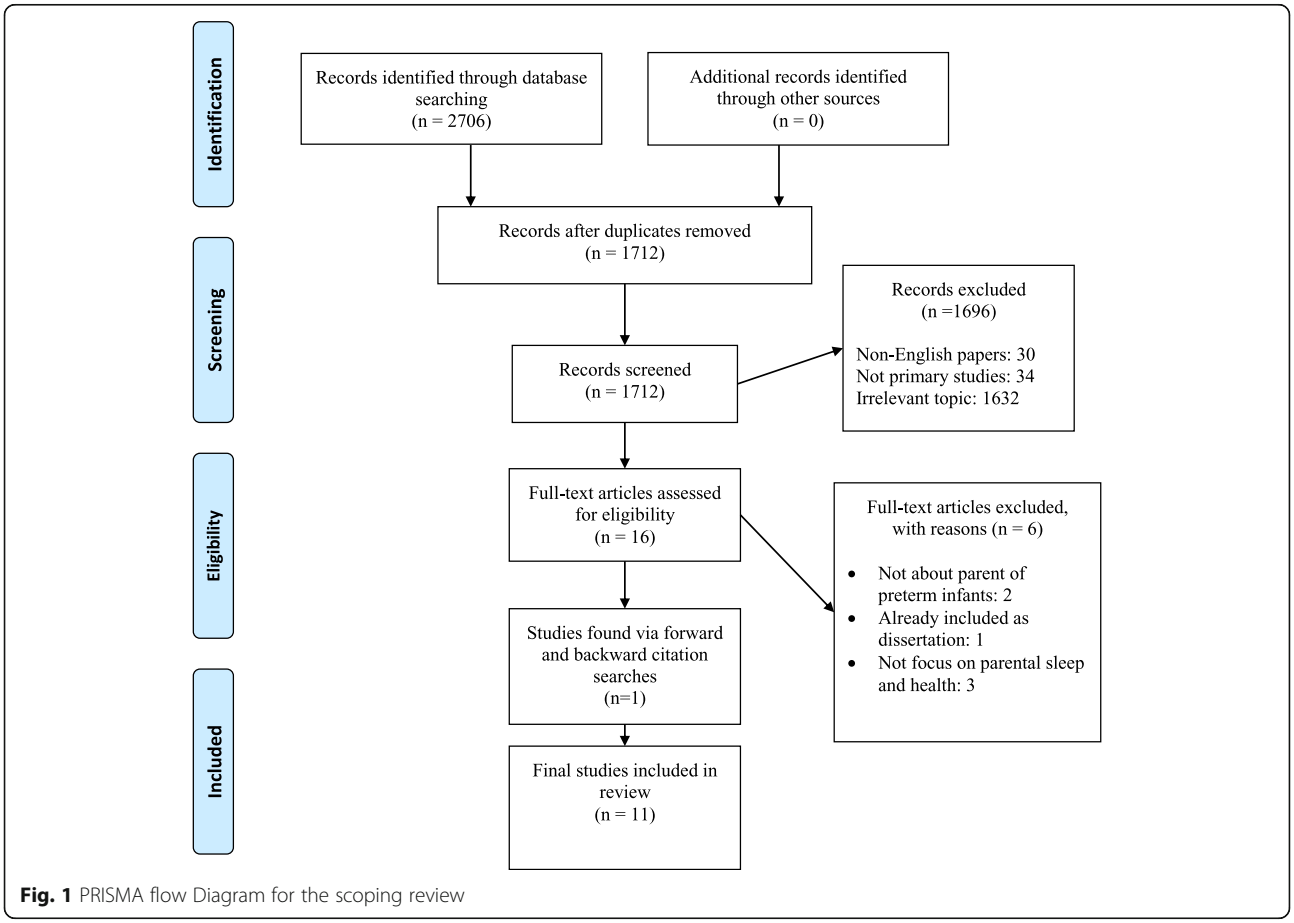

Fig. 1 PRISMA flow Diagram for the scoping review

Synthesis

Consistent with the methodology used in this review, the collating, summarizing and reporting of results were guided by Levac et al.'s recommendations [41]. The methodological process of synthesis was performed in three distinct steps. First, analyses of the included data were performed. Secondly, the results are presented in tabular form (Tables 1 and 2). Thirdly, meaning was applied to the results. Through repeated readings of each article, a thematic analysis was performed according to the purpose and research questions of the review, a process similar to the analytical technique used for qualitative data [41]. The meaning of the findings as they related to the purpose and research questions were discussed with cooperating authors. The researchers decided that the best approach to stating the outcomes and findings was a combination of results presented in tabular form (Tables 1, 2 and 3), followed by a narrative, analytical text responding to each research question.

Results

After completing the screening process, eleven studies were ultimately included in the review. Nine studies were retrieved as articles [46–54], and two were retrieved as dissertations [55, 56] (Table 1). Schaffer had published a paper based on a dissertation [56, 57], but because the dissertation contained more data, only it was included in the review. The amount of research on the topic was found to increase over time, with eight studies published after 2009, and the majority of the literature was geographically concentrated in the United states (U.S.) (Table 1). The existing evidence was dominated by quantitative literature concerning maternal sleep and mental health in the early postpartum phase. Only three studies were concerned with maternal sleep and health characteristics over time after discharge from the NICU wards (Table 1). Fathers were only represented in one qualitative study. Table 1 gives an overview of the key information of the included studies.

Study designs used to investigate sleep and health in parents of preterm infants

Ten of the included studies used a quantitative design, and only one used a qualitative design (Table 1). Among the quantitative literature, five studies used a cross sectional design [47–51], and three were cohort studies [52–54]. Schaffer used a prospective, repeated data analysis performed over an 8-week period [56]. Two clinical

Table 1 Key information included studies

Author, Country	Purpose	Study design	Sample	Key findings
Lee & Kimble (2009), USA	Explore relationships between impaired sleep and wellbeing in mothers with low birth weight infants (LBW) in the NICU.	Cross sectional	20 mothers of preterm LBW infants in the NICU	Poor sleep quality and disturbed daytime function, night-time TST was ≤7 h. The mothers took more time to fall asleep compared to normal adults. Daytime sleep was < 1 h. Mothers reported moderate depressive symptoms. HRQoL was 1 SD below the normative score for age-matched females in the US. Mothers with more sleep debt reported more fatigue severity, depression and poorer HRQoL.
Lee & Hsu (2012a), USA	Examine the relationship among sleep, stress, depression, fatigue and H- QoL among mothers with a LBW infant in the NICU early postpartum.	Cross sectional	55 mothers of preterm LBW infants in the NICU	Poor sleep quality in mothers was associated with stress, fatigue, depression and poor HRQoL. Maternal stress contributed to poor sleep quality and depression, which in turn contributed to poor HRQoL.
Lee et al. (2012b), USA	Describe daytime activity levels and their associations with sleep, fatigue, depressive symptoms and quality of life.	Cross sectional	51 mothers of preterm infants in the NICU	Compared to high activity mothers, mothers with low activity levels slept less at night-time and napped more during the daytime, and they reported more postpartum depressive symptoms. Higher daytime activity was associated with fewer depressive symptoms. More sleep was associated with less severe fatigue.
Lee & Hsu (2016), USA	Examine whether depressive symptoms and sleep disturbance in black mothers would vary as a function of the 5-HTTLPR when they faced the stress of infant hospitalization after preterm birth early postpartum.	Cross sectional	30 mothers of preterm LBW infants in the NICU	Mothers with the L/L allele reported greater sleep disturbances than those with the S/L allele. Mothers' perceived global stress, depressive symptoms, and circadian activity rhythms did not vary with their 5- HTTLPR genotype.
Shelton et al. (2014), USA	Compare the levels of self-reported perceived global and situational stress, sleep disturbance and the level of wellness between mothers with an infant in the NICU who are categorized as having high or low depressive symptoms.	Cross sectional	55 mothers of preterm infants in the NICU	All the mothers in this study experienced poor sleep. Mothers reported a moderate level of morning fatigue, and their HRQoL for physical and mental components were below the norm. Mothers with higher depressive symptoms reported greater stress and experienced poorer sleep.
Schaffer (2012), USA	Describe maternal and infant factors that influence sleep quality; examine the relationships between depression, anxiety, stress, social support and sleep quality, and describe the influence of a RGI intervention on sleep quality among a sample of mothers whose preterm babies were admitted to the NICU.	Prospective descriptive data analysis. Clinical trial.	20 mothers of preterm infants in the NICU	Anxiety, depression, stress and lower income were related to poor sleep quality; social support and increased age were related to better sleep quality. With cumulative R-GI use, sleep quality improved. The participants reported that the intervention of R-GI assisted them in falling asleep and in reducing stress.

Table 1 Key information included studies *(Continued)*

Author, Country	Purpose	Study design	Sample	Key findings
Lee et al. (2013), USA	Examine the effectiveness of a 3-week bright light therapy RCT intervention on sleep and health outcomes of mothers with LBW infants in the NICU.	Clinical trial	30 mothers of preterm LBW in the NICU	Mothers in the treatment group improved in nocturnal TST, CAR, morning fatigue, depressive symptoms, and HRQoL compared to the control group. The 3-week bright light intervention combined with sleep hygiene materials appeared promising for maternal sleep early postpartum.
Williams & Williams (1997), USA	To assess simultaneous interactions among variables in a path diagram. The variables assessed were caregiver fatigue, sleep effectiveness, perception of stress, reframing capacity within the family, family cohesion, family income, and the placement of a preterm on an apnea monitor.	Cohort	74 mothers of preterm infants in the NICU and at home	Path diagrams increased in complexity over time. At all measure points, sleep effectiveness tended to decrease fatigue. When sleep effectiveness increased, the levels of fatigue decreased.
Gennaro & Fehder (2000), USA	Examine the difference in health behaviours among mothers of preterm, VLBW infants and mothers of healthy term infants.	Cohort	64 mothers of VLBW preterm infants and 60 mothers of full-term infants in the NICU and at home	No differences were noted in sleep between mothers of preterm infants and term infants. The amount of sleep per night did not change significantly over time; the mothers were successful in managing sleep.
McMillen et al. (1993), Australia	Compare the effects of the demands of term and preterm infants on the daily rhythms of sleep and wakefulness and salivary melatonin and cortisol concentrations in mothers.	Cohort	23 mothers of term infants and 22 mothers of preterm infants at home.	Mothers of preterm infants slept less, were more awake, had less time asleep and fewer sleep bouts per 24 h compared to the mothers of full-term infants. Cortisol and melatonin salivary tests varied between the groups, maybe because of greater physio logical disruption in mothers of preterm infants.
Wollenhaupt (2010), USA	Explore the experience of mothers and fathers as they integrate their premature infant into the family at home.	Naturalistic inquiry	Parents of 10 preterm infants at home	After coming home with the baby, most of the parents described their sleeping experiences like soldiers in combat. Parents had a heightened awareness of sounds in the night, stood guard over and wakened to check on the baby. The best nights of sleep consisted of 3–5 h of interrupted sleep. Fathers described their inability to catch up on sleep; they went to work early or awakened to take care of the baby, so the mother could sleep; and they had less opportunity to take naps during the daytime compared to mothers.

Abbreviations Table 1: *TST* total sleep time, *VLBW* very low birth weight, *NICU* neonatal intensive care unit, *LBW* low birth weight, *RCT* randomized control trial, *R-GI* relaxation guided imagery intervention, *HRQoL* health related quality of life, *SD* standard deviation, *CAR* circadian activity rhythm, *5-HTTLPR* Serotonin-transporter-linked polymorphic region

Table 2 Study designs and instruments used to study sleep and health

Author Year Country	Design	Sample	Context	Time data collection	Instruments used to study sleep	Instruments used to study health
Lee & Kimble (2009), USA	Quantitative, cross sectional	20 mothers of LBW infants	NICU	Second week postpartum	Self-report: Sleep rated for the past week (GSDS), sleep diary (2 days) Objective: actigraphy for 2 days.	Fatigue: NRS-F Depression: EPDS Health related quality of life: SF36v2
Lee & Hsu (2012a), USA	Quantitative, cross sectional	55 mothers of LBW infants	NICU	Second week postpartum	Self-report: Sleep rated for the past week (GSDS), SDI, sleep diary. Objective: Actigraphy 2 days ($N = 20$) and 3 days ($N = 35$)	Fatigue: LFS Depression: EPDS Stress: PSS and IES Health related quality of life: SF36v2
Lee et al. (2012b), USA	Quantitative, cross sectional, comparative	51 mothers of preterm infants	NICU	Second week postpartum	Self-report: Sleep rated for the past week (GSDS), sleep diary. Objective: Actigraphy 2–3 days	Fatigue: LFS Depression: EPDS Health related quality of life: SF36v2 Activity: actigraphy to measure rest/activity pattern
Lee & Hsu (2016), USA	Quantitative, cross sectional, comparative	30 mothers of LBW infants	NICU	Second week postpartum	Subjective: Sleep rated for the past week (GSDS), sleep diary. Objective: Actigraphy 3 days	Depression: EPDS Stress: PSS Serum: Test serotonin transporter polymorphism (5 HTTLPR) genotype.
Shelton et al. (2014), USA	Quantitative, cross sectional comparative design	55 mothers of preterm infants	NICU	Second week postpartum	Self-report: Sleep rated for the past week (GSDS), sleep diary (2–3 days). Objective: Actigraphy 2–3 days	Fatigue: LFS Depression: EPDS Stress: PSS Health related quality of life: SF36v2
Schaffer (2012), USA	Quantitative Prospective descriptive data analysis Clinical trial	20 mothers of preterm infants	NICU	Repeated measures over eight weeks postpartum	Self-report: PSQI	Anxiety: STAI Depression: CES-D Stress: PSS Social support: FSSQ + A brief semi structured interview on the acceptability of the R-GI intervention.
Lee et al. (2013), USA	Quantitative, clinical trial	30 mothers of LBW infants randomized to a treatment or control group.	NICU	Data collected at pretreatment (second week postpartum) and after 3-week intervention.	Self-report: Sleep rated for the past week (GSDS), sleep diary for 3 days Objective: Actigraphy 3 days	Fatigue: LFS Depression: EPDS Stress: PSS Health related quality of life: SF36v2 Maternal perceived support: FSS
Williams & Williams (1997), USA	Quantitative, cohort, comparative	74 mothers of preterm infants	NICU and home T1/Baseline = NICU T2 = one-week post-discharge T3 = one-month post-discharge.	Data were collected at three-time periods; baseline, one-week post discharge and one-month post discharge	Self-report: Subscale of the VHS Sleep Scale.	Stress: PSS Fatigue: MAF, Reframe: FCOPES, Cohesion: FACES II

Table 2 Study designs and instruments used to study sleep and health *(Continued)*

Author Year Country	Design	Sample	Context	Time data collection	Instruments used to study sleep	Instruments used to study health
Gennaro & Fehder (2000), USA	Quantitative, longitudinal, comparative	124 mothers, 64 with a VLBW preterm infant and 60 with a full-term infant	NICU and home	Data collected within 24 h after birth, + home (1 month, 2 months, and 4 months postpartum)	Self-report: SWAI and SSS.	Maternal weight loss, Nutritional intake: 24-h diet recall, Exercise: FWPA
McMillen et al. (1993), Australia	Quantitative, cohort, comparative	Mothers of 23 term infants and 22 preterm infants	Home	Up to 5 months after either birth (term group) or arrival of the infant home (preterm group).	Self-report: 24-h sleep/wake chart for infant and mother (completed by mother).	Saliva: Melatonin and cortisol tests.
Wollenhaupt (2010), USA	Qualitative, Natural inqury design	Mothers and fathers in 10 families.	Home	3–5 weeks following discharge from NICU	Semi-structured interviews	

Abbreviations: *SDI* Sleep deviation Index, *LFS* Lee Fatigue Scale, *PSS* Perceived Stress Scale, *MAF* Multidimensional Assessment of Fatigue, *FCOPES* subscale of the Family Crisis Oriented Personal Evaluation Scale, *FACES II* Cohesion subscale of the Family Adaptability and Cohesion Scale, *FWPA* the four-week physical activity questionnaire, *SF36v2* The Medical Outcomes Short Form 36 version 2, *FSS* Family Support scale, *EPDS* Edinburgh Postpartum Depression scale, *FSSQ* The Duke University of North Carolina Functional Social Support Questionnaire, *STAI* State-Trait Anxiety Inventory, *CES-D* Center for Epidemiological Studies Depression Scale, *SWAI* Sleep Wake Activity Inventory scale, *SSS* Stanford Sleepiness Scale 52, *GSDS* General Sleep Disturbance scale, *VHS sleep scale* Verran and Snyder-Halpern Sleep Scale (VSH), *PSQI* The Pittsburgh Sleep Quality Index, *NICU* neonatal intensive care unit, *LBW* low birth weight, *VLBW* very low birth weight

Table 3 Significant correlations identified between sleep and health

Author, year of publication, country of origin	N=	Sleep	Mental health					Wellbeing		Social health
			Fatigue		Anxiety	Stress	Depression	HRQOL		Social support
			Morning	Evening				Mental	Physical	
Lee & Kimble (2009), USA	20	GSDS	.52*	.51*	–	–	ns	−.53*	ns	
		Sleep quality	ns	.54*	–	–	ns	−.55*	ns	
		Daytime function	.55*	.52*	–	–	ns	−.48*	−.45*	
		TST	ns		–	–	ns	ns	ns	
		WASO			–	–		ns	ns	
		Sleep debt	.48*	ns	–	–	ns	ns	ns	
Lee et al. (2012b), USA	51	CAR	ns		–	–	ns	ns	ns	
		TST	−.30*	–	–	–	ns	ns	ns	
		WASO	ns		–	–	ns	ns	ns	
		Sleep quality	.38**	–	–	–	ns	−.49*	−.38*	
Lee & Hsu (2012a), USA	55	Sleep quality index	.54**		–	.36**	ns	−.49*	−.34*	
		TST	ns		–	–	–	ns	ns	
		WASO	ns		–	–	–	ns	ns	
		SDI	ns		–	–	–	ns	ns	
Schaffer (2012), USA	20	Sleep quality	–		.514*‡	ns	.496*†	–		−.462* †
Gennaro & Fehder (2000), USA	23	SWAI	ns							
		SSS								

Notes: Asterisk (*) indicated correlation was significant at $p < .05$, (**) indicated correlation was significant at $p < .01$. ns = not statistically significant, – not measured, † baseline value, ‡ Time 2 measure point value
Abbreviations: *GSDS* General Sleep Disturbance scale, *WASO* wake after sleep onset in minutes, *CAR*, circadian activity rhythms, *SDI* sleep deviation index, *TST* nighttime total sleep time monitored from actigraphs, *SWAI* the sleep wake activity inventory, *SSS* the Stanford Sleepiness Scale

trials were identified [46, 56]. One qualitative study was based on a naturalistic inquiry design, as described by Lincoln and Guba [55]. Table 1 presents an overview of the study designs.

Questionnaires, diaries and actigraphs used to study sleep in parents of preterm infants

In the quantitative studies, a variety of research instruments were used to study sleep. Six papers reported on objective sleep data derived from wrist actigraphs, which are small monitors used to assess rest-activity patterns [58]. The actigraphs were used to study maternal sleep early postpartum for short periods of 2–3 days, and they were not used in research performed after discharge from hospital (Table 2). The objective sleep measures from actigraphs were supplemented with patient-reported outcome measures (PROMs), standardized measures developed to capture patient-reported outcomes [59]. Sleep questionnaires and sleep diaries were examples of PROMs used to assess sleep. Sleep diaries were subjective sleep assessments of individuals' sleeping and waking times, accompanied by related information [60]. The sleep questionnaires were used to evaluate various aspects of sleep, such as sleep disturbances, sleep quality, sleep characteristics and sleepiness (Table 2). The spectrum and breadth of research tools used to assess sleep in the early postpartum period provided very detailed knowledge of sleep characteristics during this phase. The breadth and specificity of research tools used after discharge from hospital was not so distinct; PROMs were used to evaluate (daytime) sleepiness [53] and maternal sleep characteristics [52]. Compared to the early postpartum period, the insights derived from these tools were less specific. The instruments used to study sleep are presented in Table 2.

Questionnaires and research instruments used to study health in parents of preterm infants

Different research tools have been used to study health, with PROMs being used most commonly in the literature. Only one study reported on objective measures exclusively [54]. Twelve different PROMs were identified, with assessments of depressive symptoms, anxiety, stress, fatigue, health-related quality of life (HRQoL), social support, reframe, cohesion, and physical health (Table 2). Physical health was studied with objective measures such as actigraphs to explore daily rest/activity patterns, measures of body weight, and blood samples (Table 2). In the research, the most frequently studied aspect of health was mental health, followed by HRQoL and physical health. Social health was the least studied health component. Table 2 provides an overview of the research instruments used to study health.

Sleep and health in parents of preterm infants

In the early phase after childbirth, maternal sleep was described as poor. Data derived from actigraphs indicated that maternal total sleep time (TST) was less than 7 h [47–51]. Sleep was also fragmented, with frequent nightly awakenings and increased sleep time during the daytime [47, 49, 50]. According to PROMs, the mothers evaluated their sleep as poor [47, 48, 56]. Surprisingly, many of the mothers slept poorly despite the fact that they spent their nights at home and did not provide care for their hospitalized preterm infants [47–51]. The post-discharge experiences of mothers with preterm infants were described as complex [52]. Two cohort studies compared sleep between mothers of preterm and term infants over time [53, 54] and found contradictory results. Gennaro and Fehder [53] did not find any differences in sleep between the two groups of mothers at any measure points, while McMillen et al. [54] found that mothers of preterm infants slept less and had fewer sleep bouts compared to mothers of term infants. The findings did not clearly suggest that the mothers of preterm infants experienced poorer sleep compared to mothers of term infants over time. Additionally, qualitative literature supported the notion that sleep was challenged after coming home with the preterm infant [55]. The majority of parents described their sleeping experiences in a similar fashion to soldiers in combat. Parents described how they got small bursts of sleep in a variety of diverse ways; some parents tried to catch sleep whenever they could because they were so affected by lack of sleep [55]. In this study, the fathers described their inability to catch up on sleep. They took care of the baby so the mother could sleep, or they went to work early in the morning and had no opportunity to nap during the day compared to the mothers [55].

According to the outcomes of their sleep, some mothers were more susceptible than others to experiencing poor sleep. Shelton et al. [51] compared mothers of preterm infants with high or low depressive symptoms and reported poorer sleep in the group with high depressive symptoms. Lee et al. [47] compared mothers with high and low daytime activity levels and reported poorer sleep in the group with low activity levels. Additionally, Lee and Hsu [50] examined whether depressive symptoms and sleep disturbances would vary as a function of the 5-HTTLPR genotype (the short allele of 5-HTTLPR has been associated with depression and sleep disturbances). Surprisingly, the mothers with the long allele for the genotype reported greater sleep disturbances compared to mothers with the short (S/L) allele.

Interventions to promote sleep and health in parents of preterm infants

Two clinical trials were identified in the material. Both interventions were developed to promote maternal sleep and health early postpartum. Lee et al. [46] tested the effect of bright light therapy on sleep and health outcomes in mothers of preterm infants hospitalized in the NICU.

The intervention was evaluated as feasible, since the mothers in the treatment group showed improvements in TST and self-rated sleep quality. Schaffer [56] tested the effects of an eight-week relaxation guided imagery intervention (R-GI) on maternal sleep quality. The R-GI intervention was found to be an effective strategy to improve maternal stress and coping early postpartum in the NICU.

Associations between sleep and health in parents of preterm infants

As shown above, different health outcomes were reported in the included studies (Table 1). Only five studies computed data analysis of statistical correlations among sleep and health variables [47–49, 53, 56], and four of these found statistically significant results (Table 3). The qualitative study also presented findings suggesting an association between sleep and health [55]. In the quantitative studies, a positive significant correlation was reported between sleep and maternal fatigue [47–49], sleep and anxiety [56], sleep and stress [48], and sleep and depression [56]. The positive correlation showed that high scores for poor sleep were associated with high scores for stress, fatigue and anxiety in mothers early postpartum (Table 3). Social support was negatively correlated with sleep [56]; when social support increased, quality-of-sleep scores decreased (decreased sleep quality scores indicated better sleep quality). Additionally, lower HRQoL (mental and physical) was associated with poorer levels of sleep quality [47, 49] and daytime functioning [49]. The qualitative literature suggested associations between sleep and parental health [55]. In Wollenhaupts dissertation [55], parents expressed how sleep loss after homecoming with a preterm baby affected their daily life. The parents felt exhausted and run down, had less ability to think clearly, and cope with daily life situations. Lack of sleep also impacted the parents' relationship in a negative way. Getting from 2 to 5 h of sleep at night over a period of weeks lead to such feelings [55]. Table 3 presents an overview of the significant correlation identified between sleep and health.

Discussion

In neonatal care, care provision is influenced by parental mental health and well-being [34]. The ability of parents to establish emotional closeness to the preterm infant may be crucial to the wellbeing of the infant [61] and has been shown to have a long-term impact on the function of affective relationships and healthy development outcomes [62]. An understanding of parents' sleep and health characteristics in the postpartum period can contribute valuable insights into how parents are affected by and adapt to incidents such as preterm birth. As shown, the mothers of hospitalized preterm infants are likely to experience clinically significant sleep disturbances in the early postpartum phase, which is surprising because many mothers slept at home and did not provide care for the preterm infants [46–51]. These findings are supported elsewhere. Blomqvist et al. [63] found significantly more severe levels of insomnia in mothers compared to fathers early postpartum, and maternal insomnia levels were independent of sleep location. A plausible explanation was that the mothers experienced the same amount of stress and anxiety regardless of sleep location [63]. Mothers of preterm infants are at risk for poor sleep, and they need help and support from health care personnel to meet their basic need for sleep, regardless of sleep location. The findings of this review not only illustrate that mothers' sleep is challenged but also highlight the major psychological stress and emotional challenges that mothers face. In addition to being associated with poor sleep, being a mother of a hospitalized preterm infant is associated with stress, anxiety, fatigue, depression and risk of poor HRQoL [46–51, 56]. In a recent study, Busse et al. [10] reported similar findings. Parents in the NICU experienced emotional and physical constellations of anxiety, depression, fatigue and sleep disruption. The findings showed that mothers of preterm infants experience a transition to motherhood that has the potential to disrupt the entire balance of their lives, and the combination of poor sleep and emotional responses described requires more attention and future effort from healthcare personnel. In neonatal care, one of the greatest challenges facing neonatal nurses is how to provide care that supports the needs of mothers and infants. Nurses must understand maternal perceptions, expectations and needs to meet these challenges [64]. Accordingly, NICU nurses must be aware and show awareness of maternal expectations and experiences. Recognizing different types of parental reactions is essential if nurses are to optimize the outcome for the parents [65]. Suggested preventive care for postpartum women includes assessing maternal sleep and depression during the postpartum period and providing sleep hygiene information to promote sleep for NICU parents [46]. Routine screening tools and inquiries about stress and sleep patterns have also been introduced as efforts to recognize symptoms in the early postpartum phase [51]. Advice from healthcare providers to maintain consistent sleep-wake schedules, as well as instruction in relaxation techniques, can be other helpful approaches to achieving more sleep and better sleep quality [66]. During the hospitalization period, parents must be confident and prepared – with tailored information and guidance – to take their infants home [67]. Ideally, neonatal nurses could begin parental support processes while infants are still in the NICU and continue these processes after discharge [68]. In future research, efforts to promote sleep must be evaluated in studies with a

long-term perspective, and interventions should be tested in studies with large study samples using assorted research instruments to assess sleep. Surprisingly, none of the studies in this review evaluated parental sleep over time by using modern research tools such as actigraphs or sleep diaries. The use of actigraphs has been shown to be a feasible way to provide sleep data in large epidemiologic studies and is considered important in follow-up studies and for examining treatment efficacy in clinical outcomes [69]. A recent study showed that actigraphs should be used for at least 7 nights to measure total sleep time, and sleep efficiency should be measured for at least 5 nights [70]. Additionally, sleep diaries have become widely used in modern sleep research and are considered today's gold standard for subjective sleep assessment [71]. Recommendations for future research are therefore to explore sleep among parents of preterm infants with both objective and subjective research tools, evaluate sleep characteristics over time, and collect data over longer time periods. Compared to recent studies, future research could also benefit from more variation in study design in the exploration of parental sleep. Qualitative study designs are considered to be particularly well suited to understanding causal relationships [72]. Qualitative studies may provide a deeper understanding of how sleep is affected and experienced by parents and may help to explore the complex association between sleep and health. Because fathers are equal partners in care for the preterm infant [73], future research could benefit from using study populations that also include fathers. Carter et al. [74] found that infant prematurity negatively impacted fathers. Fathers of preterm infants have also reported higher stress rates compared to mothers 4 months postpartum [75], but more needs to be learned about the role of sleep.

Strengths and limitations

To the best of the authors' knowledge, this was the first scoping review to summarize the existing evidence on sleep and its relationships to health in parents of preterm infants. The strengths of this review are its broad and comprehensive search in the electronic databases, inclusion of quantitative and qualitative literature, and lack of restrictions on date range in the literature searches. One limitation of the findings in this scoping review is the lack of cultural and geographical breadth. The included research was predominated by studies from U.S, resulting in findings with geographical concentration in western societies, and study populations characterized by ethnic specificity [46, 47, 50, 51]. Therefore, the extent to which the results can be used and generalized to parents in other geographical areas worldwide remains unclear.

Another limitation was the lack of qualitative research in this review's findings. Qualitative research is considered to be especially useful in contributing with in debt knowledge and a deeper understanding of complex human phenomenon's [72], and could have given valuable knowledge on this reviews topic. The existing research was also limited in time, most of the articles focused on the two first weeks after the preterm birth. Therefore, the knowledge of what happens to parental sleep and health in the later timeframe after birth, was limited. In addition to this, substantial heterogeneity in how parental sleep was documented, both subjectively and objectively, made it difficult to compare the results in the later, delayed postpartum period. A last limitation was also the lack of knowledge on fathers' sleep and health, since the overall research in this review was performed on mothers.

Conclusions

This review addresses concerns about parental sleep, health and well-being. Despite limitations on the applicability of the results to parents globally, efforts to promote sleep and health may be a prominent issue for health care providers in hospital settings worldwide. More needs to be learned about fathers' sleep and health and about whether the long-term consequences to sleep and health differ for parents of preterm infants. Knowledge of sleep and health characteristics might be the first step toward developing efforts and interventions to promote a healthy parent population.

Abbreviations

5-HTTLPR: Serotonin-transporter-linked polymorphic region; HRQoL: Health related quality of life; MeSH: Medical subject headings; NICU: Neonatal intensive care unit; PICOC: Population, intervention/exposure, comparison, outcome, context; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PROM: Patient reported outcome measures; REM: Rapid eye movement sleep; R-GI: Relaxation guided imagery intervention; TST: Total sleep time; U.S: United states; WHO: World health organization

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Authors' contributions

GNM, SH and LF were responsible for the study's conception and design. GNM and LF performed the data collection and analysis. LF and SH contributed to meetings and performed critical revisions during the review process and paper development. All authors read and approved the final manuscript.

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References
1. World health organization [WHO]. Preterm birth 2016 http://www.who.int/mediacentre/factsheets/fs363/en/. Accessed 06.11.2017.
2. Blencowe H, Cousens S, Oestergaard MZ, Chou D, Moller AB, Narwal R, et al. National, regional, and worldwide estimates of preterm birth rates in the year 2010 with time trends since 1990 for selected countries: a systematic analysis and implications. Lancet. 2012;379:2162–72. https://doi.org/10.1016/S0140-6736(12)60820-4.
3. Miles SM, Holditch-Davis AD, Schwartz AT, Scher AM. Depressive symptoms in mothers of prematurely born infants. J DevBehav Pediatr. 2007;28:36–44. https://doi.org/10.1097/01.DBP.0000257517.52459.7a.
4. Mousavi SS, Chaman R, Khosravi A, Mohagheghi P, Mousavi SA, Keramat A. The needs of parents of preterm infants in Iran and a comparison with those in other countries: a systematic review and meta-analysis. Iran J Pediatr. 2016;26:1–18. https://doi.org/10.5812/ijp.4396.
5. Davis L, Edwards H, Mohay H, Wollin J. The impact of very premature birth on the psychological health of mothers. Early Hum Dev. 2003;73:61–70. https://doi.org/10.1016/S0378-3782(03)00073-2.
6. Singer LT, Salvator A, Guo S, Collin M, Lilien L, Baley J. Maternal psychological distress and parenting stress after the birth of a very low-birth-weight infant. JAMA. 1999;281:799–805. https://doi.org/10.1001/jama.281.9.799.
7. Holditch-Davis D, Bartlett TR, Blickman AL, Miles MS. Posttraumatic stress symptoms in mothers of premature infants. J Obstet Gynecol Neonatal Nurs. 2003;32:161–71. https://doi.org/10.1177/0884217503252035.
8. Lau R, Morse CA. Stress experiences of parents with premature infants in a special care nursery. Stress Health. 2003;19:69–78. https://doi.org/10.1002/smi.964.
9. Edell-Gustafsson U, Angelhoff C, Johnsson E, Karlsson J, Morelius E. Hindering and buffering factors for parental sleep in neonatal care. A phenomenographic study. J Clin Nurs. 2015;24:717–27. https://doi.org/10.1111/jocn.12654.
10. Busse M, Stromgren K, Thorngate L, Thomas KA. Parents' responses to stress in the neonatal intensive care unit. Crit Care Nurse. 2013;33:52–60. https://doi.org/10.4037/ccn2013715.
11. Stremler R, Dhukai Z, Wong L, Parshuram C. Factors influencing sleep for parents of critically ill hospitalised children: a qualitative analysis. Intensive Crit Care Nurs. 2011;27:37–45. https://doi.org/10.1016/j.iccn.2010.11.001.
12. Luyster FS. Sleep and Health. In: Gellman MD, Turner JR, editors. Encyclopedia of behavioral medicine. New York, NY: Springer New York; 2013. p. 1799–1802.
13. Lee KA. Sleep promotion in the childbearing family. In: Redeker NS, Mcenany GP, editors. Sleep disorders and sleep promotion in nursing practice. New York: Springer publishing company; 2011. p. 261–73.
14. Hall MH. Sleep. In: Gellman MD, Turner JR, editors. Encyclopedia of behavioral medicine. New York, NY: Springer New York; 2013. p. 1795–1799.
15. Eugene AR, Masiak J. The neuroprotective aspects of sleep. MEDtube science. 2015;3:35–40.
16. Landis CA. Physiological and behavioural aspects of sleep. In: Redeker NS, McEnany GP, editors. Sleep disorders and sleep promotion in nursing practice. New York: Springer; 2011. p. 1–17.
17. Roberts RE, Duong HT. The prospective association between sleep deprivation and depression among adolescents. Sleep. 2014;37:239–44. https://doi.org/10.5665/sleep.3388.
18. Zee PC, Turek FW. Sleep and health - Everywhere and in both directions. Arch Intern Med. 2006;166:1686–8. https://doi.org/10.1001/archinte.166.16.1686.
19. Insana SP, Montgomery-Downs HE. Sleep and sleepiness among first-time postpartum parents: a field- and laboratory-based multimethod assessment. Dev Psychobiol. 2013;55:361–72. https://doi.org/10.1002/dev.21040.
20. Romano M, Cacciatore A, Giordano R, La Rosa B. Postpartum period: three distinct but continuous phases. J Prenat Med. 2010;4:22–5.
21. Holditch-Davis D, Miles MS. Mothers' stories about their experiences in the neonatal intensive care unit. Neonatal netw. 2000;19:13–21. https://doi.org/10.1891/0730-0832.19.3.13.
22. Lefkowitz D, Baxt C, Evans J. Prevalence and correlates of posttraumatic stress and postpartum depression in parents of infants in the neonatal intensive care unit (NICU). J Clin Psychol Med Settings. 2010;17:230–7. https://doi.org/10.1007/s10880-010-9202-7.
23. Alkozei A, McMahon E, Lahav A. Stress levels and depressive symptoms in NICU mothers in the early postpartum period. J Matern Fetal Neonatal Med. 2014;27:1738–43. https://doi.org/10.3109/14767058.2014.942626.
24. Shaw RJ, Deblois T, Ikuta L, Ginzburg K, Fleisher B, Koopman C. Acute stress disorder among parents of infants in the neonatal intensive care nursery. Psychosomatics. 2006;47:206–12. https://doi.org/10.1176/appi.psy.47.3.206.
25. Vigod SN, Villegas L, Dennis CL, Ross LE. Prevalence and risk factors for postpartum depression among women with preterm and low-birth-weight infants: a systematic review. BJOG. 2010;117:540–50. https://doi.org/10.1111/j.1471-0528.2009.02493.x.
26. Huang YS, Paiva T, Hsu JF, Kuo MC, Guilleminault C. Sleep and breathing in premature infants at 6 months post-natal age. BMC Pediatr 2014;14. doi: ARTN 303https://doi.org/10.1186/s12887–014–0303-6.
27. Stangenes KM, Fevang SK, Grundt J, Donkor HM, Markestad T, Hysing M, et al. Children born extremely preterm had different sleeping habits at 11 years of age and more childhood sleep problems than term-born children. Acta Paediatr. 2017;106:1966–72. https://doi.org/10.1111/apa.13991.
28. Posmontier B. Sleep quality in women with and without postpartum depression. J Obstet Gynecol Neonatal Nurs. 2008;37:722–35; quiz 35-7. https://doi.org/10.1111/j.1552-6909.2008.00298.x.
29. Gay CL, Lee KA, Lee SY. Sleep patterns and fatigue in new mothers and fathers. Biol Res Nurs. 2004;5:311–8. https://doi.org/10.1177/1099800403262142.
30. Goyal D, Gay CL, Lee KA. Patterns of sleep disruption and depressive symptoms in new mothers. J Perinat Neonatal Nurs. 2007;21:123–9. https://doi.org/10.1097/01.JPN.0000270629.58746.96.
31. Dennis CL, Ross L. Relationships among infant sleep patterns, maternal fatigue, and development of depressive symptomatology. Birth. 2005;32:187–93. https://doi.org/10.1111/j.0730-7659.2005.00368.x.
32. Stickland A, Clayton E, Sankey R, Hill CM. A qualitative study of sleep quality in children and their resident parents when in hospital. Arch Dis Child. 2016;101:546–51. https://doi.org/10.1136/archdischild-2015-309458.
33. Medina AM, Lederhos CL, Lillis TA. Sleep disruption and decline in marital satisfaction across the transition to parenthood. Fam Syst Health. 2009;27:153. https://doi.org/10.1037/a0015762.
34. Kong LP, Cui Y, Qiu YF, Han SP, Yu ZB, Guo XR. Anxiety and depression in parents of sick neonates: a hospital-based study. J Clin Nurs. 2013;22:1163–72. https://doi.org/10.1111/jocn.12090.
35. Clark CA, Woodward LJ, Horwood LJ, Moor S. Development of emotional and behavioral regulation in children born extremely preterm and very preterm: biological and social influences. Child Dev. 2008;79:1444–62. https://doi.org/10.1111/j.1467-8624.2008.01198.x.
36. Treyvaud K, Anderson VA, Lee KJ, Woodward LJ, Newnham C, Inder TE, et al. Parental mental health and early social-emotional development of children born very preterm. J Pediatr Psychol. 2010;35:768–77. https://doi.org/10.1093/jpepsy/jsp109.
37. Flacking R, Lehtonen L, Thomson G, Axelin A, Ahlqvist S, Moran VH, et al. Closeness and separation in neonatal intensive care. Acta Paediatr. 2012;101:1032–7. https://doi.org/10.1111/j.1651-2227.2012.02787.x.
38. Giallo R, Rose N, Cooklin A, McCormack D. In survival mode: mothers and fathers' experiences of fatigue in the early parenting period. J Reprod Infant Psychol. 2013;31:31–45. https://doi.org/10.1080/02646838.2012.751584.
39. Stremler R, Wong L, Parshuram C. Practices and provisions for parents sleeping overnight with a hospitalized child. J Pediatr Psychol. 2008;33:292–7. https://doi.org/10.1093/jpepsy/jsm096.

40. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol. 2005;8:19–32. https://doi.org/10.1080/1364557032000119616.
41. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. Implement Sci. 2010;5:69. https://doi.org/10.1186/1748-5908-5-69.
42. Booth A, Sutton A, Papaioannou D. Systematic approaches to a successful literature review. 2nd ed. ed. Los Angels, Cal: Sage; 2016.
43. Booth A. Unpacking your literature search toolbox: on search styles and tactics. Health Inf Libr J. 2008;25:313–7. https://doi.org/10.1111/j.1471-1842.2008.00825.x.
44. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. Ann Int Med. 2009;151:264.
45. World health organization [WHO]. About WHO. 2017. http://www.who.int/about/mission/en/. Accessed 06.11.2017.
46. Lee SY, Aycock DM, Moloney MF. Bright light therapy to promote sleep in mothers of low-birth-weight infants: a pilot study. Biol Res Nurs. 2013;15:398–406. https://doi.org/10.1177/1099800412445612.
47. Lee SY, Grantham CH, Shelton S, Meaney-Delman D. Does activity matter: an exploratory study among mothers with preterm infants? Arch Womens Ment Health. 2012b;15:185–92. https://doi.org/10.1007/s00737-012-0275-1.
48. Lee SY, Hsu HC. Stress and health-related well-being among mothers with a low birth weight infant: the role of sleep. Soc Sci Med. 2012a;74:958–65. https://doi.org/10.1016/j.socscimed.2011.12.030.
49. Lee SY, Kimble LP. Impaired sleep and well-being in mothers with low-birth-weight infants. J Obstet Gynecol Neonatal Nurs. 2009;38:676–85. https://doi.org/10.1111/j.1552-6909.2009.01064.x.
50. Lee S-Y, Hsu H-C. Genetic susceptibility and sleep disturbance in black mothers of preterm infants: an exploratory study. SAGE Open Nursing. 2016;2. https://doi.org/10.1177/2377960816643326.
51. Shelton SL, Meaney-Delman DM, Hunter M, Lee S-Y. Depressive symptoms and the relationship of stress, sleep, and well-being among NICU mothers. J Nurs Educ Pract. 2014;4. https://doi.org/10.5430/jnep.v4n8p70.
52. Williams PD, Williams AR. Transition from hospital to home by mothers of preterm infants: path analysis results over three time periods. Fam Syst Health. 1997;15:429–46.
53. Gennaro S, Fehder W. Health behaviors in postpartum women. Fam Commun Health. 2000;22:16–26.
54. McMillen IC, Mulvogue HM, Kok JSM, Deayton JM, Nowak R, Adamson TM. Circadian -rhythms in sleep and wakefulness in salivary melatonin and cortisol concentrations in mothers of term and preterm infants. Sleep. 1993;16:624–31.
55. Wollenhaupt JM. The experience of mothers and fathers with their premature infant in the family home. Milwaukee: University of Wisconsin; 2010.
56. Schaffer L. The impact of guided imagery on sleep quality in mothers of preterm infants. California: University of San Diego; 2012.
57. Schaffer L, Jallo N, Howland L, James K, Glaser D, Arnell K. Guided imagery: an innovative approach to improving maternal sleep quality. J Perinat Neonatal Nurs. 2013;27:151–9. https://doi.org/10.1097/JPN.0b013e3182870426.
58. Martin JL, Hakim AD. Wrist Actigraphy. Chest. 2011;139:1514–27. https://doi.org/10.1378/chest.10-1872.
59. Nelson EC, Eftimovska E, Lind C, Hager A, Wasson JH, Lindblad S. Patient reported outcome measures in practice. BMJ. 2015;350:1–3. https://doi.org/10.1136/bmj.g7818.
60. Ong JC, Arnedt T, Gehrman PR. Insomnia diagnosis, assessment and evaluation. In: Kryger R, Dement WC, editors. Principles and practice of sleep medicine. sixth ed. Philadelphia: Elsevier; 2017. p. 785–93.
61. Stefana A, Lavelli M. Parental engagement and early interactions with preterm infants during the stay in the neonatal intensive care unit: protocol of a mixed-method and longitudinal study. BMJ Open. 2017;7:e013824. https://doi.org/10.1136/bmjopen-2016-013824.
62. Feldman R. Parent-infant synchrony and the construction of shared timing; physiological precursors, developmental outcomes, and risk conditions. J Child Psychol Psychiatry. 2007;48:329–54. https://doi.org/10.1111/j.1469-7610.2006.01701.x.
63. Blomqvist YT, Nyqvist KH, Rubertsson C, Funkquist EL. Parents need support to find ways to optimise their own sleep without seeing their preterm infant's sleeping patterns as a problem. Acta Paediatr. 2017;106:223–8. https://doi.org/10.1111/apa.13660.
64. Hurst I. Mothers' strategies to meet their needs in the newborn intensive care nursery. J Perinat Neonatal Nurs. 2001;15:65–82.
65. Heidari H, Hasanpour M, Fooladi M. The experiences of parents with infants in neonatal intensive care unit. Iran J Nurs Midwifery Res. 2013;18:208–13.
66. Stremler R, Dhukai Z, Pullenayegum E, Weston J, Wong L, Parshuram C. Sleep, sleepiness, and fatigue outcomes for parents of critically ill children. Pediatr Crit Care Med. 2014;15:e56–65. https://doi.org/10.1097/01.pcc.0000436198.15337.15.
67. Aagaard H, Uhrenfeldt L, Ludvigsen M, Fegran L. Parents' experiences of transition when their infants are discharged from the neonatal intensive care unit: a systematic review protocol. JBI Database System Rev Implement Rep. 2015;13:123–32. https://doi.org/10.11124/jbisrir-2015-2287.
68. Adama EA, Bayes S, Sundin D. Parents' experiences of caring for preterm infants after discharge from neonatal intensive care unit: a meta-synthesis of the literature. J Neonatal Nurs. 2016;22:27–51. https://doi.org/10.1016/j.jnn.2015.07.006.
69. Stone KL, In A-ISA. Principles and practice of sleep medicine. In: Kryger R, Dement WC, editors. . 6th ed. Philadelphia: Elsevier; 2017.
70. Aili K, Astrom-Paulsson S, Stoetzer U, Svartengren M, Hillert L. Reliability of Actigraphy and subjective sleep measurements in adults: the Design of Sleep Assessments. J Clin Sleep Med. 2017;13:39–47. https://doi.org/10.5664/jcsm.6384.
71. Short MA, Arora T, Gradisar M, Taheri S, Carskadon MA. How many sleep diary entries are needed to reliably estimate adolescent sleep? Sleep. 2017;40:1–10. https://doi.org/10.1093/sleep/zsx006.
72. Polit DF, Beck CT. Essentials of nursing research : appraising evidence for nursing practice. 7th ed. Philadelphia: Wolters Kluwer/Lippincott Williams & Wilkins; 2010.
73. Shields L, Zhou H, Pratt J, Taylor M, Hunter J, Pascoe E. Family-centred care for hospitalised children aged 0-12 years. Cochrane Database Syst Rev. 2012;10:CD004811. https://doi.org/10.1002/14651858.CD004811.pub3.
74. Carter JD, Mulder RT, Bartram AF, Darlow BA. Infants in a neonatal intensive care unit: parental response. Arch Dis Child Fetal Neonatal Ed. 2005;90:F109–13. https://doi.org/10.1136/adc.2003.031641.
75. Shaw RJ, Bernard RS, Deblois T, Ikuta LM, Ginzburg K, Koopman C. The relationship between acute stress disorder and posttraumatic stress disorder in the neonatal intensive care unit. Psychosomatics. 2009;50:131–7. https://doi.org/10.1176/appi.psy.50.2.131.

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RESEARCH

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Sleep patterns and psychosocial health of parents of preterm and full-born infants: a prospective, comparative, longitudinal feasibility study

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Abstract

Background: The early birth and hospitalization of a preterm infant in neonatal intensive care unit can produce several emotional and behavioural responses including sleep problems for parents. Few studies have explored sleep and its associations with health and HRQoL over time in this vulnerable parent population. This purpose of this study was to evaluate the feasibility of a prospective, comparative, longitudinal study of the sleep patterns and psychosocial health of preterm and full-born infants' parents during the first postpartum year.

Methods: A prospective, comparative, longitudinal feasibility study was conducted. Parents of preterm infants were compared to parents of full-born infants to identify if there were differences in outcomes between the groups. The parents were instructed to wear actigraphs and complete sleep diaries for two consecutive weeks, and responded to a digital questionnaire covering stress, insomnia, fatigue, depression, social support, self-efficacy, and health-related quality of life. Survey data were collected at infant ages of 2, 6, and 12 months, actigraphy and sleep diary data were collected at infant age of 2 months only. Descriptive analysis was used to describe recruitment and attrition rates. Differences between completers and dropouts were analysed with a chi-square test (categorical data) and Mann–Whitney–Wilcoxon test for two independent samples (continuous variables).

Results: Between June 2019 and March 2020, 25 parents of a preterm infant and 78 parents of a full-born infant were recruited from four neonatal intensive care units and two maternity wards, respectively, in four Norwegian hospitals. Feasibility was predefined as recruiting ≥ 75 parents each of preterm and full-born infants. The target for the full-born group was reached. However, the preterm group recruitment was challenging. Actigraphs, sleep diaries, and questionnaires were evaluated as feasible for use in a future study. Attrition rates were high in both groups at 6 and 12 months. No parent-related characteristics were associated with participation at 6 months. At 12 months, dropouts had a statistically significantly lower age in the full-born group (both parents) and higher age and body mass index in the preterm group (fathers).

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Conclusions: A longitudinal study is feasible; however, procedural changes, including using active methods and contacting participants, are necessary to increase the recruitment of preterm infants' parents.

Keywords: Feasibility, Longitudinal, Parental sleep, Preterm, Full-born, Postpartum, Health, Nurses, Psychosocial health, Health related quality of life

Background

Sleep affects physical and mental health outcomes [1, 2]. Restorative sleep is important for physical, cognitive, and psychological well-being [3]. In the literature, six to eight hours of sleep have been associated with the lowest risk of mortality in healthy adults [3]. The "postpartum period" refers to the period from childbirth to up to six months or until the infant sleeps through the night [2]. During the first three months, parental sleep patterns can be greatly disturbed and lead to daytime sleepiness and fatigue [4]. An unpredictable infant sleep pattern, night-time feedings, and maternal hormonal changes are common causes of sleep disturbances [5]. Despite large variations among infants, most achieve a stabilised sleep pattern at 6 months, and at 12 months, most infants sleep through the night [6].

Preterm births are "births that occur before 37 weeks of gestation" [7]. Fifteen million infants are born prematurely every year worldwide [8]. Despite advances in medical care, preterm births still represent a leading cause of infant mortality and mortality [8]. Parents of preterm infants have described early birth as a traumatic life experience accompanied by long-lasting emotional stress and anxiety [9]. High levels of daily stress can adversely affect parental sleep [10, 11]. Sleep quantity and quality of new mothers of preterm infants have been described as poor in the early postpartum phase, even though they sleep at home and do not participate in the care of the preterm infant [12].

Sleep affects many domains of life [13]. The relationship between sleep and health has been described as bidirectional: poor sleep can increase the severity of health conditions, and the same conditions can adversely affect sleep [14]. "Psychosocial factors" are "psychological sensations or experiences" related to an individual's physical and social status [15]. Sleep and psychosocial factors are often closely linked [16–18]. Stress is the most consistent factor associated with poor sleep after a preterm birth [11, 19]. Stress adversely affects sleep and has therefore been associated with increased fatigue, anxiety, depression, and reduced HRQoL [10, 12, 20].

Two previous longitudinal cohort studies compared sleep outcomes between mothers of preterm and full-born infants up to four [21] and five months postpartum [22] and reported incongruent results. Gennaro and Fehder [21] did not find any differences in sleep quantity between mothers of preterm and full-born infants, while McMillen et al. [22] reported that mothers of preterm infants had a shorter sleep duration compared to mothers of full-born infants. Neither of these studies included associations between sleep and psychosocial health–related variables or presented data collected over longer periods to assess possible long-term differences between the two groups. To the best of our knowledge, no study has explored sleep and its associations with health and HRQoL over time in this vulnerable parent population [19, 20].

Sleep can be studied either objectively or subjectively using self-reported measures [23]. Actigraphs are small monitors with high reliability to objectively assess circadian rhythm [24]. Sleep diaries are self-reports of sleep and are usually used to measure sleep parameters over days or weeks [25]. Actigraphs and sleep diaries are commonly used in modern sleep research, possessing high accuracy and validity to assess sleep patterns in epidemiological studies [24, 26]. Still, no study has evaluated the feasibility of using such measures in longitudinal studies involving parents of preterm and full-born infants [20].

A feasibility study can provide valuable insights into parts of a future project [27] by answering the following questions: Can it be done? Should we proceed with it? If so, how? [28]. A recent study described the recruitment of preterm infants' parents as a challenge, as the frequent transportation of infants between hospitals and wards can affect recruitment opportunities [29]. Poor recruitment can threaten internal and external validity in research [30]. An understanding of barriers regarding recruitment and retention in studies can help researchers to develop strategies to overcome these issues [30]. The overall aim of the study was to evaluate the feasibility of a prospective, comparative, longitudinal study of the sleep and psychosocial health of preterm and full-born infants' parents during the first postpartum year. The primary aim was to assess recruitment and attrition rates. The secondary aims were to 1) describe and compare the characteristics of the participants, 2) evaluate measures and outcomes, and 3) identify possible associations between the selected variables and the attrition rates.

Methods

Study design

A feasibility longitudinal study with a case–control design was conducted to meet this study's aims. Sleep and health-related outcomes from two parent groups (parents of preterm and full-born infants) were evaluated and compared prospectively, with preplanned assessment points at 2, 6, and 12 months after birth.

Participants

Sample size consideration

This feasibility study aimed to recruit ≥ 75 parent couples with a preterm infant and ≥ 75 parent couples with a full-born infant. The sample size was anticipated to be achievable within a limited period – between June and December 2019. The sample size was estimated using data from two previous studies reporting on differences in total sleep time [11, 31]. Mothers of preterm infants slept on average 6.3 (SD 2) hours per night [11], compared to 7.0 (SD 1) hours in a group of mothers of full-born babies [31]. We assumed there was a one-hour difference in the total sleep time between the groups. To account for multiple testing, we estimated that it would be sufficient to include ≥ 75 couples in both groups.

Recruitment

Between June 2019 and March 2020, postpartum parent couples were recruited from neonatal intensive care units and maternity wards into two groups: Group A and Group B. Parents of preterm infants (born *before* the 37th week of pregnancy) were included in Group A, while parents of full-born infants (born *after* the 37th week of pregnancy) were included in Group B. Recruitment took place two days per week – on Tuesdays and Thursdays.

Parents of preterm infants (Group A) were recruited from four neonatal intensive care units in hospitals in southeastern Norway. Three of the neonatal intensive care units (Hospitals 1, 2, and 3) were at Level 3c, while the last one was at Level 3b (Hospital 4). In Norway, Level 3c units have the highest medical competence to treat extremely preterm infants down to gestational age 23. Level 3b units have the second highest competence and treat preterm infants from gestational age 26 [32].

Parent couples with a full-born infant (Group B) were recruited from two maternity wards (Hospitals 2 and 4) which treat healthy mothers with uncomplicated births. Eligible parents were over 16 years of age, lived together, and had a sufficient command of a Nordic language (written and oral). Both mother-father parents and same-sex parents were included. Parents were recruited within the first five weeks after birth. Parents were excluded if they had a serious drug addiction (recorded in the patient journal, cf. ICD-10 or DSM-IV), the newborn had serious deformities/or a life-threatening condition that could affect survival, the mother had given birth to multiple infants, or the mother had a condition/diagnosis which made participation in the project ethically challenging (serious, life-affecting health issues). Parents with shift work were excluded, as working at night impacts sleep.

Eligible participants were identified by a dedicated nurse in each hospital department. The nurses received informed consent from parents who wanted to participate. Collaborating nurses had been trained to demonstrate how to use an actigraph and a sleep diary.

Data collection and measurements

All participants wore actigraphs, completed sleep diaries, and filled out questionnaires at baseline (2 months). After the COVID-19 outbreak in March 2020, actigraphs and sleep diaries could not be distributed due to the risk of spreading the virus. At 6 and 12 months, parents responded to questionnaires only. Participating parents received a postal package containing two preprogrammed Actiwatch 2 actigraphs (AW2; Philips Respironics, Mini-Mitter) and preplotted (dates only) sleep diaries at the infant ages of 2 months. Actigraphs and sleep diaries were returned to the first author in a prepaid envelope. In addition, each parent responded to a digital questionnaire composed of questions about insomnia, HRQoL, self-efficacy, depression, social support, fatigue, and stress after two weeks with sleep recordings. Baseline sociodemographic data (age, educational level, income, employment status, ethnicity, weight, height, parity) and infant-related data (gestational age at birth, birthweight, length) were collected at the baseline measurement.

Sleep assessment

Actigraphy was used to monitor sleep–wake activity. The parents were instructed to wear actigraphs and complete sleep diaries for two consecutive weeks. Actigraphy data were downloaded via a computer and processed with Actiware software (version 6.0.9). Actigraphy has been tested and found reliable compared to polysomnography, especially for total sleep time estimates [33]. Parents were instructed to press an "event button" when they went to bed to sleep for the night and when they got out of bed in the morning. The following measures were retrieved from the actigraphs: sleep-onset latency, time in bed, sleep efficiency, wake after sleep onset, total wake time, and total sleep time.

Sleep diaries were used to detect self-reported sleep data. A sleep diary presented by Morin [34] was used. The following measures were reported from the sleep diary: number of daytime naps, daytime nap duration, daytime function (1, *very good*; 5, *very poor*), sleep-onset latency, wake after sleep onset, number of night-time

awakenings, early morning awakening, total wake time, total sleep time, time in bed, sleep efficiency, and sleep quality rating (1, *very restless*; 5, *very poor*).

Self-report questionnaires

Insomnia was assessed with the Bergen Insomnia Scale, a six-item questionnaire [35]. The questionnaire specifies if participants have experienced insomnia symptoms in the last three months based on the updated DSM-5/International Classification of Sleep Disorders-3 [36]. The Bergen Insomnia Scale has demonstrated good psychometric properties [35].

HRQoL was measured using RAND-36, a 36-item questionnaire that assesses 8 subscales with 35 multi-item scales. Both physical and mental health outcomes are scored using the eight subscales [37]. The Norwegian version of RAND-36 has been reported as a valid and reliable instrument for assessing HRQoL [38].

Self-efficacy was assessed with the Generalized Self-Efficacy Scale, a 10-item scale for the assessment of optimistic self-belief in coping with different life challenges [39]. A revised five-item version of the original scale was used in this study. The short form of the Generalized Self-Efficacy Scale has been found valid and reliable [40].

Postpartum depression was measured using the Edinburgh Postnatal Depression Scale, a 10-item questionnaire measuring depressive symptoms experienced over the past seven days [41]. The Norwegian version of the Edinburgh Postnatal Depression Scale is a valid screening instrument for detecting postpartum depression [42].

Social support was assessed with the Duke-University of North Carolina Functional Social Support Questionnaire [43]. The instrument has been validated as reliable in several samples internationally [43, 44]. No Norwegian version of the Functional Social Support Questionnaire exists; therefore, we translated the English version. The version was not validated.

Fatigue was measured with the Chalder Fatigue Questionnaire (CFQ). The original version was revised and is now more widely used to measure the severity of "tiredness" rather than just chronic fatigue syndrome [45]. The CFQ has demonstrated good clinical validity and internal consistency [46]. A Norwegian validated version of the CFQ was used [47].

Stress was assessed using the Perceived Stress Questionnaire, originally developed to measure stress-related disorders in clinical research [48, 49]. The instrument is considered useful in psychosomatic research on stress [50]. The Perceived Stress Questionnaire has been validated as feasible in the assessment of stress in adolescents but not in adult populations in Norway.

This study included several measures to evaluate sleep and health outcomes in parents. The measures were evaluated according to response rate and the feasibility of collecting data on sleep and selected health-related variables. Based on general acceptance, we considered that a response rate $\geq 70\%$ would be feasible to ensure that the data were sufficiently representative of the sample [51]. Compliant data from the actigraphs were defined as ≥ 1 day with ≥ 24 h of daily wear time on the accelerometer, and compliant data from the sleep diaries were defined as ≥ 1 day with ≥ 24 h of response in the diary. The feasibility of the questionnaire was evaluated regarding receiving a response/no response.

Statistical analysis

Descriptive analysis was used to describe the study sample and feasibility outcomes (recruitment and attrition rates). Categorical data were presented as frequencies and percentages. Continuous data were described using median, range, and minimum and maximum values.

From the sleep diaries and actigraphs, median values obtained for seven days (five weekdays and two weekend days) were analysed. In the case of missing data, the seven days with the least combined missing data from both measures (actigraphy and sleep diary) were used. Possible differences between completers and dropouts were assessed for available baseline variables. We compared the baseline (2 month) and 6-month data, as well as the baseline (2 month) and 12-month data. Categorical data were analysed with a chi-square test. Pairs of continuous variables were compared using a nonparametric Mann–Whitney–Wilcoxon test for two independent samples. IBM SPSS Statistics for Windows version 26 (IBM Corp., Armonk, NY, USA) was used to conduct statistical analysis.

Validity and reliability

The questionnaires used to collect data on stress [50], fatigue [47], self-efficacy [40], depression [42], insomnia [35], and HRQoL [38] all represent well-validated, standardised measurements for assessing perceived psychosocial health outcomes. Demographic data were collected by questionnaires from the Norwegian Mother and Child Cohort Study [52]. Previous studies have provided evidence on the use of actigraphy to provide consistent objective data on sleep insomnia and circadian rhythm sleep–wake disorders [53]. Sleep diaries have also been well established to provide data on various sleep parameters (bedtime, SOL, and sleep duration; [54].

Ethical considerations

This study was designed and implemented according to the Declaration of Helsinki and standard, common clinical research principles [55]. The Norwegian Regional Committee for Medical Research Ethics approved the

project (reference no. 2018/1025). Research committees at each hospital gave permission to implement the study in the respective wards. Leaders in each department permitted teaching nursing staff and recruiting parents. Informed consent was obtained from all study participants. Participants were informed that they could withdraw at any time during the study without penalty. Only members of the research team had access to the participant data. In this project, none of the refusing participants were asked the reason for their refusal.

Results

Feasibility of recruitment

Recruitment was evaluated by calculating a) eligibility rates, the number of parents who met the inclusion criteria was divided by the total number of parents in neonatal intensive care units and maternity wards, and b) consent rates, computed by dividing parents who met the inclusion criteria by the number that consented to participate. Figure 1 illustrates the recruitment process.

Recruitment of parents of preterm infants (Group A)

In total, 195 parent couples with a preterm infant were screened for participation in the study, of which 114 (58%) were excluded (Fig. 1). The refusal rate was high (62%). In total, 25 couples were finally included in the study, representing a consent rate of 31%. The target set of ≥ 75 couples for this group was never reached. Hospitals permitted different periods to recruit parents. We got permission to recruit for eight weeks each at Hospitals 1 and 2. At Hospital 4, we were permitted to recruit without any time limitation and recruited parents for 22 weeks. The recruitment period was extended past December 2019 due to a low recruitment rate. We also added one more hospital in January 2020 (Hospital 3), where we recruited for three weeks. In March 2020, the Coronavirus disease 2019 (COVID-19) pandemic ended all recruitment efforts.

Recruitment of parents of full-born infants (Group B)

In total, 429 couples with a full-born infant were screened for participation in the study. Of those, 299 couples were eligible, resulting in an eligibility rate of 70%. A total of 112 couples (37%) refused to participate in the study, resulting in a consent rate of 26%. A total of 109 parent couples were never asked to participate; the high volume of eligible parents overstretched our recruitment capacity. The group consisted of 78 couples. As two couples withdrew their consent before the baseline measurement, 76 couples participated at baseline (Fig. 1). We recruited for 15 (Hospital 1) and 6 (Hospital 2) weeks. The feasibility target was reached by December 2019.

Attrition rates at 6 and 12 months

Rates of attrition were calculated as participants that completed the questionnaire at 6 and 12 months divided by the number of participants at baseline, 2 months. Table 1 illustrates participants' completion of measures.

Attrition rates for preterm group (Group A)

A total of nine mothers and six fathers completed the questionnaire at 6 months, producing an attrition rate of 64% for mothers and 76% for fathers. Surprisingly, a few more individuals decided to participate between 6 and 12 months, resulting in attrition rates of 60% (mothers) and 68% (fathers) at 12 months. Two initially nonresponding mothers (baseline) reentered the study at 6 months and one mother reentered at 12 months. Compared to Group B, fathers of preterm infants had the highest attrition rates, with 76% (6 months) and 68% (12 months).

Attrition rates for full-born group (Group B)

For mothers, the completion rate of the questionnaire was 63.9% at 6 and 50% at 12 months, resulting in attrition rates of 49% (6 months) and 61% (12 months). For fathers, the completion rates were 50.8% (6 months) and 53.4% (12 months), producing attrition rates of 59% at both 6 and 12 months. Similar to preterm group, nonresponders (baseline) reentered the study at 6 and 12 months: one mother and one father reentered at 6, and one father reentered at 12 months.

Sample evaluation

Description and comparison of the participants

Sociodemographic characteristics of the sample (baseline, 2 months) are presented in Tables 2 (parents) and 3 (infants). For parents, there were no large differences between the groups in parental age, body mass index, education, or income level. Most of the parents were primiparas, ethnically Norwegian, and highly educated, and most had an annual income ≥ Norwegian Krone (NOK) 500,000 (≥ €50,000).

The baseline characteristics of the infants showed that most of the preterm infants were in the least serious preterm category, with most categorised as with a moderate/late gestational level (GA: 32–36) (Table 3). Only one infant was categorised as "extremely preterm (GA < 28)," and only one was "very preterm" (GA: 28–31). According to infant birthweight, seven preterm infants had "normal" birthweight or higher (≥ 2,500- 4,199 g), nine had "low" birthweight (1,500–2,499). Only one had an "extremely" low birthweight (≤ 999 g). For the full-born group, 57 infants had "normal" birthweight (≥ 2,500–4,199 g), and 4 had "high" birthweight (≥ 4,200 g).

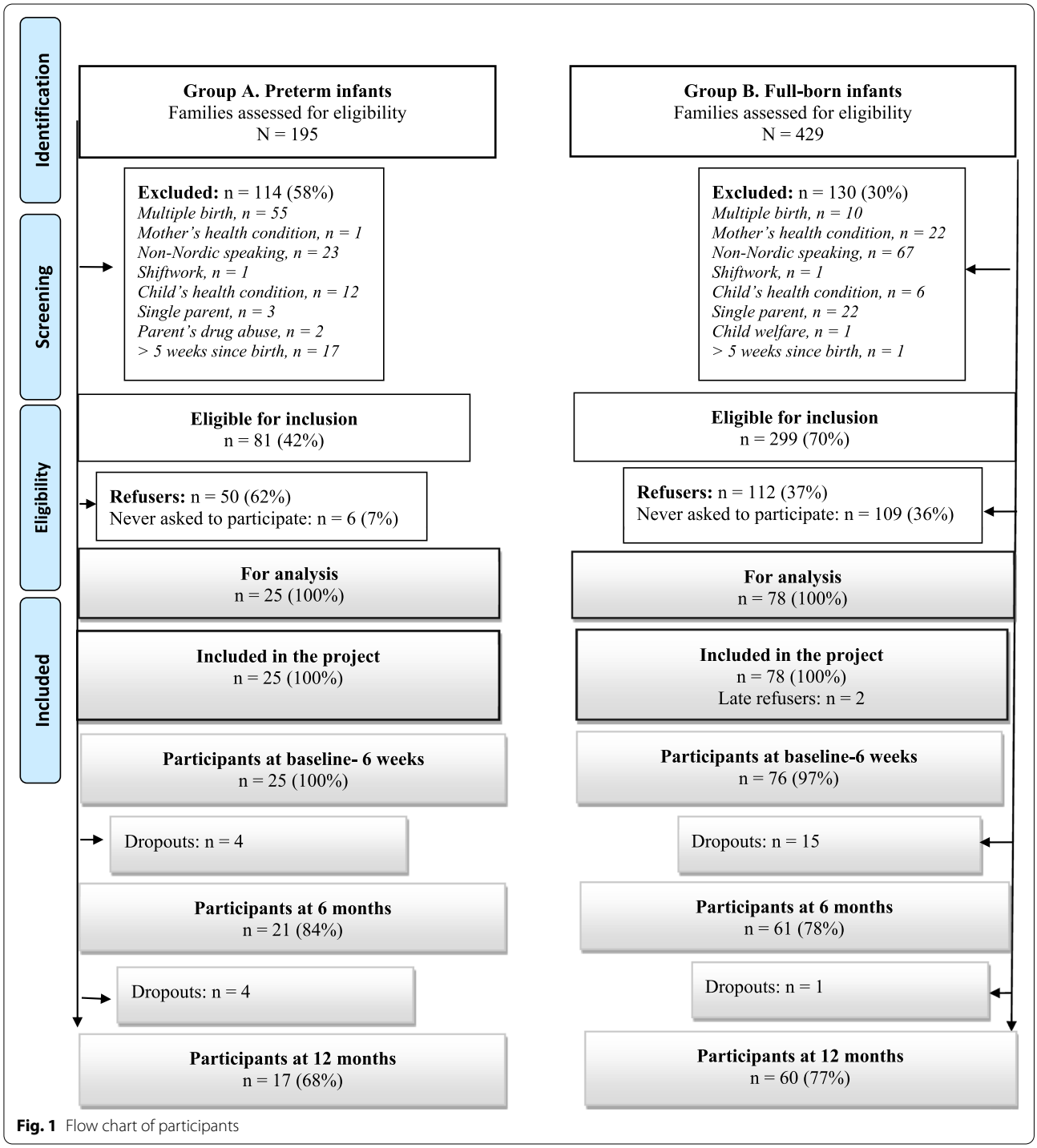

Fig. 1 Flow chart of participants

Representativeness of the sample

Parents

The representativeness of the parent sample was evaluated by comparing their sociodemographic characteristics regarding education with those of the general Norwegian population for the same geographic area (Oslo and Sorlandet). Data were obtained from Statistics Norway https://www.ssb.no/en/, and the 2019 numbers were compared with the distribution of background variables in our sample.

Regarding the level of education, the proportion of individuals in preterm group with less than four years

Table 1 Completion of measures, 2,6 and 12 months

	2 months postpartum		6 months postpartum		12 months postpartum	
	Mothers	Fathers[c]	Mothers	Fathers[c]	Mothers	Fathers[c]
Group A Preterm group						
n (%)	25 (100%)	25 (100%)	21 (100%)	21 (100%)	17 (100%)	17 (100%)
Questionnaire						
Responders	16 (64.0)	14 (56.0)	9 (42.9)	6 (28.6)	10 (58.9)	8 (47.0)
Non- responders	9 (36.0)	11 (44.0)	12 (57.1)	15 (71.4)	7 (41.1)	9 (52.9)
Actigraphy						
Compliant data[a]	18 (72.0)	18 (72.0)				
Non- compliant data	7 (28.0)	7 (28.0)				
Device error						
Sleep diary						
Compliant data[b]	18 (72.0)	18 (72.0)				
Non- compliant data	7 (28.0)	7 (28.0)				
Group B Full- born group						
n (%)	76 (100%)	76 (100%)	61 (100%)	61 (100%)	60 (100%)	60 (100%)
Questionnaire						
Responders	58 (76.3)	46 (60.5)	39 (63.9)	31 (50.8)	30 (50.0)	31 (51.6)
Non -responders	18 (23.7)	30 (39.4)	22 (36.0)	30 (49.1)	30 (50.0)	29 (48.3)
Actigraphy						
Compliant data[a]	53 (69.7)	53 (69.7)				
Non- compliant data	21 (27.6)	23 (30.2)				
Device error	2 (2.6)					
Sleep diary						
Compliant data[b]	51 (67.1)	51 (67.1)				
Non- compliant data	25 (32.9)	25 (32.8)				

[a] Compliant data were defined as ≥ 1 day with ≥ 24 h of daily wear time on accelerometer

[b] Compliant data were defined as ≥ 1 day with ≥ 24 h of response to sleep diary

[c] Including Non- birthgiving mothers

at university (here coded as the highest level of education) was high. Half of the mothers (50%) and one-fifth of the fathers in our sample were highly educated. For the full- born group, 44.8% (mothers) and 48.9% (fathers) had achieved the highest level of education. Fathers in preterm group had a slightly lower proportion (21.4%) of individuals with higher education compared to those in full- born group.

When compared with the general population, for women, 21.6% and 6.9% had the highest level of education for Oslo and Sorlandet, respectively [56]. For men, the figures were 22.3% and 8.2%, respectively [56]. The level of education in our sample for both preterm and full-born group was much higher compared to the general population from the same geographical region.

When we compared the total family income for the Oslo region, parents in our sample earned slightly less than the median annual income of the general population. The parents in preterm group earned slightly below the median total income for the same area (€76,616 vs €95,770), while full-born group parents earned €86,193 versus €95,770. In the Sorlandet area, the median total family income of preterm group and full-born group was about €86,193, which was equal to the median total income for the region [57]. We consider our sample to be representative of the Norwegian population in terms of socioeconomic class, with possibly a slight bias in relation to lower income for parents of preterm infants from the Oslo area.

Infants

In 2019, 3,374 infants were born prematurely in Norway [58]. Of those, 754 infants (22%) were born at Hospitals 1 and 2, 171 (5%) at Hospital 4, and 206 (6%) at Hospital 3. The distribution of preterm infants by gestational level and hospital is presented in Additional file 1.

The distribution of the gestational levels of preterm infants was quite similar between the neonatal intensive care units and wards. Despite this, most infants in our sample were in the upper gestational levels, with

Table 2 Baseline parent characteristics

	Group A. Parents of preterm infants		Group B. Parents of full-born infants	
	Mothers, *n* = 25 (100%) (Responders, *n* = 16)	**Fathers, *n* = 25 (100%) (Responders, *n* = 14)**	**Mothers, *n* = 76 (100%) (Responders, *n* = 58)**	**Fathers[b], *n* = 76 (100%) (Responders, *n* = 46)**
	Median (min–max)	**Median (min–max)**	**Median (min–max)**	**Median (min–max)**
Age	30.5 (27.0–36.0)	32.0 (27.0–36.0)	31.5 (22.0–42.0)	33.0 (25.0–44.0)
Body mass index (kg/m^2)	25.1 (19.9–39.8)	25.3.0 (19.6–34.4)	24.4 (19.6–38.6)	26.6 (20.7–35.9)
	n (%)	**n (%)**	**n (%)**	**n (%)**
Ethnicity				
Norway	15 (93.8)	13 (92.9)	50 (86.2)	42 (91.3)
Nordic Country	1 (6.3)		1 (1.7)	2 (4.4)
Europe			2 (3.4)	1 (2.2)
Asia			2 (3.4)	
South-America		1 (7.1)	2 (3.4)	1 (2.2)
Africa			1 (1.7)	
Parity				
0[a]	12 (75.0)	11 (78.6)	38 (65.5)	29 (63.0)
1	4 (25.0)	3 (21.4)	14 (24.1)	10 (21.7)
2			5 (8.6)	6 (13.0)
3			1 (1.7)	1 (2.2)
Education (level/years)				
Primary school (up to 10 years)				1 (2.2)
Secondary school (up to 13 years)	4 (25.0)	7 (50.0)	10 (17.0)	9 (20.0)
University/college (up to 4 years)	3 (18.8)	4 (28.6)	22 (37.9)	12 (26.1)
University/college (> 4 years)	8 (50.0)	3 (21.4)	26 (44.8)	22 (47.8)
Other	1 (6.3)			2 (4.3)
Annual income (NOK)				
0–399,000	5 (31.3)	3 (21.4)	12 (20.7)	7 (15.6)
400,000–499,000	3 (18.8)	3 (21.4)	18 (31.0)	4 (8.7)
≥ 500,000	8 (50.0)	8 (57.1)	28 (48.3)	35 (76.1)
Employment status				
Non-income-generating work situation	1 (6.3)	2 (14.3)	6 (10.3)	3 (6.5)
Income-generating work situation	15 (93.8)	12 (85.7)	52 (89.7)	43 (93.5)
Missing (nonresponders)	9 (36.0)	11 (44.0)	18 (23.7)	30 (38.3)

[a] First-time parents (primiparas)

[b] Including non-birth-giving mothers

birthweight in the upper categories. Thus, we consider our sample to be representative of moderate/late preterm (gestational level ≥ 33) infants with birthweight ≥ 1,500 g.

Evaluation of measures and outcomes

Measures

In summary, the amount of compliant data derived from the actigraphs, and sleep diaries was high (≥ 70%) at baseline for parents in preterm group. Table 1 shows the participants' completion of measures at baseline and throughout the study. For the full-born group, the number was slightly below 70% (Table 1). Two parents requested additional guidance for completing the sleep diary. Two actigraphs had defects; hence, the data were unusable. Three participants reported that they had skin allergies due to their actigraphs; therefore, the wear time was reduced. Otherwise, no adverse events affected the data collection of sleep. For the questionnaire, the response rate was less than 70% in both groups (except for mothers in full-born group at baseline) at all three measure points (Table 1). At 6 months, the response rate in preterm group decreased significantly, despite the fact that the number of participants that remained in the study was relatively high (Fig. 1).

Table 3 Baseline infant characteristics

	Group A. Preterm group, *n* = 25 (100%) (Responders, *n* = 17)	**Group B. Full-born group, *n* = 76 (100%) (Responders, *n* = 61)**
	n (%)	**n (%)**
Infant gestational age (GA)		
Extremely preterm (GA < 28)	1 (4.0)	–
Very preterm (GA: 28–31)	1 (4.0)	–
Moderate/Late preterm (GA: 32–36)	15 (60.0)	–
Term born (GA ≥ 37)	–	61 (80.0)
Missing	8 (32.0)	15 (19.7)
Infant birthweight		
Extremely low (≤ 999 g)	1 (4.0)	–
Flow chart of participants		
Very low (1,000–1,499 g)	–	–
Low (1,500–2,499 g)	9 (36.0)	–
Normal weight (≥ 2,500–4,199 g)	7 (28.0)	57 (75.0)
High (≥ 4,200 g)	–	4 (5.2)
Missing	8 (32.0)	15 (19.7)

Note: GA, gestational age

Table 4 Descriptive variables for subjective and objective sleep at baseline (2 months postpartum) for Groups A and B

	Group A. Preterm group Median (min–max)		**Group B. Full-born group Median (min–max)**	
	Mothers	**Fathers[a]**	**Mothers**	**Fathers[a]**
Sleep diary	**Responders *n* = 18**	**Responders *n* = 18**	**Responders *n* = 51**	**Responders *n* = 51**
Daytime function (1, *very good*; 5, *very poor*)	2.5 (1.6–3.1)	2.4 (1.4–3.1)	2.1 (1.0–3.9)	2.3 (1.0–3.3)
Sleep quality (1, *very restless*; 5, *very sound*)	3.4 (1.6–4.8)	3.4 (2.0–4.7)	3.0 (1.5–4.6)	3.4 (1.6–4.3)
Number of daytime naps	0.4 (0–0.9)	0.2 (0–0.9)	0.1 (0–1.1)	0.0 (0–0.7)
Daytime nap duration (min)	24.0 (0–62.0)	7.9 (0–70.0)	4.3 (0–60)	0.0 (0–49.0)
Sleep onset latency (min)	10.8 (1–82.0)	12.3 (0–70.0)	31.4 (1–89.0)	13.5 (0–98.0)
Number of nighttime awakenings	2.4 (1.3–4.9)	1.8 (0.6–3.7)	2.7 (0.6–5.0)	1.4 (0–4.7)
Wake after sleep onset (min)	114.3 (12.4–253.8)	29.9 (3–96.0)	71.4 (8.6–155.0)	13.6 (0–74.3)
Early morning awakening (min)	13.1 (5.7–43.3)	9.6 (0–85.0)	15.7 (0.7–72.9)	13.3 (0–51.9)
Total wake time (min)	147.4 (40.0–247.5)	68.6 (30.0–132.7)	125.0 (29.7–237.1)	45.0 (1.6–131.0)
Time in bed (min)	538.2 (421.4–707.9)	475.0 (373.0–621.4)	569.3 (415.4–743.6)	475.7 (346.3–647.1)
Total sleep time (min)	415.1 (301.3–516.4)	411.9 (309.3–507.1)	427.0 (302.9–582.9)	425.7 (274.4–567.0)
Sleep efficiency (%)	72.6 (52.3–91.2)	85.2 (73.9–93.8)	78.1(59.6–93.4)	90.6 (71.8–99.6)
Actigraph	**Responders *n* = 18**	**Responders *n* = 18**	**Responders *n* = 53**	**Responders *n* = 53**
Time in bed (min)	528.8 (431.2–695.4)	466.0 (336.6–625.6)	538.0 (395.0–702.6)	462.0 (356.6–560.0)
Total sleep time (min)	421.0 (343.4–500.8)	387.4 (292.1–500.9)	433.0 (328.0–561.8)	397.7 (315.1–468.9)
Sleep onset latency (min)	13.1 (2.4–30.6)	15.3 (1.6–59.1)	13.0 (1.0–65.4)	13.0 (2.9–48.2)
Sleep efficiency (%)	78.3 (65.8–87.9)	85.8 (64.7–91.0)	81.5 (66.7–90.1)	85.3 (77.1–91.2)
Wake after sleep onset (min)	100.0 (31–192.2)	37.6 (26.1–88.4)	61.7 (31.5–143.0)	34.0 (14.4–73.0)

[a] including non-birth-giving mothers

Outcomes

The descriptive statistics for sleep (actigraphy and sleep diary) at baseline are presented in Table 4. Sleep data were successfully reported for all selected sleep variables, except for daytime naps (actigraph). Many parents forgot to press the event button to register daytime naps and marked night-time sleep only. Descriptive statistics for selected health variables are presented at all three measure points (2, 6, and 12 months) in Table 5.

Parents in preterm group had lower median total sleep time compared to parents in full-born group, as reported in the sleep diaries. According to the sleep diaries, mothers in preterm group also had the lowest median sleep efficiency (72.6%), followed by mothers in full-born group (78.1%). Fathers in both groups reported sleep efficiency $\geq$ 85% in the sleep diaries; normal sleep efficiency is considered to be 85% or higher [59]. Similarly, for actigraphy, mothers in preterm group had the lowest median value for sleep efficiency (78.3%), followed by mothers in full-born group (81.5%). Fathers were above the normal sleep efficiency value cut-off (Table 4). When compared, mothers in preterm group showed a tendency to sleep more during the daytime and reported a median daytime nap duration of 24 min (sleep diary) compared to mothers in full-born group. The former group also tended to report the highest wake after sleep onset (median = 114.3 min, sleep diary; 100 min, actigraph) per week. Overall, participants in both groups rated their sleep quality as medium; daytime function was good (Table 4).

For the selected health variables, there was a tendency towards high frequencies of insomnia at baseline. The prevalence remained high, particularly for mothers (Table 5) at follow-ups. Fathers in preterm group reported the highest baseline proportions, with 78.6% at baseline. At 6 and 12 months, mothers showed higher

Table 5 Descriptive variables for insomnia, depression, fatigue, depression, social support, self-efficacy, stress and HRQoL at 2, 6 and 12 months postpartum for preterm and full- born infants parents

	2 months postpartum		6 months postpartum		12 months postpartum	
	Mothers	**Fathers[a]**	**Mothers**	**Fathers[a]**	**Mothers**	**Fathersa**
Group A. Preterm group	Responders, *n* = 16	Responders, *n* = 14	Responders, *n* = 9	Responders, *n* = 6	Responders, *n* = 10	Responders, *n* = 8
Insomnia, n (%)	10 (62.5)	10 (71.4)	5 (55.6)	2 (33.3)	5 (50.0)	1 (12.5)
Fatigue, n (%)	9 (56.3)	6 (42.9)	5 (55.6)	1 (16.7)	4 (40.0)	3 (37.5)
Depression, n (%)	2 (12.5)	2 (14.3)	3 (33.3)	–	3 (30.0)	1 (12.5)
HRQoL (median, min/max)						
Physical well-being	49.6 (20.8–64.5)	49.7 (42.8–58.7)	55.1 (40.6–61.5)	52.6 (50.6–55.8)	51.7 (38.4–58.0)	50.0 (41.8–56.4)
Mental well-being	48.7 (32.0–59.2)	48.7 (28.1–58.3)	47.5 (32.2–57.2)	50.7 (43.5–58.0)	50.8 (26.3–66.6)	50.5 (31.2–58.0)
Self-efficacy (median, min/max)	14.5 (8.0–19.0)	16.5 (11.0–20.0)	15.0 (10.0–18.0)	17.0 (13.0–20.0)	14.5 (12.0–20.0)	15.5 (10.0–20.0)
Social support (median, min/max)	1.1 (1.0–2.5)	1.3 (1.0–1.8)	1.3 (1.0–2.4)	1.3 (1.0–2.3)	1.5 (1.0–2.38)	1.6 (1.0–2.6)
Stress (median, min/max)	0.3 (0.1–0.6)	0.3 (0.1–0.6)	0.3 (0.2–0.5)	0.2 (0.1–0.3)	0.3 (0.2–0.6)	0.3 (0.1–0.5)
Group B. Full-born group	Responders, *n* = 58	Responders, *n* = 46	Responders, *n* = 39	Responders, *n* = 31	Responders, *n* = 30	Responders, *n* = 31
Insomnia, n (%)	31 (53.4)	20 (4.5)	27 (69.2)	13 (41.9)	20 (66.7)	13 (41.9)
Fatigue, n (%)	37 (63.8)	15 (33.3)	21 (53.8)	13 (41.9)	16 (53.3)	12 (38.7)
Depression, n (%)	11 (19.0)	7 (15.2)	11 (28.2)	4 (12.9)	12 (40.0)	9 (29.0)
HRQoL (median, min/max)						
Physical well-being	50.0 (25.0–65.5)	53.7 (37.0–61.3)	52.6 (50.6–55.8)	54.0 (30.7–65.2)	51.9 (24.1–62.7)	52.7 (40.1–65.5)
Mental well being	50.0 (32.0–59.2)	51.5 (23.8–59.5)	52.3 (21.9–60.0)	52.4 (24.2–59.6)	50.2 (18.8–61.5)	50.5 (18.7–60.6)
Self-efficacy (median, min/max)	16.5 (7.0–20.0)	16.5 (11.0–20.0)	17.0 (9.0–20.0)	16.0 (9.0–20.0)	16.0 (8.0–20.0)	15.0 (9.0–20.0)
Social support (median, min/max)	1.6 (1.0–4.5)	1.6 (1.0–4.6)	1.6 (1.0–4.0)	1.8 (1.0–3.8)	1.8 (1.0–4.0)	1.9 (1.0–4.6)
Stress (median, min/max)	0.4 (0–0.9)	0.3 (0.2–0.9)	0.3 (0.9–0.71)	0.3 (0.4–0.8)	0.4 (0–0.8)	0.3 (0–0.9)

[a] Including non-birth-giving mothers

proportions of insomnia compared to fathers. Fatigue level was also high, with mothers reporting higher median values at all three measure points compared to fathers, and the difference remained stable at 6 and 12 months. For HRQoL, there were no large differences between both genders and both groups throughout the study.

Identification of selected variables associated with attrition rates at 6 and 12 months

Participation at 6 months

At 6 months, we did not find any baseline characteristics associated with parents' participation in preterm or full-born group. Additional files 2 and 3 illustrate participant characteristics associated with completion/dropout at 6 months (see Additional files 2 and 3).

Participation at 12 months

At 12 months, maternal dropouts in full-born group were of a significantly lower age ($p=0.03$) compared to completers. No other characteristics were found to be statistically associated with mothers' participation. For fathers, we found that higher age ($p=0.05$) and body mass index ($p=0.03$) were statistically significantly associated with dropout in preterm group. Conversely, a lower age was statistically associated with dropout in full-born group ($p=0.03$) at T2. No other characteristics at baseline were associated with participation at 12 months. Additional file 4 and 5 illustrate participant characteristics associated with completion/dropout at 12 months [see Additional file 4 and 5].

Discussion

This is, to our knowledge, the first study to evaluate the feasibility of a prospective, comparative, longitudinal study of the sleep and psychosocial health of parents of preterm and full-born infants during the first postpartum year. The primary aim was to assess recruitment and attrition rates. The secondary aims were to 1) describe and compare the characteristics of the participants, 2) evaluate measures and outcomes, and 3) identify possible associations between the selected variables and attrition rates.

Based on our findings, a future longitudinal study may be feasible; however, changes are recommended, particularly to optimise recruitment to the preterm group. Efforts to minimise attrition rates at 6 and 12 months are needed. The lessons learned from this feasibility study may be helpful to other researchers planning similar studies.

The recruitment of parents of preterm infants represented a major barrier in this study; the predefined feasibility target of 75 couples was never reached. A low eligibility rate (42%) was a large barrier to the inclusion of parents. The volume of twins/multiple infants was surprisingly high (48.2%) and contributed to many exclusions. Parents of twins and multiple newborns have more severe sleep problems than parents of singletons [60, 61]. For this reason, they were excluded from the study.

Additionally, a high volume of non-Nordic speaking individuals (20%) contributed to a high exclusion rate. Parents without a sufficient command of a Nordic language were not included because there were only Norwegian versions of the information sheets and questionnaires. The child's health condition was also often poorer for parents of preterm infants, leading to 10.5% of exclusions. Preterm infants are often hospitalised for weeks/months and frequently transported between hospitals for medical care [29]. For such reasons, 14.9% of the preterm infants were excluded because they were too old (> 5 weeks) when we tried to recruit them for the project.

The refusal rate was high (62%) for parents in preterm group, compared to full-born group (37%). Since refusers did not have to provide any reason for their denial, it is difficult to ascertain possible explanations. Infants with low gestational levels have a higher risk of morbidity and mortality [62]. Parents have described mental unpreparedness, stress, and concern for their infant's health condition [63]. This can affect parents' willingness to participate in research [64]. To compensate for the low recruitment rate, we prolonged the recruitment period for the preterm group by several months after December 2019. Moreover, an additional neonatal intensive care unit (Hospital 3) was included in January 2020. In March 2020, the COVID-19 pandemic ended all recruitment efforts. By then, only 25 couples with preterm infants had been recruited to preterm group.

In total, 78 parent couples with full-born infants were recruited to full-born group, thus confirming that the feasibility target of 75 couples was attainable. The eligibility rate for this group was high (70%). The most common reason for ineligibility was having insufficient command of a Nordic language and being a single parent (Fig. 1). However, the consent rate was low (26%), indicating a need for support. Childbirth and transition to parenthood is generally considered a stressful period for parents [65]. The low consent rate might have been impacted by such factors. Parents were recruited early after childbirth when the situation was still new and demanding. Postpartum parents are difficult to recruit for research [66–68], and our findings support this.

Failure to recruit study participants is a common problem in research; hence, it is important to identify barriers and overcome them [69]. Our findings reveal a need for changes in the recruitment procedure. For preterm

group, a broadening of the inclusion criteria is necessary to include a larger group of parents, particularly considering that many parents with minority backgrounds were excluded. A study from Sweden recently confirmed our results; minority parents and twins were common reasons for the exclusion of parents in a similar project [29]. English and translated versions of questionnaires could be designed to include parents with multiple ethnicities. Understanding how ethnic factors are related to sleep and health is essential to meet the care needs of the parent population [70].

On forehand, we anticipated that parents of preterm infants would be more difficult to recruit since they have a higher burden compared to parents of healthy full-born infants [9]. Parents of extremely preterm infants with low birthweight have described the situation as psychologically demanding due to a higher risk of infant mortality and morbidity [71]. Such circumstances can explain why our sample primarily consisted of mainly moderate/late preterm infants (Table 3). The most vulnerable parents (those of infants with the lowest gestational level) were never recruited for the project, even though we collaborated with large Level 3c units with a high admission of extremely/very preterm infants per year (see Additional file 1). New research participants might be difficult to reach for various reasons [72]. "Hidden" groups can be underrepresented in research with large samples, and the research does not entirely reflect their status [73]. Previous studies have shown that different factors can impact parents participation in research negatively; having infant with lower gestational age, infant illness, lack of socioeconomic support, lower parental education level, race, or lack of intact family [74–78]. Despite that previous research successfully has included parents of preterm infants in several studies; we have identified significant methodological challenges if these parents shall be successfully recruited in future cohort studies. Several adjustments are necessary to increase success of these parents. Standard recruitment strategies may not be appropriate to recruit "hidden subgroups" like e.g., parents with extremely low gestational level. More in-depth knowledge regarding their special situation, with particular focus on mental and physical demands might be required to successfully recruit them to research. Strategies to do research participation less burdensome, and support of families with particular high risk of recruitment and retainment issues may facilitate their participation [79]. Reduction of risks, support of resources, building of trust with participants, and use of flexible and creative recruitment strategies might be examples of ways to support recruitment of vulnerable and "hidden" research participants [80]. Fathers of preterm infants with very low birthweight have reported that a lack of emotional support negatively affects their willingness to be recruited for research [64]. Parents need emotional support from health personnel and require help to cope with the unexpected and demanding situation [81]. More focus on face-to-face consultations, family-centred care, and emotional and practical support can increase recruitment success [64]. Improving health personnel's competence in addressing parents' psychosocial needs and strengthening communication skills can also heighten recruitment potential [81].

The recruitment of parents of preterm infants raised many ethical questions for our recruiters (nurses). Parents sometimes experience stress levels that meet the diagnostic criteria for acute stress disorder or posttraumatic stress disorder [82, 83]. If parents had a temporary difficult situation (e.g., related to an uncertain infant health situation), our recruiters postponed the formal request of participation until the next recruitment day. Individuals' capacity to give valid consent can be affected by their emotional state, degree of understanding, and available time to decide [84]. For the recruitment of parents to be successful in future studies, a close collaboration between researchers and clinical staff is essential [51]. Our collaboration with NICU nurses was important since they had a unique position to observe and follow up postpartum parents' mental health situation during the hospitalization period. Our recruiting nurses had the ability to contact inside- hospital support like psychologist or mental health services if parents needed such support. Parents were also informed to contact their own doctor or health centre if experiencing mental health challenges after discharge from hospital.

A long recruitment period and collaboration with several neonatal intensive care units in Nordic countries may be necessary to recruit parents of preterm infants in forthcoming projects.

Recruitment to the full-born group was faster, considering the volume of parents willing to participate was higher than expected. The nurses' capacity was often overstretched, and 109 parent couples were never asked to participate. In future projects, a sufficient number of collaborating nurses is needed to assess the high volume of parents of full-born infants. The high volume of parents of full-born infants also challenged our actigraphy resources. Although actigraphs offer many advantages for sleep research [85], they represented a high cost in this study and later limited our recruitment opportunities. We were also dependent on parents returning the actigraphs after use to have them available for new participants.

The identification of potential barriers is important to support recruitment in the future [30]. Seeking the involvement of nurses in recruitment was a challenge

since it added to their daily tasks in the wards. The use of health care personnel as recruiters can be challenging because they often have limited time and a high workload [86, 87]. Similar barriers have been reported in other studies [29]. Future studies should ensure that sufficient resources are available for the recruitment of participants, particularly parents of full-born infants.

Recruiting parents as couples was another barrier. Inclusion demanded consent from both parents, representing a problem if only one parent was present in the ward. Similar barriers have been reported elsewhere [29, 64]. Our recruiters attempted to overcome this by recruiting parents at different times of the day. Information sheets were left for absent parents, and postboxes were hung in the wards to collect consent forms from absent parents.

Failure to recruit a representative sample can result in poor generalisability of results [51]. Our sample of parents was representative of the Norwegian population in terms of socioeconomic class, with a slight bias in relation to lower income for preterm infants from the Oslo area. Similar to other projects, individuals with a lower socioeconomic status, low income, or poor education were underrepresented [30, 51, 88, 89].

This study included various research instruments to assess sleep and health outcomes. Based on our evaluations, all measures were feasible for use in a forthcoming project. There were some minor issues regarding some of the measures used in the study. First, it was noted that some participants, for unknown reasons, had some off-time events during the day. Some actigraphy recordings, therefore, had missing intervals. Previous studies have reported that low wear time is a problem [90]. Our overall evaluation demonstrated that actigraphy, sleep diaries, and questionnaires are feasible for use in a forthcoming study; thus, support of the response rates (sleep diary, baseline for full- born group, and questionnaire) is necessary in the future.

A longitudinal study requires a large number of motivated participants who can commit themselves to the study and long-term follow-up [51]. A long study duration and the use of repeated measures can be experienced as burdensome by participants and increase attrition [89]. "Attrition" refers to the failure of participants to complete their participation after being enrolled in a study [79]. Attrition is associated with a loss of statistical power and the risk of selective attrition bias [30]. Bias is expected in study results if attrition exceeds 20% [91, 92]. In the present study, we did not identify any similar determinants associated with attrition at 6 months. At 12 months, dropouts had a lower age in full- born group (both parents) and a higher age and body mass index in preterm group (fathers). Future projects might benefit from testing methods to minimise attrition of these respective participants. In sum, attrition at 6 and 12 months was high for both groups.

Attrition could sometimes be temporary; individuals reentered the study at 6 and 12 months. Other cohorts have reported similar tendencies [92]. To minimise attrition in general, active methods such as reminder letters and phone calls can be helpful [30]. "Barrier-reducing strategies" are particularly important within longitudinal studies [93, 94]. Difficulties, discomfort, or high demands from research design negatively affect participation [30]. Reduction in participant burden (e.g. from data collection) has especially been highlighted to minimize attrition [93]. Collection of sleep and health data using survey alone could be considered [95]. A long study duration, along with a burdensome data collection procedure, can represent a large barrier for the recruitment and retainment of parents [62, 64]. A study design with less extensive data collection could also be appropriate for some parent subgroups. Qualitative study designs could provide a deeper understanding of sleep and health matters [96] and be a less burdensome approach to studying sleep and health in parents with extremely preterm infants.

Limitations

This study had strengths and limitations. A lack of demographic data on refusers limited our possibility to observe if certain groups were overrepresented in those who declined to participate. Data on individuals who declined participation can provide valuable information to develop more successful recruitment strategies [97, 98]. Some parents did not respond to the baseline questionnaire, and we did not have sociodemographic and infant data on the entire sample. To increase the amount of data for statistical analyses, compliant data from the actigraphs and sleep diaries were defined as ≥ 1 day with ≥ 24 h of daily wear time. Seeking involvement from hospitals was a time-demanding challenge; approvals from ethical committees and hospital leaders took longer than we anticipated. It was also difficult to find collaborating nurses who were willing to spend time recruiting for the project. The COVID-19 pandemic ended our recruitment efforts of parents of preterm infants; otherwise, recruitment would have continued until the targeted number of parents was reached. The sample size was limited and for categorical variables, some of the categories included too few individuals to make any statistical comparisons possible. The pandemic also prevented adequate assessment of the feasibility of using actigraphs and sleep diaries in the long term. Parents of preterm infants were also more vulnerable than expected; this adversely affected recruitment. Lastly, more resources should have been

prioritised for the recruitment of parents of healthy full-born infants to meet the high volume of couples.

The strength of this study was sleep and health assessment over time with extensive data collection, as well as the inclusion of fathers. To our knowledge, no similar study has studied sleep and selected health variables over time using a similar study design [19, 20].

Conclusions

A feasibility study can provide valuable insight into parts of a future project by asking "whether something can be done, should we proceed with it, and if so, how" [28]. Based on our findings, a future study can be done, but several changes are recommended. Particularly, recruitment and attrition need support. Refinement of the inclusion criteria is important to increase the recruitment of preterm infants' parents. We suggest including English-speaking parents and minority groups, as well as teaching clinical personnel about recruitment. We also recommend a long recruitment period and cooperation with several neonatal intensive care units in Nordic countries to reach a higher volume of parents. Parents of infants with severe and extremely low gestational levels are vulnerable; hence, we suggest simplifying the data collection procedure and investigating sleep and health outcomes with qualitative study designs. For parents of full-born infants, a focus on sufficient recruitment resources is important. Attrition can be minimized with barrier-reducing efforts. We recommend using active methods such as contacting participants. The findings of this study are important for other researchers planning similar studies with the same parent populations.

Abbreviations

COVID-19: Corona Virus Disease-2019; RAND-36: Rand Medical Outcome Study; BIS: Bergen insomnia scale; GA: Gestational level; SOL: Sleep onset wake after sleep onset; WASO: Wake after sleep onset; TWT: Total wake time; TST: Total sleep time; TIB: Time in bed; SE: Sleep efficiency.

Supplementary Information

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Additional file 1.

Additional file 2.

Additional file 3.

Additional file 4.

Additional file 5.

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Authors' contributions

All authors (GNM, SH, LF, MS, SB, and BB) made substantial contributions to the conception, design, and data collection, analysis, and interpretation. All authors were involved in drafting the manuscript and critically revising it for important intellectual content, and all gave their final approval of the version to be published. Each author participated sufficiently in the work to take public responsibility for appropriate portions of the content. All authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Availability of data and materials

The datasets used in this current study is available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by the Norwegian Regional committee for Medical Research Ethics (REK) (Reference 2018/1025). The study was carried out in accordance with relevant ethical guidelines and regulations. Research departments and respective leaders at the hospitals permitted implementation of the study in hospital wards. Informed written consent was obtained from participants in the study. Participants were able to withdraw at any time during the study, without penalty.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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References

1. Da Costa D, Lai JK, Zelkowitz P. A prospective study on the course of sleep disturbances in first-time fathers during the transition to parenthood. Infant Ment Health J. 2021;42(2):222–32.
2. Stremler R, Sharkey KM, Wolfson AR. Postpartum Period and Early motherhood. In: Kryger M, Roth TC, Dement WC, editors. Principles and Practice of sleep medicine. 6th ed. Philadelphia: Elsevier; 2017. p. 1547–52.
3. Alvarez GG, Ayas NT. The impact of daily sleep duration on health: a review of the literature. Prog Cardiovasc Nurs. 2004;19(2):56–9.
4. Gay CL, Lee KA, Lee S-Y. Sleep patterns and fatigue in new mothers and fathers. Biol Res Nurs. 2004;5(4):311–8.
5. McGuire E. Maternal and infant sleep postpartum. Breastfeed Rev. 2013;21(2):38–41.
6. Bruni O, Baumgartner E, Sette S, Ancona M, Caso G, Di Cosimo ME, Mannini A, Ometto M, Pasquini A, Ulliana A, et al. Longitudinal study of sleep behavior in normal infants during the first year of life. J Clin Sleep Med. 2014;10(10):1119–27.
7. Preterm birth [http://www.who.int/news-room/fact-sheets/detail/preterm-birth] Accessed 28 Nov 2021.

8. Blencowe H, Cousens S, Chou D, Oestergaard M, Say L, Moller AB, Kinney M, Lawn J. Born Too Soon: The global epidemiology of 15 million preterm births. Reprod Health 2013;10(Suppl 1):2–14.
9. Treyvaud K, Doyle LW, Lee KJ, Roberts G, Cheong JL, Inder TE, Anderson PJ. Family functioning, burden and parenting stress 2 years after very preterm birth. Early Hum Dev. 2011;87(6):427–31.
10. Busse M, Stromgren K, Thorngate L, Thomas KA. Parents' responses to stress in the neonatal intensive care unit. Crit Care Nurse. 2013;33(4):52–60.
11. Lee SY, Hsu HC. Stress and health-related well-being among mothers with a low birth weight infant: The role of sleep. Soc Sci Med. 2012;74(7):958–65.
12. Lee SY, Kimble LP. Impaired sleep and well-being in mothers with low-birth-weight infants. J Obstetr Gynecol Neonatal Nurs. 2009;38(6):676–685.
13. Zee PC, Turek FW. Sleep and health - Everywhere and in both directions. Arch Intern Med. 2006;166(16):1686–8.
14. Medic G, Wille M, Hemels MEH. Short- and long-term health consequences of sleep disruption. Nat Sci Sleep. 2017;9:151–61.
15. Ng YM, Voo P, Maakip I. Psychosocial factors, depression, and musculoskeletal disorders among teachers. BMC Public Health. 2019;19(1):1–10.
16. Tahmasian M, Samea F, Khazaie H, Zarei M, Kharabian Masouleh S, Hoffstaedter F, Camilleri J, Kochunov P, Yeo BTT, Eickhoff SB, et al. The interrelation of sleep and mental and physical health is anchored in grey-matter neuroanatomy and under genetic control. Commun Biol. 2020;3(1):1–13.
17. Chow CM. Sleep and Wellbeing, Now and in the Future. Int J Environ Res Public Health. 2020;17(8):1–4.
18. Kent de Grey RG. Uchino BN, Trettevik R, Cronan S, Hogan JN: Social support and sleep: A meta-analysis. Health Psychol. 2018;37(8):787–98.
19. Haddad S, Dennis CL, Shah PS, Stremler R. Sleep in parents of preterm infants: A systematic review. Midwifery. 2019;73:35–48.
20. Marthinsen GN, Helseth S, Fegran L. Sleep and its relationship to health in parents of preterm infants: a scoping review. BMC Pediatr. 2018;18(1):352.
21. Gennaro S, Fehder W. Health Behaviors in Postpartum Women. Fam Community Health. 2000;22(4):16–26.
22. McMillen IC, Mulvogue HM, Kok JS, Deayton JM, Nowak R, Adamson TM. Circadian rhythms in sleep and wakefulness and in salivary melatonin and cortisol concentrations in mothers of term and preterm infants. Sleep. 1993;16(7):624–31.
23. Bakken LN, Kim HS, Finset A, Lerdal A. Subjective sleep quality in relation to objective sleep estimates: comparison, gender differences and changes between the acute phase and the six-month follow-up after stroke. J Adv Nurs. 2014;70(3):639–50.
24. Stone KL. Ancoli-Israel, Sonia: Actigraphy. In: Kryger M, Roth T, Dement WC, editors. Principles and practice of sleep medicine. 6th ed. Philadelphia: Elsevier; 2017. p. 1671–8.
25. Luyster FS: Sleep and Health. In: Encyclopedia of Behavioral Medicine. edn. Edited by Gellman MD, Turner JR. New York: Springer New York; 2013: 1799–1802.
26. Aili K, Astrom-Paulsson S, Stoetzer U, Svartengren M, Hillert L. Reliability of Actigraphy and Subjective Sleep Measurements in Adults: The Design of Sleep Assessments. J Clin Sleep Med. 2017;13(1):39–47.
27. Donald G. A brief summary of pilot and feasibility studies: Exploring terminology, aims, and methods. Eur J Integrative Med. 2018;24:65–70.
28. Eldridge SM, Lancaster GA, Campbell MJ, Thabane L, Hopewell S, Coleman CL, Bond CM. Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework. PLoS ONE. 2016;11(3):1–22.
29. Mörelius E, Olsson E, Sahlén Helmer C, Thernström Blomqvist Y, Angelhoff C. External barriers for including parents of preterm infants in a randomised clinical trial in the neonatal intensive care unit in Sweden: a descriptive study. BMJ Open. 2020;10(12):1–5.
30. Gul RB, Ali PA. Clinical trials: the challenge of recruitment and retention of participants. J Clin Nurs. 2010;19(1–2):227–33.
31. Montgomery-Downs HE, Insana SP, Clegg-Kraynok MM, Mancini LM. Normative longitudinal maternal sleep: the first 4 postpartum months. Am J Obstet Gynecol. 2010;203(5):1–7.
32. The Norwegian Directorate of Health: Guidance for maternity care. In. Edited by Directorate of Social Affairs and Health; 2007.
33. Weiss AR, Johnson NL, Berger NA, Redline S. Validity of activity-based devices to estimate sleep. J Clin Sleep Med. 2010;6(4):336–42.
34. Morin CM. Insomnia: Psychological assessment and management. New York, NY, USA: Guilford Press; 1993.
35. Pallesen S, Bjorvatn B, Nordhus IH, Sivertsen B, Hjornevik M, Morin CM. A new scale for measuring insomnia: the Bergen Insomnia Scale. Percept Mot Skills. 2008;107(3):691–706.
36. Bjorvatn B, Waage S, Pallesen S. The association between insomnia and bedroom habits and bedroom characteristics: an exploratory cross-sectional study of a representative sample of adults. Sleep Health J National Sleep Found. 2018;4(2):188–93.
37. Hays RD, Morales LS. The RAND-36 measure of health-related quality of life. Ann Med. 2001;33(5):350–7.
38. Garratt AM, Stavem K. Measurement properties and normative data for the Norwegian SF-36: results from a general population survey. Health Qual Life Outcomes. 2017;15(1):51.
39. Bonsaksen T, Lerdal A, Heir T, Ekeberg O, Skogstad L, Grimholt TK, Schou-Bredal I. General self-efficacy in the Norwegian population: Differences and similarities between sociodemographic groups. Scand J Public Health. 2019;47(7):695–704.
40. Kraft P, Røysamb E. Perceived self-efficacy in health behaviour research: Conceptualisation, measurement and correlates AU - Leganger. Anette Psychol Health. 2000;15(1):51–69.
41. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. Br J Psychiatry. 1987;150:782–786.
42. Eberhard-Gran M, Eskild A, Tambs K, Schei B, Opjordsmoen S. The Edinburgh Postnatal Depression Scale: validation in a Norwegian community sample. Nord J Psychiatry. 2001;55(2):113–7.
43. Broadhead WE, Gehlbach SH, de Gruy FV, Kaplan BH. The Duke-UNC Functional Social Support Questionnaire. Measurement of social support in family medicine patients. Med Care. 1988;26(7):709–723.
44. Isaacs KB, A. Hall L: A Psychometric Analysis of the Functional Social Support Questionnaire in Low-Income Pregnant Women. Issues Ment Health Nurs. 2011; 32(12):766–773.
45. Chalder T, Berelowitz G, Pawlikowska T, Watts L, Wessely S, Wright D, Wallace EP. Development of a fatigue scale. J Psychosom Res. 1993;37(2):147–53.
46. Chilcot J, Norton S, Kelly ME, Moss-Morris R. The Chalder Fatigue Questionnaire is a valid and reliable measure of perceived fatigue severity in multiple sclerosis. Mult Scler J. 2015;22(5):677–84.
47. Loge JH, Ekeberg O, Kaasa S. Fatigue in the general Norwegian population: normative data and associations. J Psychosom Res. 1998;45(1):53–65.
48. Fliege H, Rose M, Arck P, Walter OB, Kocalevent RD, Weber C, Klapp BF. The Perceived Stress Questionnaire (PSQ) reconsidered: validation and reference values from different clinical and healthy adult samples. Psychosom Med. 2005;67(1):78–88.
49. Levenstein S, Prantera C, Varvo V, Scribano ML, Berto E, Luzi C, Andreoli A. Development of the perceived stress questionnaire: A new tool for psychosomatic research. J Psychosom Res. 1993;37(1):19–32.
50. Østerås B, Sigmundsson H, Haga M. Psychometric Properties of the Perceived Stress Questionnaire (PSQ) in 15–16 Years Old Norwegian Adolescents. Front Psychol. 1850;2018(9):1–10.
51. Patel M, Doku V, Tennakoon L. Challenges in recruitment of research participants. Adv Psychiatr Treat. 2003;9:229–38.
52. Norwegian Mother, Father and Child Cohort Study (MoBa) [https://www.fhi.no/en/studies/moba/] Accessed 28 Nov 2021.
53. Smith MT, McCrae CS, Cheung J, Martin JL, Harrod CG, Heald JL, Carden KA. Use of Actigraphy for the Evaluation of Sleep Disorders and Circadian Rhythm Sleep-Wake Disorders: An American Academy of Sleep Medicine Systematic Review, Meta-Analysis, and GRADE Assessment. J Clin Sleep Med. 2018;14(7):1209–30.
54. Short MA, Arora T, Gradisar M, Taheri S, Carskadon MA. How Many Sleep Diary Entries Are Needed to Reliably Estimate Adolescent Sleep? Sleep. 2017;40(3):1–10.
55. Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects [https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/] Accessed 28 Nov 2021.
56. Educational attainment of the population [https://www.ssb.no/en/statbank/table/12935/] Accessed 28 Nov 2021.
57. Income and wealth statistics for households [https://www.ssb.no/en/statbank/table/09903/]

58. Medical Birth Registry of Norway (MBRN) [https://www.fhi.no/en/hn/health-registries/medical-birth-registry-of-norway/medical-birth-registry-of-norway/]
59. Desjardins S, Lapierre S, Hudon C, Desgagne A. Factors involved in sleep efficiency: a population-based study of community-dwelling elderly persons. Sleep. 2019;42(5):1–9.
60. Kondo C, Takada S. The Transition of Sleep Behaviors in Twin Infants and Their Mothers in Early Infancy. Kobe J Med Sci. 2018;64(4):E126–33.
61. Damato EG, Burant C. Sleep Patterns and Fatigue in Parents of Twins. J Obstet Gynecol Neonatal Nurs. 2008;37(6):738–49.
62. Glass HC, Costarino AT, Stayer SA, Brett CM, Cladis F, Davis PJ. Outcomes for extremely premature infants. Anesth Analg. 2015;120(6):1337–51.
63. Arnold L, Sawyer A, Rabe H, Abbott J, Gyte G, Duley L, Ayers S. Parents' first moments with their very preterm babies: a qualitative study. BMJ Open. 2013;3(4):1–7.
64. Bagge SR, Westgate B, Few K, Clarke P, Adlam A, Walsh J, O'Brien M. Acceptability and feasibility of collecting psychosocial data from fathers of very low birth weight infants. J Child Health Care. 2017;21(3):283–91.
65. Epifanio MS, Genna V, De Luca C, Roccella M, La Grutta S. Paternal and Maternal Transition to Parenthood: The Risk of Postpartum Depression and Parenting Stress. Pediatr Rep. 2015;7(2):1–42.
66. Kuhlmann AKS, Dietz PM, Galavotti C, England LJ. Weight-Management Interventions for Pregnant or Postpartum Women. Am J Prev Med. 2008;34(6):523–8.
67. Macleod M, Craigie AM, Barton KL, Treweek S, Anderson AS. WeighWell t: Recruiting and retaining postpartum women from areas of social disadvantage in a weight-loss trial–an assessment of strategies employed in the WeighWell feasibility study. Matern Child Nutr. 2013;9(3):322–31.
68. Haste A, Adamson AJ, McColl E, Araujo-Soares V, Bell R. Problems recruiting and retaining postnatal women to a pilot randomised controlled trial of a web-delivered weight loss intervention. BMC Res Notes. 2018;11(1):1–7.
69. Gross D, Fogg L. Clinical trials in the 21st century: the case for participant-centered research. Res Nurs Health. 2001;24(6):530–9.
70. Rochon PA, Mashari A, Cohen A, Misra A, Laxer D, Streiner DL, Clark JP, Dergal JM, Gold J. The inclusion of minority groups in clinical trials: problems of under representation and under reporting of data. Account Res. 2004;11(3–4):215–23.
71. Baraldi E, Allodi MW, Smedler AC, Westrup B, Lowing K, Aden U. Parents' Experiences of the First Year at Home with an Infant Born Extremely Preterm with and without Post-Discharge Intervention: Ambivalence, Loneliness, and Relationship Impact. Int J Environ Res Public Health. 2020;17(24):1–26.
72. Rockliffe L, Chorley AJ, Marlow LAV, Forster AS. It's hard to reach the "hard-to-reach": the challenges of recruiting people who do not access preventative healthcare services into interview studies. Int J Qual Stud Health Well-being. 2018;13(1):1479582.
73. Iribarren SJ, Ghazzawi A, Sheinfil AZ, Frasca T, Brown W 3rd, Lopez-Rios J, Rael CT, Balán IC, Crespo R, Dolezal C, et al. Mixed-Method Evaluation of Social Media-Based Tools and Traditional Strategies to Recruit High-Risk and Hard-to-Reach Populations into an HIV Prevention Intervention Study. AIDS Behav. 2018;22(1):347–57.
74. Wariyar UK, Richmond S. Morbidity and preterm delivery: importance of 100% follow-up. Lancet. 1989;1(8634):387–8.
75. Cooper N, Lynch M. Lost to follow up: A study of nonattendance at a general paediatric outpatient clinic. Arch Dis Child. 1979;54:765–9.
76. Wolke D, Sohne B, Ohrt B, Riegel K. Follow-up of preterm children: important to document dropouts. Lancet. 1995;345(8947):447.
77. Callanan C, Doyle LW, Rickards AL, Kelly E, Ford GW, Davis NM. Children followed with difficulty: How do they differ? J Paediatr Child Health. 2001;37:152–6.
78. Constantine WL, Haynes CW, Spiker D, Kendall-Tackett K, Constantine NA. Recruitment and retention in a clinical trial for low birth weight, premature infants. J Dev Behav Pediatr. 1993;14(1):1–7.
79. DeMauro SB, Bellamy SL, Fernando M, Hoffmann J, Gratton T, Schmidt B. Patient, Family, and Center-Based Factors Associated with Attrition in Neonatal Clinical Research: A Prospective Study. Neonatology. 2019;115(4):328–34.
80. Savard I, Kilpatrick K. Tailoring research recruitment strategies to survey harder-to-reach populations: A discussion paper. J Adv Nurs. 2022;78(4):968–78.
81. Bry A, Wigert H. Psychosocial support for parents of extremely preterm infants in neonatal intensive care: a qualitative interview study. BMC Psychology. 2019;7(1):1–12.
82. Feeley CA, Turner-Henson A, Christian BJ, Avis KT, Heaton K, Lozano D, Su X. Sleep quality, stress, caregiver burden, and quality of life in maternal caregivers of young children with bronchopulmonary dysplasia. J Pediatr Nurs. 2014;29(1):29–38.
83. Lefkowitz D, Baxt C, Evans J. Prevalence and Correlates of Posttraumatic Stress and Postpartum Depression in Parents of Infants in the Neonatal Intensive Care Unit (NICU). J Clin Psychol Med Settings. 2010;17(3):230–7.
84. Wilman E, Megone C, Oliver S, Duley L, Gyte G, Wright JM. The ethical issues regarding consent to clinical trials with pre-term or sick neonates: a systematic review (framework synthesis) of the empirical research. Trials. 2015;16(1):1–13.
85. Berger AM, Wielgus KK, Young-McCaughan S, Fischer P, Farr L, Lee KA. Methodological challenges when using actigraphy in research. J Pain Symptom Manage. 2008;36(2):191–9.
86. Hummers-Pradier E, Scheidt-Nave C, Martin H, Heinemann S, Kochen MM, Himmel W. Simply no time? Barriers to GPs' participation in primary health care research. Fam Pract. 2008;25(2):105–12.
87. Broyles L, Rodriguez K, Price P, Bayliss N. Overcoming Barriers to the Recruitment of Nurses as Participants in Health Care Research. Qual Health Res. 2011;21:1705–18.
88. Cox K, McGarry J. Why patients don't take part in cancer clinical trials: an overview of the literature. Eur J Cancer Care (Engl). 2003;12(2):114–22.
89. Davis LL, Broome ME, Cox RP. Maximizing retention in community-based clinical trials. J Nurs Scholarsh. 2002;34(1):47–53.
90. Galea JT, Ramos K, Coit J, Friedman LE, Contreras C, Duenas M, Hernandez N, Muster C, Lecca L, Gelaye B. The Use of Wearable Technology to Objectively Measure Sleep Quality and Physical Activity Among Pregnant Women in Urban Lima, Peru: A Pilot Feasibility Study. Matern Child Health J. 2020;24(7):823–8.
91. Dumville JC, Torgerson DJ, Hewitt CE. Reporting attrition in randomised controlled trials. BMJ (Clinical research ed). 2006;332(7547):969–71.
92. Launes J, Hokkanen L, Laasonen M, Tuulio-Henriksson A, Virta M, Lipsanen J, Tienari PJ, Michelsson K. Attrition in a 30-year follow-up of a perinatal birth risk cohort: factors change with age. PeerJ. 2014;2:1–19.
93. Teague S, Youssef GJ, Macdonald JA, Sciberras E, Shatte A, Fuller-Tyszkiewicz M, Greenwood C, McIntosh J, Olsson CA, Hutchinson D, et al. Retention strategies in longitudinal cohort studies: a systematic review and meta-analysis. BMC Med Res Methodol. 2018;18(1):1–22.
94. Newington L, Metcalfe A. Factors influencing recruitment to research: qualitative study of the experiences and perceptions of research teams. BMC Med Res Methodol. 2014;14:1–11.
95. Jones TL, Baxter MAJ, Khanduja V. A quick guide to survey research. Ann R Coll Surg Engl. 2013;95(1):5–7.
96. Polit DF, Beck CT: Essentials of nursing research : appraising evidence for nursing practice, 9th ed. edn. Philadelphia, Pa: Wolters Kluwer; 2018.
97. Dwyer CP, Moses A, Rogers FM, Casey D, Joyce R, Hynes SM. A qualitative investigation of reasoning behind decisions to decline participation in a research intervention: A study-within-a-trial. J Health Psychol. 2021;00(0):1–14.
98. Brintnall-Karabelas J, Sung S, Cadman ME, Squires C, Whorton K, Pao M. Improving recruitment in clinical trials: why eligible participants decline. J Empir Res Hum Res Ethics. 2011;6(1):69–74.

Publisher's Note

Paper 3

BMC Pediatrics

Title: A comparison of subjective and objective sleep measures, insomnia symptoms, and health-related quality of life between mothers and fathers of preterm versus full-born infants: A longitudinal study from Norway

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Abstract

Background: Poor sleep may negatively affect parents' health-related quality of life (HRQoL). This study aimed to describe and compare sleep and HRQoL in mothers and fathers of preterm and full-born infants over time. We also assessed possible associations between sleep, insomnia, and HRQoL over time in the total sample.

Methods: A longitudinal study of parents of preterm (n = 25 couples) and full-born (n = 76 couples) infants was conducted. To assess sleep, parents wore wrist actigraphs and filled out sleep diaries for 2 consecutive weeks before responding to a digital questionnaire regarding insomnia symptoms and HRQoL. Actigraphy and sleep diary data were collected at the infant age of 2 months, while questionnaire data were collected at the infant ages of 2, 6, and 12 months. Statistical analyses included linear regression and linear mixed models for repeated measures.

Results: There were no statistically significant differences in total sleep time (actigraphy and sleep diary) between the parent groups (preterm and full-born) at 2 months postpartum. Sleep efficiency was significantly higher for the full-born group. All mothers reported significantly shorter total sleep time and lower sleep efficiency compared to fathers (all $p < 0.01$). In the whole sample, insomnia incidence at 2 months postpartum was high (> 43.5%), and for mothers, it remained high at 6 and 12 months (> 50%). No significant HRQoL differences were identified between the parent groups over time. Fathers reported significantly higher physical HRQoL levels compared to mothers ($p = 0.04$). There were no significant associations between total sleep time or sleep efficiency and HRQoL. Insomnia symptoms were associated with reduced mental and physical HRQoL at all measurement points.

Conclusions: Sleep efficiency (actigraphy and sleep diary) was significantly higher for the full-born group compared to the preterm group. Mothers (both groups) experienced

significantly shorter total sleep time and lower sleep efficiency compared to fathers. The incidences of insomnia symptoms were high at 2 months postpartum for the whole sample and remained high at follow-up for mothers. Fathers (both groups) reported higher physical HRQoL compared to mothers. Insomnia symptoms had a significantly negative impact on parents' long-term HRQoL.

Keywords: Health-related quality of life, parents, postpartum, sleep, insomnia, preterm infant, full-born infant, nurse.

Background

Sleep is important for the normal function and recovery of all body systems [1]. Sleep affects physical, cognitive, and mental health; the immune system; and social functions [2]. The 'postpartum period' refers to the immediate period from childbirth up to 6 months after [3]. During this period, parents often experience reduced opportunities for sleep, along with increased wakefulness at night, daytime sleepiness, fatigue, and reduced neurobehavioral performance [4]. Maternal sleep is often the most affected [5], but parental sleep often gradually improves from 10–12 weeks postpartum [6]. Between 6 and 12 months postpartum, several infants develop a more stabilized sleep pattern and sleep through the night [7]. However, some parents develop more significant sleep problems than others and are more vulnerable to changes following childbirth [8]. Postpartum sleep disturbances have been associated with a wide array of negative health consequences, including postpartum depression [9, 10].

Although sleep deprived, most parents experience the birth of an infant as a happy life event [11]. In contrast, parents have described a preterm birth as a crisis and a traumatic life experience [11]. Preterm births are defined as deliveries before 37 completed weeks of gestation [12]. The early birth and admission of a preterm infant to the neonatal intensive care unit (NICU) has been associated with considerable stress for caregivers, particularly if infants are in the lower birthweight categories and have a higher risk of mortality and morbidity (very low birthweight ≥ 1,500 g) [13]. Preterm infants can be hospitalized for weeks or even months and discharged from the hospital with complex health needs [14]. For parents, the consequences of a preterm birth can be far-reaching and influence several life aspects [15]. Two reviews reported that the sleep quality and quantity of mothers of preterm infants are poor in the first few postpartum months [16, 17]. High levels of perceived stress negatively affect these mothers' sleep outcomes [9, 11, 16]. Stress can lead to poor sleep and, in turn, increase the risk of fatigue, anxiety, and depression, as well as reduce health-related quality of life (HRQoL), early after childbirth [11, 18]. Previous research has mainly focused on sleep among mothers of preterm infants early in the postpartum period, while there has been little focus on fathers' sleep [16, 17]. There is also a lack of comparative studies to determine whether sleep differs between parents of preterm and full-born infants over time [17].

Pregnancy and postpartum have been identified as vulnerable periods for developing sleep problems such as insomnia, particularly for women [8, 19]. The diagnostic criteria for insomnia diagnosis are defined as 'difficulty initiating or maintaining sleep for at least 3 months, in addition to impaired daytime functioning caused by the sleep disturbance' [20]. Previous publications have reported that insomnia prevalence for postpartum mothers is very high (60%) immediately after childbirth and remains high (41%) after 2 years [8, 19]. Different factors, such as genetic, environmental, social, medical, and mental conditions (including stressful life events), can contribute to the onset of insomnia [21-23]. Although

parents of preterm infants may be at risk of developing insomnia due to the stressful birth event, few studies have examined the prevalence of insomnia for these parents. In a Swedish study, Blomqvist et al. [24] identified a high insomnia prevalence in parents of preterm infants early after childbirth, particularly mothers. Insomnia has been associated with significant physical and mental health impairments, including poor HRQoL, in other populations [25, 26].

HRQoL is an important outcome and a prominent indicator of how various conditions affect individuals' lives [27]. HRQoL is a multidimensional concept covering physical, psychological, social, and spiritual aspects of life [28]. Previous cohort studies have compared the quality of life (QoL) of parents of preterm and full-term infants. Some studies have reported no differences in QoL [29, 30], while others have indicated lower QoL for parents of preterm infants [31-33]. None of these studies, however, have included an assessment of sleep or insomnia. To our knowledge, no longitudinal study has explored sleep and its associations with health and HRQoL over time in this vulnerable parent population [16, 17].Considering that a preterm delivery might be a stressful life event with the potential to adversely affect parental sleep [9, 11, 34], we hypothesized that parents of preterm infants have higher sleep impairment than parents of full-born infants. Based on the literature, we also hypothesized that mothers of preterm infants would be more susceptible to sleep disturbances than mothers of full-born infants [35] and fathers [24, 36]. Lastly, we hypothesized that poor sleep might have the potential to negatively affect parents' overall HRQoL [11]. This study aimed to describe and compare sleep and HRQoL in mothers and fathers of preterm and full-born infants over time. We also assessed possible associations between sleep, insomnia, and HRQoL over time in the total sample.

Methods

Study design, setting, and population

A comparative longitudinal study was conducted between June 2019 and March 2020. Parents were recruited as couples into two separate groups: one group included parents with preterm infants (born *before* the 37th week of pregnancy), recruited from NICUs and maternity wards, whereas the other group (comparison group) included parents with full-born infants (born *after* the 37th week of pregnancy), recruited from two maternity wards.

The inclusion criteria for both parent groups were that parents needed to be over 16 years of age, be living together, and have a sufficient command of a Nordic language (written and oral). Both mother–father parents and same-sex parents (referred to as birth-giving and non-birth-giving mothers) were included in the study.

Parents were excluded if they had a serious drug addiction (recorded in the patient journal; cf. *International Classification of Diseases* (*ICD-10)* or *Diagnostic and Statistical Manual for Mental Disorders* [4th ed.]), the newborn had serious deformities/or a life-threatening condition that could affect survival, the mother had given birth to multiple infants, or the mother had a condition/diagnosis which made participation in the project ethically challenging (serious, life-affecting health issues). Parents with shift work were excluded, as working at night impacts sleep. Those with sleep diagnoses were also excluded. See Figures 1a and 1b for a flow chart of the participants.

PLACE FIGURES 1A AND 1B HERE

Parents with preterm infants were recruited from four different NICUs and one maternity ward in southeastern Norway. Three of the NICUs were at Level 3c, while one was at Level 3b. In Norway, Level 3c units have the highest medical competence to treat extremely preterm infants, starting from gestational age (GA) 23. Level 3b units have the second-highest competence and treat preterm infants from GA 26 [37]. Parents with full-born infants were recruited from two maternity wards which treated healthy mothers with uncomplicated births.

Sample size

The study sample size was estimated using data from two previous studies reporting on differences in total sleep time (TST) for mothers of preterm [11] and full-born infants [38]. Previous research has shown that mothers of preterm infants sleep, on average, for 6.3 (SD 2) hours per night [11], compared to 7.0 (SD 1) hours for a group of mothers of full-born infants [38]. Thus, we assumed a one-hour difference in the TST between the groups. To account for multiple testing, we estimated that it would be sufficient to include ≥ 75 couples with a preterm infant and ≥ 75 couples with a full-born infant.

Recruitment

A collaborating nurse within each hospital ward was responsible for the recruitment of parents of preterm and parents of full-born (comparison group) infants. The nurses identified eligible parent couples and received informed consent from parents who wanted to participate.

The original plan was to recruit the targeted number of parent couples to the preterm and full-born groups between June and December 2019. For the preterm group, the recruitment period was more extensive due to a low recruitment rate. The total recruitment period for the preterm

group was 33 weeks, until March 2020 when coronavirus disease 2019 (COVID-19) restrictions ended all recruitment efforts. By then, only 25 parent couples had been recruited to the preterm group.

For the full-born group, 78 parent couples were recruited within 15 weeks from the two maternity wards. Two couples withdrew their consent before the baseline measurement. Therefore, a total of 76 parent couples participated in the full-born group.

Data collection

All parent couples were included before 5 weeks postpartum so that actigraphs and sleep diaries could be sent to parents' home addresses before the first data collection. Subjective and objective sleep data were collected at the infant age of 2 months (6–8 weeks postpartum). Participants received a postal mail with two preprogrammed actigraphs – Respironics Actiwatch 2 (Philips Healthcare, Philips.com; https://www.philips.no/healthcare) – and two preplotted (dates only) sleep diaries to be completed over the same period as the actigraphs. After 2 weeks of sleep recordings, parents responded to a digital questionnaire regarding insomnia and HRQoL. The actigraphs and sleep diaries were returned to the first author in a prepaid envelope. The data collection occurred before and during the first wave of the COVID-19 pandemic. The pandemic introduced great uncertainties regarding how the virus was spread; hence, it was decided to not distribute actigraphs and sleep diaries to parents after March 2020. Sleep data from actigraphs and sleep diaries were therefore only collected at 2 months.

Parents responded to a digital questionnaire at three measurement points (2, 6, and 12 months). The questionnaire included items on parental sociodemographic variables such as age, educational level, income, employment status, ethnicity, weight, height, and parity. The

questionnaire also included items on the infants' data, including GA at birth, birthweight, and infant length. All sociodemographic variables have been associated with sleep in previous research [16].

Sleep measurements

Subjective sleep (sleep diary)

Subjective sleep data was collected using sleep diaries. At baseline, both parents independently completed a sleep diary for 2 weeks. A sleep diary similar to Carney et al.'s [39] recommendation was used. The diary consisted of the parents' estimates of own daytime and nighttime sleep patterns, including perceived sleep quality. The following measures were reported in the sleep diary: number of daytime naps, daytime nap duration, daytime function (1, *very good*; 5, *very poor*), sleep onset latency (SOL – the number of minutes to fall asleep), wake after sleep onset (WASO – the number of minutes awake between sleep onset and sleep offset), number of nighttime awakenings, early morning awakening, total wake time (SOL + WASO + early morning awakening), TST (number of minutes asleep in bed after 'lights off', considered nighttime sleep), time in bed (TIB = the duration spent in bed), sleep efficiency (SE = % TST as a percentage of TIB), and sleep quality rating (1, *very restless*; 5, *very poor*) [40, 41].

Objective sleep (wrist actigraphy)

Objective sleep-wake data was assessed at baseline using wrist actigraphs – Actiwatch 2 (Philips Healthcare, Philips.com; https://www.philips.no/healthcare). Actigraphs are noninvasive motion sensors used to assess sleep-wake patterns in adults [42, 43]. Actigraphy

has been tested and found reliable compared to polysomnography, especially for TST estimates [44]. The sensitivity of the Actiwatch was set to medium. Data was collected in 30-second epochs (activity counts) and transferred to a computer for analysis. Parents were asked to press an event marker to indicate when they went to bed to sleep for the night and when they got out of bed in the morning. Parents wore the Actiwatch on their nondominant wrist. The following measures were derived from the actigraphs: SOL, TIB, SE, WASO, total wake time, and TST.

Questionnaire

Insomnia

The Bergen Insomnia Scale (BIS) was used to assess insomnia symptoms at all three measurement points (2, 6, and 12 months) [45]. The BIS was originally developed to correspond with the diagnostic criteria for insomnia presented in the *Diagnostic and Statistical Manual for Mental Disorders* (4th ed., Text Revision) [46]. Each BIS item is scored along a scale from 0 to 7, indicating the number of days per week for which a specific insomnia symptom was experienced (0–7 days). The first four items measure sleep impairment, assessing sleep onset (sleep latency > 30 minutes), WASO (> 30 minutes), early morning awakening (> 30 minutes), and nonrestorative sleep, and the last two items measure daytime impairment and dissatisfaction with sleep [45]. The BIS provides a total score and may be used as a dichotomous score for the presence or absence of chronic insomnia [8]. Chronic insomnia disorder was defined as scoring 3 days per week or more on at least one of the first three items, as well as 3 days per week or more on at least one of the latter two items [45]. The BIS originally defined insomnia as symptoms experienced during the past month but was modified to a wider time frame of the last 3 months in the updated *Diagnostic and*

Statistical Manual for Mental Disorders (5th ed.)/*International Classification of Sleep Disorders-3* diagnostic criteria [47]. The BIS has acceptable test–retest reliability and good validity in relation to other self-report measures and polysomnography [45].

HRQoL

HRQoL was assessed using the RAND Medical Outcomes Study 36-Item Short Form Survey (RAND-36) [48]. The RAND-36 is a self-reported generic HRQoL questionnaire that includes eight domains: general health, bodily pain, physical function, role limitation (physical), mental health, vitality, social function, and role limitations (emotional). The domains can be combined into physical and mental scales reflecting both physical (physical component summary [PCS]) and mental (mental component summary [MCS]) well-being [48, 49]. The RAND-36 is scored using values from 0 to 100, with 100 representing optimal health [50]. The Norwegian version of the RAND-36 has been reported as a valid and reliable instrument for assessing HRQoL [51].

Attrition

Attrition refers to the failure of participants to complete their measurements after being enrolled in a study [52]. Not all participants responded to the questionnaire. Consequently, the number of participants at a given assessment point did not always correspond to the number of returned questionnaires. Therefore, we decided to compute attrition based on the number of participants (mothers and fathers) and not couples. Attrition rates were calculated as participants (mothers or fathers) who completed the questionnaire at 6 and 12 months divided by the number of participants (mothers and fathers) at baseline, 2 months (Figures 1a and 1b).

Statistical analysis

IBM SPSS Statistics version 26 (IBM Corp., Armonk, NY, USA) was used for the statistical analyses. Descriptive statistics were used to describe the study sample. Categorical data are presented as frequencies and percentages, and continuous data are presented as median, minimum, and maximum values.

The mean values of sleep obtained from 7 days of actigraphy and sleep diary data were analysed. In the case of missing data, the 7 days with the least combined missing data from both measures (actigraphy and sleep diary) were used. Daytime nap time was not collected from actigraphs since many participants had forgotten to use the Actiwatch's button to register daytime sleep. Therefore, daytime sleep was registered in sleep diaries only.

To assess possible differences in TST and SE between the parent groups (preterm compared to full-born) and genders (mothers compared to fathers), we fitted four linear regression models with TST and SE as the dependent variables and parent (mother or father) and group (preterm or full-born) as the independent variables. To investigate if there was an interaction between the group and parent variables, in addition to the additive effect (e.g. if being a mother of a preterm infant presented an additional burden), we fitted an interaction term (group * parent). This interaction was not significant for any of the models, so we further adopted models fitted with group and parent variables only.

To assess whether there was a difference in TST and SE between parents of preterm and full-born infants, we fitted four different regression models assessing four dependent variables: the sleep diary variables were a) TST and b) SE, while the actigraphy variables were c) TST and d) SE. The independent (indicator) variables were

- Group (preterm or full-born)
- Parent (mother or father)
- Interaction (parent and group)

Longitudinal data analyses were performed using linear mixed models for repeated measures to include multiple repeated measurements of each patient's outcome over time. Possible associations between sleep, insomnia, and HRQoL were assessed with multiple linear regression.

To ease interpretation of the linear regression results, we also computed effect sizes (ESs) [53]. The ES is interpreted as follows: d < 0.1, *very small effect*; d < 0.2, *small effect*; d < 0.5, *moderate effect*; and d < 0.8, *large effect* [53].

Results

Attrition and missing data

The longitudinal sample included 25 parent couples with preterm infants and 76 couples with full-born infants. At 6 months, 21 (preterm) and 61 (full-born) couples participated in the study. At 12 months, 17 (preterm) and 60 (full-born) couples participated in the final measurement (Figures 1a and 1b).

For the preterm group, 25 couples (25 mothers and 25 fathers) were recruited for the study. Nine mothers and 6 fathers responded to the questionnaire at 6 months, producing attrition rates of 64% (mothers) and 76% (fathers). At 12 months, 10 mothers and 8 fathers responded, producing attrition rates of 60% (mothers) and 68% (fathers; Figure 1a).

For the full-born group, 76 parent couples (76 mothers, 73 fathers, and 3 non-birth-giving mothers) were recruited for the study. Thirty-nine mothers and 31 fathers responded to the questionnaire at 6 months, producing attrition rates of 49% and 59%, respectively. At 12 months, 30 mothers and 31 fathers responded; attrition rates were 61% and 59%, respectively (Figure 1b).

Characteristics of the sample

Tables 1a and 1b present the sociodemographic characteristics of the parent and infant samples. The median maternal age was 30.5 years (preterm group) and 31.5 years (full-born group). For fathers, the median age was 32.0 years (preterm) and 33.0 years (full-born). The parent groups were quite similar according to age, body mass index, education, and income level. Most participants were first-time parents (primiparas) and had Norwegian ethnicity and an income level ≥ NOK 500,000 (about €50,000) per year. As many as 15 (60%) of the infants in the preterm group were in the 'moderate/late' category, with GA between 32 and 36 weeks. Only 2 (8%) were in the extremely preterm (GA < 28) and very preterm (GA 28–31) categories.

PLACE TABLES 1A AND 1B HERE

Subjective and objective sleep in the parent sample

Descriptive data for the parents' subjective and objective sleep at baseline (2 months) are presented in Table 2. There was a general tendency towards mothers (preterm and full-born) reporting lower SE (sleep diary) compared to fathers. Fathers' SE was above the cutoff for

normal values, which is considered ≥ 85% [54]. Mothers (preterm group) reported the highest WASO and seemed to compensate for this by sleeping during daytime. Parents' daytime function and self-rated sleep quality were quite similar and comparable for all responders.

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Group differences in subjective and objective sleep

TST

Regarding TST (baseline), there were no statistically significant differences between the parent groups for either the sleep diary or actigraphy (data not shown).

SE

For SE, there were statistically significant differences between the parent groups. Parents in the full-born group reported higher SE values compared to those in the preterm group when assessed with actigraphy (B = 2.20, 95% CI [0.28 to 4.13], $p < 0.025$) and the sleep diary (B = 3.68, 95% CI [0.67 to 6.69], $p = 0.017$).

Gender differences in subjective and objective sleep

TST

Comparing TST differences regarding gender, mothers (preterm and full-born) reported, on average, 40 minutes shorter TST compared to fathers in their sleep diaries (B = 39.15; 95% CI [22.62 to 55.67], $p < 0.001$). No similar differences were assessed by actigraphy.

SE

When genders were compared for SE differences, mothers (preterm and full-born) reported significantly lower SE levels (4% lower) compared to fathers on actigraphy (B = 4.26, 95% CI [2.58 to 5.94], $p < 0.001$). When SE was assessed with the sleep diary, mothers (preterm and full-born) reported, on average, about 12% lower SE compared to fathers (B = 11.93, 95% CI [9.29 to 14.58], $p < 0.01$). Gender differences were more pronounced when SE was assessed with a sleep diary than when using actigraphy data.

Insomnia

The prevalence of insomnia symptoms was high for both parents in both groups at baseline (Table 3), but parents in the preterm group demonstrated higher baseline incidences: 62.5% CI [35.4 to 84.8] for mothers and 71.4% CI [41.9 to 91.6] for fathers. The incidences for the full-born group were 53.4% CI [39.9 to 66.6] for mothers and 43.5% CI [28.9 to 58.9] for fathers. Over time, the insomnia incidence remained high (> 50%) for mothers (preterm and full-born) at both 6 and 12 months postpartum. However, the tendency between the parent groups was reversed, as parents in the full-born group reported a higher incidence of insomnia. There was also a tendency towards mothers (preterm and full-born) reporting a higher incidence of insomnia compared to fathers at the 6- and 12-month measurements (Table 3).

PLACE TABLE 3 HERE

HRQoL

HRQoL was assessed at 2, 6, and 12 months postpartum (Table 3). Considering the entire follow-up, there was no statistically significant difference between parents of preterm and full-born infants regarding PCS (B = 1.42; 95% CI [-1.11 to 3.94], p = 0.273) or MCS (B = -0.10, 95% CI [-3.83 to 3.6], p = 0.962).

However, fathers (preterm and full-born) reported significantly higher PCS levels compared to mothers (preterm and full-born; B = 2.24; 95% CI [0.11 to 4.37], p = 0.04). The difference between mothers and fathers was present at baseline and did not change over time. Further, the PCS levels remained unchanged over the entire observation period. For the MCS, our data did not reveal any differences between mothers and fathers (B = 0.76; 95% CI [-2.41 to 3.93], p = 0.640). Notably, MCS levels remained unchanged from baseline (2 months) to 6 months but decreased significantly for both groups at 12 months (B = -2.16; 95% CI [-4.31 to -0.02], p = 0.048).

Associations between sleep variables, insomnia, and HRQoL over time

Associations between parents' TST, SE, and insomnia and their HRQoL were analysed using multiple linear regression. For SE and TST (sleep diary and actigraphy), there were no significant associations between the sleep variables at baseline and the PCS or MCS (Additional Files 1–4). Using mixed models for repeated measures adjusted for gender, insomnia was strongly associated with lower HRQoL (Table 4). The effect was more pronounced for the MCS (B = -6.93 95% CI [-10.31 to -3.55] p < 0.001) compared to the PCS (B = -3.64 95% CI [-6.04 to -1.25], p = 0.003). For mental well-being (MCS), the reduction for those with insomnia was twice as large as that estimated for physical well-being (PCS). However, due to high data variations, the ESs were small (0.24 for the mental component and

0.18 for the physical component). Time, gender, and group did not affect the highly significant association between insomnia and HRQoL at any measurement point. Table 4 lists the changes over time in the PCS and MCS.

PLACE TABLE 4 HERE

Discussion

To the best of our knowledge, this is the first study to examine parental sleep, insomnia symptoms, and HRQoL in mothers and fathers of preterm and full-born infants over time during the first postpartum year. Our key findings were that SE was lower for parents in the preterm group compared to those in the full-born group at 2 months postpartum. Moreover, our data revealed significant differences in sleep between the genders in the total sample. Mothers (preterm and full-born) reported significantly shorter TST and lower SE than fathers. Gender differences were most pronounced when sleep was assessed using subjective sleep diaries.

Additionally, we identified a very high prevalence of insomnia symptoms in both parent groups at 2 months postpartum. Although the prevalence decreased, the insomnia incidence remained stable and high for mothers (preterm and full-born) at the 6- and 12-month measurements. We also identified a statistically highly significant association between insomnia symptoms (at 2 months postpartum) and parents' mental and physical well-being. The association was most pronounced for mental well-being.

In line with our hypotheses, our results confirmed that parents of preterm infants are significantly more susceptible to experiencing poor sleep, with lower SE, than parents of full-

born infants. The explanation for these results might be that parents of preterm infants' transition to parenthood is far more stressful, with a higher risk of infant hospitalization and concerns for the infant's medical condition and long-term health outcomes [55]. Stress has been highlighted as a major factor causing sleep problems for these parents [11, 16, 56]. Parents have described the NICU environment as unfamiliar and frightening [57]. They are often constantly present [58, 59] and underprioritize their own sleep [34, 60]. The NICU environment is primarily dedicated for the provision of advanced medical care and not for parental sleep [58, 61]. High levels of parental stress, together with concerns for the infant, and hospitalization in the NICU [58, 59] might explain the sleep differences in our parent samples.

We also hypothesized there could be gender differences in sleep between mothers and fathers. Our baseline results confirmed this hypothesis: the mothers in our sample (preterm and full-born) experienced shorter TST and lower SE compared to fathers. The literature supports our results [62-64]. Postpartum mothers often struggle to achieve restorative sleep during the first postpartum months [62]. Despite maternal sleep pattern changes being a 'normal phenomenon' [65], it is important to note that some mothers develop more serious sleep problems of a more chronic nature [66]. Mothers with significant sleep problems may have a higher risk of developing mental health issues – such as postpartum depression [6], which has been associated with negative outcomes for the whole family [67].

Our results indicated that gender differences regarding sleep were most pronounced when sleep was assessed using subjective sleep diaries. This is in line with previous research, which has reported discrepancies between subjective and objective sleep measurements [68, 69]. Subjective and objective sleep measurements are often used in combination to provide more in-depth sleep assessments [70, 71]. Although subjective and objective sleep measurements

(such as sleep diary and actigraphy, respectively) have different strengths and limitations, both measurements have been found reliable to give a valid indication of TST and SE.

Our results particularly raise concerns for mothers giving birth to preterm infants. These mothers reported the lowest SE among all participants. This is in line with previous studies that have raised concerns about these mothers' sleep and mental health outcomes in the early postpartum period [11, 18, 72-74]. Mothers of preterm infants have a higher risk of postpartum depression compared to those of full-born infants [75, 76]. Sleep disturbances and stress are often closely linked [11]. The high levels of maternal stress described in the literature [11, 16, 18, 34] may partly explain these mothers' poor sleep outcomes, but further research is required. Efforts to reduce stress may be one way to support sleep for future mothers with preterm infants [11].

There was an overall pattern indicating a high prevalence of insomnia symptoms for both parent groups at 2 months postpartum. For mothers, the prevalence remained high at 6 and 12 months postpartum. Our results are in line with the literature confirming that postpartum mothers generally have a high prevalence of insomnia, which could be chronic [8, 19, 77]. The high prevalence of maternal insomnia symptoms is of concern since insomnia is associated with mental health issues [78-81].

For parental HRQoL, we did not identify any differences between the groups or genders, which was surprising. We hypothesized that for parents with preterm infants, poor sleep could have a negative impact on parents' HRQoL, as described in the literature [10]. We did not find any significant associations between the baseline variables for TST or SE and parental HRQoL. However, there was a highly significant association between insomnia symptoms and reduced parental HRQoL over time, particularly for the subscale mental well-being. This is of concern since the prevalence of insomnia symptoms was high in our sample.

Insomnia is a rising public health problem with both individual and economic consequences [23, 82, 83]. Our results indicate the need for insomnia prevention and treatment in postpartum parents, with a particular focus on mothers. The use of screening tools to evaluate sleep, insomnia symptoms, and depression should be implemented as standard care to identify vulnerable parents [84]. Different interventions should also be tested to treat insomnia among new parents. Nonpharmacological treatments, such as cognitive behavioural therapy, have been tested to be effective [85].

We suggest a stronger focus on sleep promotion, with guidance from early in the postpartum period. Evaluations of sleep disturbances and depression, with advice for sleep optimization, should be included as standard postpartum care for all parents within neonatal caregiving [86]. Nurses/midwives in hospital wards are in a unique position to provide guidance and recommendations to new parents so they can maintain a consistent sleep pattern [87]. Such guidance could be implemented as standard information for parents [88]. More studies on factors that affect postpartum parents' sleep are needed so that sleep-promoting efforts can be developed.

Strengths and limitations

This is, to our knowledge, the first comparative longitudinal study to evaluate sleep, insomnia, and HRQoL in parents of preterm and full-born (comparison group) infants over time. The strengths of this study are the longitudinal study design, with collection of sleep and HRQoL data for both mothers and fathers in both groups over time.

The recruitment of parents of preterm infants represented a challenge in this study. We aimed to recruit a homogenous sample, which was reflected in rather strict inclusion criteria. The volume of twins/multiple infants (48.2%) and non-Nordic speaking individuals (20%) was

surprisingly high for parents of preterm infants, and the inclusion criteria contributed to many exclusions (Figures 1a and 1b). Around two-thirds of the preterm infant group refused to participate, compared to one-third of the full-born group (Figures 1a and 1b). Due to the low number of participants, the statistical power was limited, and many of our estimates had low precision (increased risk of type 2 error). Retainment of parents over time was another challenge. The failure of parents to complete their participation at 6 and 12 months was high for both parent groups. This reduced the power for statistical analyses in this longitudinal study, compared to what was originally planned.

Other strengths of this study are the long-term sleep and HRQoL assessment, as well as the subjective and objective sleep measurements. The measurements give a broad picture of sleep pattern and relevant sleep variables, as high night-to-night variability is common for individuals suffering from insomnia [89] and postpartum parents in general [62, 90]. It was unforeseen that COVID-19 restrictions would interfere with recruitment and the long-term use of sleep measures; thus, we only could present actigraphy and sleep diary data at baseline.

We defined usable data for the actigraphs and sleep diaries as ≥ 1 day with ≥ 24 hours of daily wear time; data that did not fulfil these criteria had to be discarded. This represents a limitation for our results since studies suggest that actigraphs should be used for at least 5–7 nights to accurately measure TST and SE [91].

Overall, the difficult recruitment of parents with preterm infants, high attrition rates, and the COVID-19 outbreak hampered recruitment and data collection in this longitudinal study. However, the statistically significant association between insomnia symptoms and HRQoL was highly noteworthy, and we considered it clinically relevant.

Conclusions

This study introduces knowledge about sleep and HRQoL in parents of newborn babies. Insomnia was identified as a frequently occurring sleep disorder among the studied parents. The prevalence was high in both groups 2 months postpartum and remained high at 6 and 12 months postpartum for the mothers. An important finding was that insomnia was the only sleep variable that had a significant negative impact on parents' HRQoL. Mental HRQoL was particularly negatively affected.

Another important result was that parents of preterm children had poorer sleep quality at 2 months postpartum, assessed with subjective and objective measures, compared to parents of full-born infants. Mothers in both groups had significantly lower SE and shorter TST compared to the fathers for the same period. When HRQoL was compared between parent groups, no statistically significant differences were identified. Fathers in both groups had higher physical HRQoL compared to the mothers at all assessment points.

Our results indicate that postpartum parents have impaired sleep after childbirth, and this requires increased attention from health professionals. We suggest a stronger focus on sleep support and the prevention of sleep disorders, especially for new mothers. A particular concern should be paid to developing sleep support for vulnerable groups, such as mothers of preterm infants. Within clinical caregiving, sleep screening should be introduced as a standard routine so that parents with sleep problems can be identified and receive sleep-promoting help. Insomnia prevention is important to promote HRQoL among future postpartum parents.

Abbreviations

BIS: Bergen Insomnia Scale, COVID-19: coronavirus disease 2019, ES: effect size, GA: gestational age, HRQoL: health-related quality of life, MCS: mental component summary, NICU: neonatal intensive care unit, PCS: physical component summary, QoL: quality of life, RAND-36: RAND Medical Outcomes Study 36-Item Short Form Survey, SE: sleep efficiency, SOL: sleep onset latency, TIB: time in bed, TST: total sleep time, WASO: wake after sleep onset.

Declarations

Ethics approval and consent to participate

The study was approved by the Norwegian National Research Ethics Committees (reference no. 2018/1025). The study was conducted in accordance with relevant ethical guidelines and regulations. Research departments and respective leaders at the hospitals permitted implementation of the study in hospital wards. All parents gave their informed consent.

Consent for publication

Not applicable

Availability of data and materials

The datasets used in the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare they have no competing interests.

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This study did not receive any financial support.

Authors' contributions

GNM was responsible for the overall conception and design of this study, statistical analysis and interpretation of data, and writing of the manuscript. LF, SH, MS, and BB took part in all decisions and were involved in the writing process. All authors revised the manuscript and approved the final work.

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References

[1] Carscadon M, Dement W. Normal human sleep: an overview. In: Kryger M, Roth T, Dement, WC, editor. Principles and practice of sleep medicine. 6 ed. Philadelphia: Elsevier; 2017. p. 15-23.

[2] Redeker NS. Developmental aspects of normal sleep. In: Redeker NS MP, editor. Sleep disorders and sleep promotion in nursing practice. New York: Springer Publishing; 2011. p. 19-32.

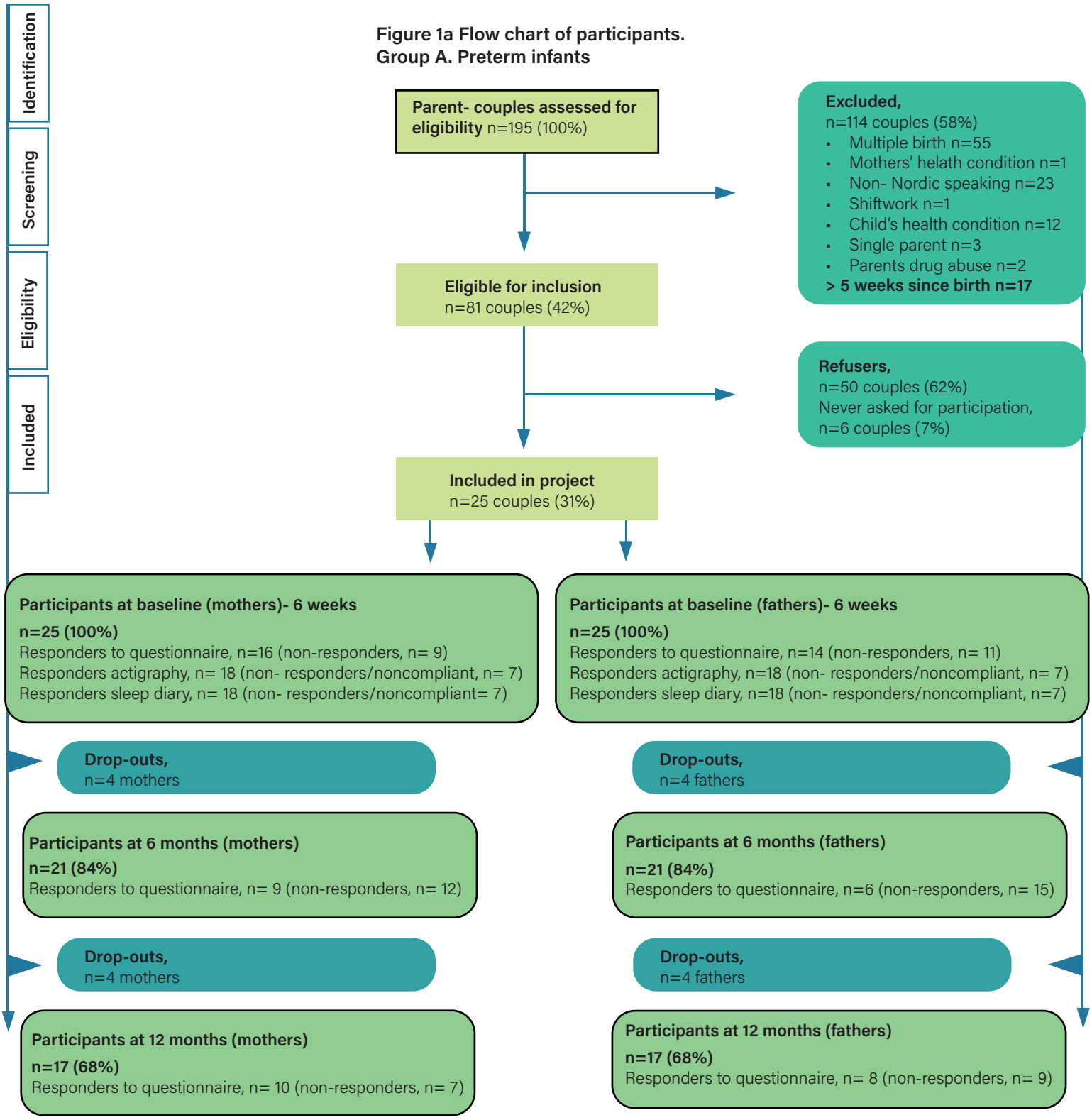
[3] Romano M, Cacciatore A, Giordano R, La Rosa B. Postpartum period: three distinct but continuous phases. J Prenat Med 2010;4:22-25.
[4] Insana SP, Garfield CF, Montgomery-Downs HE. A mixed-method examination of maternal and paternal nocturnal caregiving. J Pediatr Health Care 2014;28:313-321. doi:10.1016/j.pedhc.2013.07.016.
[5] Montgomery-Downs H, Stremler R, Insana S. Postpartum Sleep in New Mothers and Fathers. Open Sleep J 2013;6:87-97. doi:10.2174/1874620901306010087.
[6] Dørheim S, Bondevik G, Eberhard-Gran M, Bjorvatn B. Sleep and depression in postpartum women: a population-based study. Sleep 2009;32:847-855.
[7] Bruni O, Baumgartner E, Sette S, Ancona M, Caso G, Di Cosimo ME, Mannini A, Ometto M, Pasquini A, Ulliana A, Ferri R. Longitudinal study of sleep behavior in normal infants during the first year of life. J Clin Sleep Med 2014;10:1119-1127. doi:10.5664/jcsm.4114.
[8] Sivertsen B, Hysing M, Dørheim SM, Eberhard-Gran M. Trajectories of maternal sleep problems before and after childbirth: a longitudinal population-based study. BMC Pregnancy Childbirth 2015;15:129. doi:10.1186/s12884-015-0577-1.
[9] Busse M, Stromgren K, Thorngate L, Thomas KA. Parents responses to stress in the neonatal intensive care unit. Crit Care Nurse 2013;33:52-60. doi:10.4037/ccn2013715.
[10] Vigod SN, Villegas L, Dennis CL, Ross LE. Prevalence and risk factors for postpartum depression among women with preterm and low-birth-weight infants: a systematic review. BJOG 2010;117:540-550. doi:10.1111/j.1471-0528.2009.02493.x.
[11] Lee SY, Hsu HC. Stress and health-related well-being among mothers with a low birth weight infant: the role of sleep. Soc Sci Med 2012a;74:958-965. doi:10.1016/j.socscimed.2011.12.030.
[12] World health organization.Preterm birth, from http://www.who.int/news-room/fact-sheets/detail/preterm-birth (2023).
[13] Singer LT, Salvator A, Guo S, Collin M, Lilien L, Baley J. Maternal psychological distress and parenting stress after the birth of a very low-birth-weight infant. JAMA 1999;281:799-805. doi:10.1001/jama.281.9.799.
[14] McAndrew S, Acharya K, Westerdahl J, Brousseau DC, Panepinto JA, Simpson P, Leuthner J, Lagatta JM. A Prospective Study of Parent Health-Related Quality of Life before and after Discharge from the Neonatal Intensive Care Unit. J Pediatr 2019;213:38-45 doi:10.1016/j.jpeds.2019.05.067.
[15] Moura MR, Araujo CG, Prado MM, Paro HB, Pinto RM, Abdallah VO, Mendonca TM, Silva CH. Factors associated with the quality of life of mothers of preterm infants with very low birth weight: a 3-year follow-up study. Qual Life Res 2017;26:1349-1360. doi:10.1007/s11136-016-1456-6.
[16] Haddad S, Dennis CL, Shah PS, Stremler R. Sleep in parents of preterm infants: a systematic review. Midwifery 2019;73:35-48. doi:10.1016/j.midw.2019.01.009.
[17] Marthinsen GN, Helseth S, Fegran L. Sleep and its relationship to health in parents of preterm infants: a scoping review. BMC Pediatr 2018;18:352. doi:10.1186/s12887-018-1320-7.
[18] Lee SY, Kimble LP. Impaired sleep and well-being in mothers with low-birth-weight infants. J Obstet Gynecol Neonatal Nurs 2009;38:676-685. doi:10.1111/j.1552-6909.2009.01064.x.
[19] Sivertsen B, Petrie KJ, Skogen JC, Hysing M, Eberhard-Gran M. Insomnia before and after childbirth: The risk of developing postpartum pain-a longitudinal population-based study. Eur J Obstet Gynecol Reprod Biol 2017;210:348-354. doi:10.1016/j.ejogrb.2017.01.020.
[20] Bjorvatn B, Waage S, Pallesen S. The association between insomnia and bedroom habits and bedroom characteristics: an exploratory cross-sectional study of a representative sample of adults. Sleep Health 2018;4:188-193. doi:10.1016/j.sleh.2017.12.002.
[21] Morin CM, Rodrigue S, Ivers H. Role of stress, arousal, and coping skills in primary insomnia. Psychosom Med 2003;65:259-267. doi:10.1097/01.psy.0000030391.09558.a3.

[22] de Zambotti M, Goldstone A, Colrain IM, Baker FC. Insomnia disorder in adolescence: Diagnosis, impact, and treatment. Sleep Med Rev 2018;39:12-24. doi:10.1016/j.smrv.2017.06.009.
[23] Sivertsen, Lallukka, Salo, Pallesen, Hysing, Krokstad, Øverland. Insomnia as a risk factor for ill health: results from the large population-based prospective HUNT Study in N orway. J Sleep Res 2014;23:124-132. doi:10.1111/jsr.12102.
[24] Blomqvist YT, Nyqvist KH, Rubertsson C, Funkquist EL. Parents need support to find ways to optimise their own sleep without seeing their preterm infant's sleeping patterns as a problem. Acta Paediatr 2017;106:223-228. doi:10.1111/apa.13660.
[25] Baglioni C, Battagliese G, Feige B, Spiegelhalder K, Nissen C, Voderholzer U, Lombardo C, Riemann D. Insomnia as a predictor of depression: a meta-analytic evaluation of longitudinal epidemiological studies. J Affect Disord 2011;135:10-19. doi:10.1016/j.jad.2011.01.011.
[26] Hertenstein E, Feige B, Gmeiner T, Kienzler C, Spiegelhalder K, Johann A, Jansson-Frojmark M, Palagini L, Rucker G, Riemann D, Baglioni C. Insomnia as a predictor of mental disorders: A systematic review and meta-analysis. Sleep Med Rev 2019;43:96-105. doi:10.1016/j.smrv.2018.10.006.
[27] Pagels AA, Stendahl M, Evans M. Patient-reported outcome measures as a new application in the Swedish Renal Registry: health-related quality of life through RAND-36. Clin Kidney J 2020;13:442-449. doi:10.1093/ckj/sfz084.
[28] Post MW. Definitions of quality of life: what has happened and how to move on. Top Spinal Cord Inj Rehabil 2014;20:167-180. doi:10.1310/sci2003-167.
[29] Donohue PK, Maurin E, Kimzey L, Allen MC, Strobino D. Quality of life of caregivers of very low-birthweight infants. Birth 2008;35:212-219. doi:10.1111/j.1523-536X.2008.00242.x.
[30] Eiser C, Eiser JR, Mayhew AG, Gibson AT. Parenting the premature infant: balancing vulnerability and quality of life. J Child Psychol Psychiatry 2005;46:1169-1177. doi:10.1111/j.1469-7610.2005.00415.x.
[31] Witt WP, Litzelman K, Spear HA, Wisk LE, Levin N, McManus BM, Palta M. Health-related quality of life of mothers of very low birth weight children at the age of five: results from the Newborn Lung Project Statewide Cohort Study. Qual Life Res 2012;21:1565-1576. doi:10.1007/s11136-011-0069-3.
[32] Klassen AF, Lee SK, Raina P, Chan HW, Matthew D, Brabyn D. Health status and health-related quality of life in a population-based sample of neonatal intensive care unit graduates. Pediatrics 2004;113:594-600. doi:10.1542/peds.113.3.594.
[33] Hill PD, Aldag JC. Maternal perceived quality of life following childbirth. J Obstet Gynecol Neonatal Nurs 2007;36:328-334. doi:10.1111/j.1552-6909.2007.00164.x.
[34] Al Maghaireh DF, Abdullah KL, Chong MC, Chua YP, Al Kawafha MM. Stress, Anxiety, Depression and Sleep Disturbance among Jordanian Mothers and Fathers of Infants Admitted to Neonatal Intensive Care Unit: A Preliminary Study. J Pediatr Nurs 2017;36:132-140. doi:10.1016/j.pedn.2017.06.007.
[35] McMillen IC, Mulvogue HM, Kok JS, Deayton JM, Nowak R, Adamson TM. Circadian rhythms in sleep and wakefulness and in salivary melatonin and cortisol concentrations in mothers of term and preterm infants. Sleep 1993;16:624-631. doi:10.1093/sleep/16.7.624.
[36] Lee SY, Lee KA, Rankin SH, Weiss SJ, Alkon A. Sleep disturbance, fatigue, and stress among Chinese-American parents with ICU hospitalized infants. Issues Ment Health Nurs 2007;28:593-605. doi:10.1080/01612840701354505.
[37] Helsedirektoratet.Nyfødtavdelinger, kompetanse og kvalitet, from https://www.helsedirektoratet.no/retningslinjer/nyfodtintensivavdelinger-kompetanse-og-kvalitet/bemanning-og-kompetanse-ved-avdelinger-for-syke-nyfodte#kompetanse-i-kategori-3c-avdelinger-behandler-alle-grupper-premature (2017).
[38] Montgomery-Downs HE, Insana SP, Clegg-Kraynok MM, Mancini LM. Normative longitudinal maternal sleep: the first 4 postpartum months. Am J Obstet Gynecol 2010;203:1-7. doi:10.1016/j.ajog.2010.06.057.

[39] Carney CE, Buysse DJ, Ancoli-Israel S, Edinger JD, Krystal AD, Lichstein KL, Morin CM. The consensus sleep diary: standardizing prospective sleep self-monitoring. Sleep 2012;35:287-302. doi:10.5665/sleep.1642.
[40] Fekedulegn D, Andrew ME, Shi M, Violanti JM, Knox S, Innes KE. Actigraphy-Based Assessment of Sleep Parameters. Ann Work Expo Health 2020;64:350-367. doi:10.1093/annweh/wxaa007.
[41] Fung MM, Peters K, Ancoli-Israel S, Redline S, Stone KL, Barrett-Connor E, Osteoporotic Fractures in Men Research G. Total sleep time and other sleep characteristics measured by actigraphy do not predict incident hypertension in a cohort of community-dwelling older men. J Clin Sleep Med 2013;9:585-591. doi:10.5664/jcsm.2756.
[42] Martin JL, Hakim AD. Wrist Actigraphy. Chest 2011;139:1514-1527.
[43] Marino M, Li Y, Rueschman MN, Winkelman JW, Ellenbogen JM, Solet JM, Dulin H, Berkman LF, Buxton OM. Measuring sleep: accuracy, sensitivity, and specificity of wrist actigraphy compared to polysomnography. Sleep 2013;36:1747-1755. doi:10.5665/sleep.3142.
[44] Weiss AR, Johnson NL, Berger NA, Redline S. Validity of activity-based devices to estimate sleep. J Clin Sleep Med 2010;6:336-342.
[45] Pallesen S, Bjorvatn B, Nordhus IH, Sivertsen B, Hjornevik M, Morin CM. A new scale for measuring insomnia: the Bergen Insomnia Scale. Percept Mot Skills 2008;107:691-706. doi:10.2466/pms.107.3.691-706.
[46] American Psychiatric A: Diagnostic and statistical manual of mental disorders : DSM-IV-TR, 4th , text revision. edn. Washington, DC: American Psychiatric Association; 2000.
[47] American Psychiatric A: Diagnostic and statistical manual of mental disorders : DSM-5, 5th edn. Washington, D.C: American Psychiatric Association; 2013.
[48] Hays RD, Morales LS. The RAND-36 measure of health-related quality of life. Ann Med 2001;33:350-357. doi:10.3109/07853890109002089.
[49] Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473-483. doi:10.1097/00005650-199206000-00002.
[50] Kvien TK, Kaasa S, Smedstad LM. Performance of the Norwegian SF-36 Health Survey in patients with rheumatoid arthritis. II. A comparison of the SF-36 with disease-specific measures. J Clin Epidemiol 1998;51:1077-1086. doi:10.1016/s0895-4356(98)00099-7.
[51] Garratt AM, Stavem K. Measurement properties and normative data for the Norwegian SF-36: results from a general population survey. Health Qual Life Outcomes 2017;15:51. doi:10.1186/s12955-017-0625-9.
[52] DeMauro SB, Bellamy SL, Fernando M, Hoffmann J, Gratton T, Schmidt B, Investigators P. Patient, Family, and Center-Based Factors Associated with Attrition in Neonatal Clinical Research: A Prospective Study. Neonatology 2019;115:328-334. doi:10.1159/000494105.
[53] Sawilowsky SS. New Effect Size Rules of Thumb. J Mod Appl Stat Methos 2009;8:597-599. doi:10.22237/jmasm/1257035100.
[54] Desjardins S, Lapierre S, Hudon C, Desgagne A. Factors involved in sleep efficiency: a population-based study of community-dwelling elderly persons. Sleep 2019;42:1-9. doi:10.1093/sleep/zsz038.
[55] Schappin R, Wijnroks L, Uniken Venema MMAT, Jongmans MJ. Rethinking Stress in Parents of Preterm Infants: A Meta-Analysis. PLoS One 2013;8:1-19. doi:10.1371/journal.pone.0054992.
[56] Da Costa D, Lai JK, Zelkowitz P. A prospective study on the course of sleep disturbances in first-time fathers during the transition to parenthood. Infant Ment Health J 2021;42:222-232. doi:10.1002/imhj.21911.
[57] Heidari H, Hasanpour M, Fooladi M. The experiences of parents with infants in Neonatal Intensive Care Unit. Iran J Nurs Midwifery Res 2013;18:208-213.
[58] Edell-Gustafsson U, Angelhoff C, Johnsson E, Karlsson J, Morelius E. Hindering and buffering factors for parental sleep in neonatal care. A phenomenographic study. J Clin Nurs 2015;24:717-727. doi:10.1111/jocn.12654.

[59] Lee SY, Aycock DM, Moloney MF. Bright Light Therapy to Promote Sleep in Mothers of Low-Birth-Weight Infants: A Pilot Study. Biol Res Nurs 2013;15:398-406. doi:10.1177/1099800412445612.
[60] Garcia M, Manrique G, Fernandez SN, Puerta Y, Paredes P, Corchado AM, Garcia-Moreno AB, Jimenez B, Mencia S. Sleep characteristics of the parents of children admitted to a pediatric intensive care unit: risk factors and repercussion on their daily life activities. Sleep Med X 2020;2:100020. doi:10.1016/j.sleepx.2020.100020.
[61] Stremler R, Dhukai Z, Pullenayegum E, Weston J, Wong L, Parshuram C. Sleep, sleepiness, and fatigue outcomes for parents of critically ill children. Pediatr Crit Care Med 2014;15:e56-65. doi:10.1097/01.pcc.0000436198.15337.15.
[62] E. Montgomery-Downs H, Stremler R, Insana S: Postpartum Sleep in New Mothers and Fathers, vol. 6; 2013.
[63] Richter D, Krämer MD, Tang NKY, Montgomery-Downs HE, Lemola S. Long-term effects of pregnancy and childbirth on sleep satisfaction and duration of first-time and experienced mothers and fathers. Sleep 2019;42. doi:10.1093/sleep/zsz015.
[64] Kenny S, Burdayron R, E EML, Dubois-Comtois K, Beliveau MJ, Pennestri MH. Mothers' and fathers' sleep: Is there a difference between first-time and experienced parents of 6-month-olds? J Sleep Res 2021;30:e13238. doi:10.1111/jsr.13238.
[65] McGuire E. Maternal and infant sleep postpartum. Breastfeed Rev 2013;21:38-41.
[66] Polo-Kantola P. Sleep disturbances in pregnancy: Why and how should we manage them? Acta Obstet Gynecol Scand 2022;101:270-272. doi:10.1111/aogs.14325.
[67] Letourneau NL, Dennis CL, Benzies K, Duffett-Leger L, Stewart M, Tryphonopoulos PD, Este D, Watson W. Postpartum depression is a family affair: addressing the impact on mothers, fathers, and children. Issues Ment Health Nurs 2012;33:445-457. doi:10.3109/01612840.2012.673054.
[68] Trimmel K, Eder HG, Böck M, Stefanic-Kejik A, Klösch G, Seidel S. The (mis)perception of sleep: factors influencing the discrepancy between self-reported and objective sleep parameters. J Clin Sleep Med 2021;17:917-924. doi:10.5664/jcsm.9086.
[69] Rezaie L, Fobian AD, McCall WV, Khazaie H. Paradoxical insomnia and subjective-objective sleep discrepancy: A review. Sleep Med Rev 2018;40:196-202. doi:10.1016/j.smrv.2018.01.002.
[70] Ibanez V, Silva J, Cauli O. A survey on sleep assessment methods. PeerJ 2018;6:e4849. doi:10.7717/peerj.4849.
[71] Natale V, Plazzi G, Martoni M. Actigraphy in the Assessment of Insomnia: A Quantitative Approach. Sleep 2009;32:767-771. doi:10.1093/sleep/32.6.767.
[72] Lee SY, Grantham CH, Shelton S, Meaney-Delman D. Does activity matter: an exploratory study among mothers with preterm infants? Arch Womens Ment Health 2012b;15:185-192. doi:10.1007/s00737-012-0275-1.
[73] Schaffer L. The Impact of Guided Imagery on Sleep Quality in Mothers of Preterm Infants. San Diego: University of San Diego; 2012.
[74] Shelton SL, Meaney-Delman DM, Hunter M, Lee S-Y. Depressive symptoms and the relationship of stress, sleep, and well-being among NICU mothers. Journal of Nursing Education and Practice 2014;4:1-10. doi:10.5430/jnep.v4n8p70.
[75] Lefkowitz D, Baxt C, Evans J. Prevalence and Correlates of Posttraumatic Stress and Postpartum Depression in Parents of Infants in the Neonatal Intensive Care Unit (NICU). J Clin Psychol Med Settings 2010;17:230-237. doi:10.1007/s10880-010-9202-7.
[76] Beck CT. Recognizing and screening for postpartum depression in mothers of NICU infants. Adv Neonatal Care 2003;3:37-46. doi:10.1053/adnc.2003.50013.
[77] Paavonen E, Saarenpaa-Heikkila O, Polkki P, Kylliainen A, Porkka-Heiskanen T, Paunio T. Maternal and paternal sleep during pregnancy in the Child-sleep birth cohort. Sleep Med 2017;29:47-56. doi:10.1016/j.sleep.2016.09.011.

[78] Emamian F, Khazaie H, Okun ML, Tahmasian M, Sepehry AA. Link between insomnia and perinatal depressive symptoms: A meta-analysis. J Sleep Res 2019;28:e12858. doi:10.1111/jsr.12858.
[79] Harvey AG, Murray G, Chandler RA, Soehner A. Sleep disturbance as transdiagnostic: consideration of neurobiological mechanisms. Clin Psychol Rev 2011;31:225-235. doi:10.1016/j.cpr.2010.04.003.
[80] Ross LE, Murray BJ, Steiner M. Sleep and perinatal mood disorders: A critical review. J Psychiatry Neurosci 2005;30:247-256.
[81] Cox RC, Olatunji BO. Sleep in the anxiety-related disorders: A meta-analysis of subjective and objective research. Sleep Med Rev 2020;51:101282. doi:10.1016/j.smrv.2020.101282.
[82] Sivertsen B, Lallukka T, Salo P. The economic burden of insomnia at the workplace. An opportunity and time for intervention? Sleep 2011;34:1151-1152. doi:10.5665/sleep.1224.
[83] Daley M, Morin CM, LeBlanc M, Grégoire JP, Savard J. The economic burden of insomnia: direct and indirect costs for individuals with insomnia syndrome, insomnia symptoms, and good sleepers. Sleep 2009;32:55-64.
[84] Baglioni C, Tang NKY, Johann AF, Altena E, Bramante A, Riemann D, Palagini L. Insomnia and poor sleep quality during peripartum: a family issue with potential long term consequences on mental health. J Matern Fetal Neonatal Med 2022;35:4534-4542. doi:10.1080/14767058.2020.1854718.
[85] Tang NKY. Cognitive-behavioral therapy for sleep abnormalities of chronic pain patients. Curr Rheumatol Rep 2009;11:451. doi:10.1007/s11926-009-0066-5.
[86] Stremler R, Sharkey KM, Wolfson AR. Postpartum Period and Early motherhood. In: Kryger M, Roth T. C., Dement W.C,, editor. Principles and practice of sleep medicine. 6 ed. Philadelphia: Elsevier; 2017. p. 1547-1552.
[87] Redeker NS. Sleep Health in Women of Childbearing Age. J Womens Health (Larchmt) 2020;29:430-434. doi:10.1089/jwh.2020.8349.
[88] Schaffer L, Jallo N, Howland L, James K, Glaser D, Arnell K. Guided imagery: an innovative approach to improving maternal sleep quality. J Perinat Neonatal Nurs 2013;27:151-159. doi:10.1097/JPN.0b013e3182870426.
[89] Perlis ML, Zee J, Swinkels C, Kloss J, Morgan K, David B, Morales K. The incidence and temporal patterning of insomnia: a second study. J Sleep Res 2014;23:499-507. doi:10.1111/jsr.12150.
[90] Insana SP, Montgomery-Downs HE. Sleep and sleepiness among first-time postpartum parents: a field- and laboratory-based multimethod assessment. Dev Psychobiol 2013;55:361-372. doi:10.1002/dev.21040.
[91] Aili K, Astrom-Paulsson S, Stoetzer U, Svartengren M, Hillert L. Reliability of Actigraphy and Subjective Sleep Measurements in Adults: The Design of Sleep Assessments. J Clin Sleep Med 2017;13:39-47. doi:10.5664/jcsm.6384.



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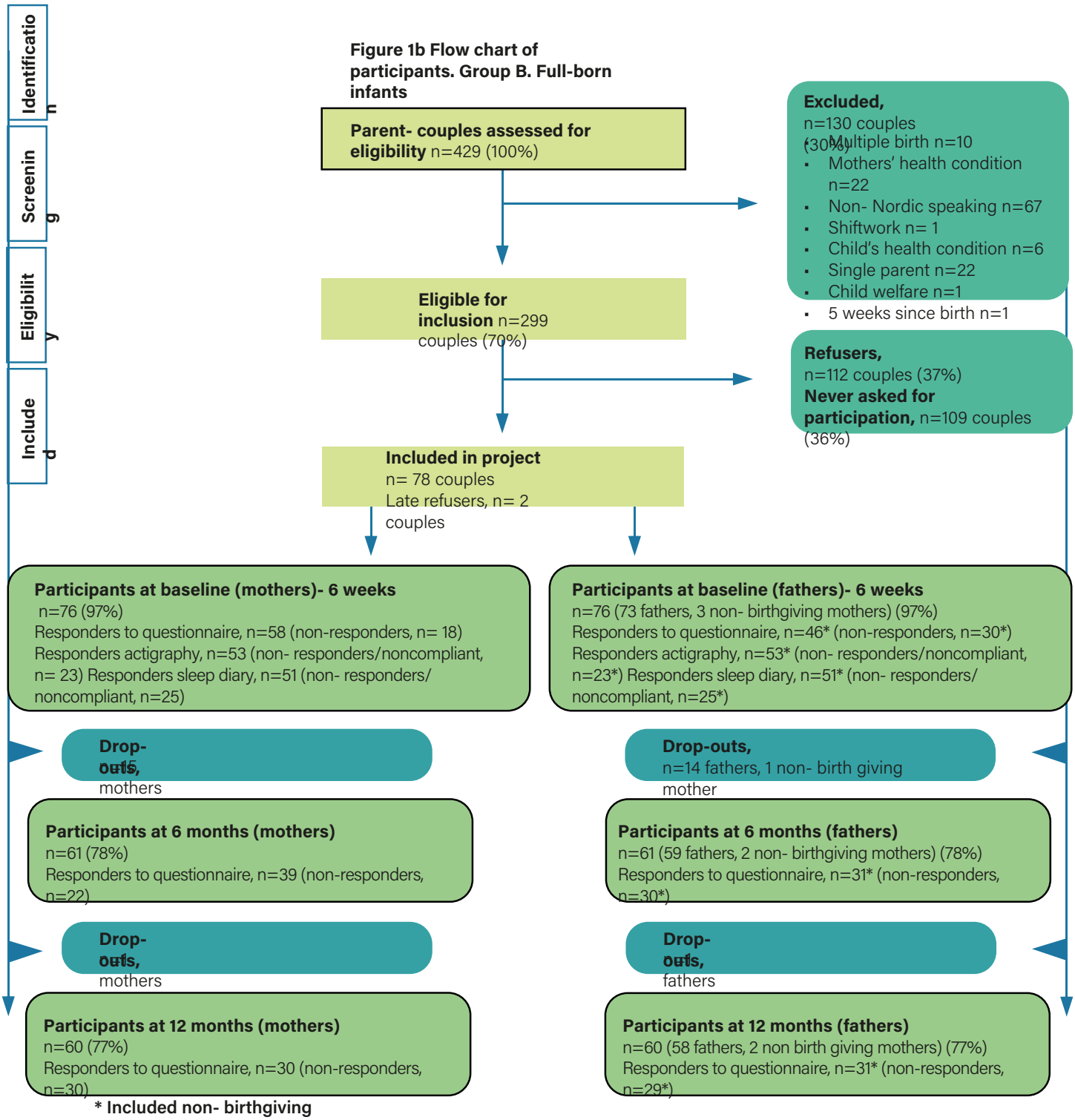

Figure 1b Flow chart of participants. Group B. Full-born infants

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Table 1a. Sociodemographic characteristics of parents at baseline

	Group A. Parents of preterm infants		***Group B. Parents of full-born infants***	
	Mothers, n = 25 (100%) (Responders, n = 16)	Fathers, n = 25 (100%) (Responders, n = 14)	Mothers, n = 76 (100%) (Responders, n = 58)	Fathers**, n = 76 (100%) (Responders, n = 46)
	Median (min–max)	**Median (min–max)**	**Median (min–max)**	**Median (min–max)**
Age	30.5 (27.0–36.0)	32.0 (27.0–36.0)	31.5 (22.0–42.0)	33.0 (25.0–44.0)
Body mass index (kg/m^2)	25.1 (19.9–39.8)	25.3.0 (19.6–34.4)	24.4 (19.6–38.6)	26.6 (20.7–35.9)
	n (%)	**n (%)**	**n (%)**	**n (%)**
Ethnicity				
Norway	15 (93.8)	13 (92.9)	50 (86.2)	42 (91.3)
Nordic Country	1 (6.3)		1 (1.7)	2 (4.4)
Europe			2 (3.4)	1 (2.2)
Asia			2 (3.4)	
South-America		1 (7.1)	2 (3.4)	1 (2.2)
Africa			1 (1.7)	
Parity				
*0**	12 (75.0)	11 (78.6)	38 (65.5)	29 (63.0)
1	4 (25.0)	3 (21.4)	14 (24.1)	10 (21.7)
2			5 (8.6)	6 (13.0)
3			1 (1.7)	1 (2.2)
Education (level/years)				
Primary school (up to 10 years)				1 (2.2)
Secondary school (up to 13 years)	4 (25.0)	7 (50.0)	10 (17.0)	9 (20.0)
University/college (up to 4 years)	3 (18.8)	4 (28.6)	22 (37.9)	12 (26.1)
University/college (> 4 years)	8 (50.0)	3 (21.4)	26 (44.8)	22 (47.8)
Other	1 (6.3)			2 (4.3)
Annual income (NOK)				

0–399,000	5 (31.3)	3 (21.4)	12 (20.7)	7 (15.6)
400,000–499,000	3 (18.8)	3 (21.4)	18 (31.0)	4 (8.7)
≥ 500,000	8 (50.0)	8 (57.1)	28 (48.3)	35 (76.1)
Employment status				
Non-income-generating work situation	1 (6.3)	2 (14.3)	6 (10.3)	3 (6.5)
Income-generating work situation	15 (93.8)	12 (85.7)	52 (89.7)	43 (93.5)
Missing (nonresponders)	9 (36.0)	11 (44.0)	18 (23.7)	30 (38.3)

***** First-time parents (primiparas)
****** Including non-birth-giving mothers

Table 1b. Baseline infant characteristics

	Group A. Preterm group, *n = 25 couples (100%) (Responders, n = 17)*	***Group B. Full-born group***, *n = 76 couples (100%) (Responders, n = 61)*
	n (%)	**n (%)**
Infant GA		
Extremely preterm (GA < 28)	1 (4.0)	–
Very preterm (GA: 28–31)	1 (4.0)	–
Moderate/Late preterm (GA: 32–36)	15 (60.0)	–
Term born (GA ≥ 37)	–	61 (80.0)
Missing	8 (32.0)	15 (19.7)
Infant birthweight		
Extremely low (≤ 999 g)	1 (4.0)	–
Very low (1,000–1,499 g)	–	–
Low (1,500–2,499 g)	9 (36.0)	–
Normal weight (≥ 2,500–4,199 g)	7 (28.0)	57 (75.0)
High (≥ 4,200 g)	–	4 (5.2)
Missing	8 (32.0)	15 (19.7)

Note: GA; gestational age.

Table 2. Descriptive variables for subjective and objective sleep at 2 months postpartum for parents of preterm and full- born infants

	Group A. Preterm Median (min–max)		*Group B. Full-born Median (min–max)*	
	Mothers	**Fathers***	**Mothers**	**Fathers***
Sleep diary	**Responders**	**Responders**	**Responders**	**Responders**
	n = 18	**n = 18**	**n = 51**	**n = 51**
Daytime function (1, very good; 5, very poor)	2.5 (1.6–3.1)	2.4 (1.4–3.1)	2.1 (1.0–3.9)	2.3 (1.0–3.3)
Sleep quality (1, very restless; 5, very sound)	3.4 (1.6–4.8)	3.4 (2.0–4.7)	3.0 (1.5–4.6)	3.4 (1.6–4.3)
Number of daytime naps	0.4 (0–0.9)	0.2 (0–0.9)	0.1 (0–1.1)	0.0 (0–0.7)
Daytime nap duration (min)	24.0 (0–62.0)	7.9 (0–70.0)	4.3 (0–60)	0.0 (0–49.0)
Sleep onset latency (min)	10.8 (1–82.0)	12.3 (0–70.0)	31.4 (1–89.0)	13.5 (0–98.0)
Number of nighttime awakenings	2.4 (1.3–4.9)	1.8 (0.6–3.7)	2.7 (0.6–5.0)	1.4 (0–4.7)
Wake after sleep onset (min)	114.3 (12.4–253.8)	29.9 (3–96.0)	71.4 (8.6–155.0)	13.6 (0–74.3)
Early morning awakening (min)	13.1 (5.7–43.3)	9.6 (0–85.0)	15.7 (0.7–72.9)	13.3 (0–51.9)
Total wake time (min)	147.4 (40.0–247.5)	68.6 (30.0–132.7)	125.0 (29.7–237.1)	45.0 (1.6–131.0)
Time in bed (min)	538.2 (421.4–707.9)	475.0 (373.0–621.4)	569.3 (415.4–743.6)	475.7 (346.3–647.1)
Total sleep time (min)	415.1 (301.3–516.4)	411.9 (309.3–507.1)	427.0 (302.9–582.9)	425.7 (274.4–567.0)
Sleep efficiency (%)	72.6 (52.3–91.2)	85.2 (73.9–93.8)	78.1(59.6–93.4)	90.6 (71.8–99.6)
Actigraph	**Responders**	**Responders**	**Responders**	**Responders**
	n = 18	**n = 18**	**n = 53**	**n = 53**
Time in bed (min)	528.8 (431.2–695.4)	466.0 (336.6–625.6)	538.0 (395.0–702.6)	462.0 (356.6–560.0)
Total sleep time (min)	421.0 (343.4–500.8)	387.4 (292.1–500.9)	433.0 (328.0–561.8)	397.7 (315.1–468.9)
Sleep onset latency (min)	13.1 (2.4–30.6)	15.3 (1.6–59.1)	13.0 (1.0–65.4)	13.0 (2.9–48.2)
Sleep efficiency (%)	78.3 (65.8–87.9)	85.8 (64.7–91.0)	81.5 (66.7–90.1)	85.3 (77.1–91.2)
Wake after sleep onset (min)	100.0 (31–192.2)	37.6 (26.1–88.4)	61.7 (31.5–143.0)	34.0 (14.4–73.0)

* including non-birth-giving mothers.

Table 3. Insomnia and HRQoL at 2, 6 and 12 months postpartum.

	2 months postpartum				6 months postpartum				12 months postpartum			
	Mothers		Fathers*		Mothers		Fathers*		Mothers		Fathers*	
Group A Preterm group	Responders n=16		Responders n=14		Responders n=9		Responders n=6		Responders n=10		Responders n=8	
	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI
Insomnia	10 (62.5)	[35.4 - 84.8]	10 (71.4)	[41.9 - 91.6]	5 (55.6)	[21.2 - 86.3]	2 (33.3)	[4.3 -77.7]	5 (50.0)	[18.7 - 81.3]	1 (12.5)	[0.3 - 52.6]
HRQOL (median, min/max)												
Physical well- being (PCS)	49.6 (20.8-64.5)		49.7(42.8-58.7)		55.1 (40.6-61.5)		52.6 (50.6 - 55.8)		51.7 (38.4-58.0)		50.0 (41.8-56.4)	
Mental well- being (MCS)	48.7 (32.0-59.2)		48.7 (28.1-58.3)		47.5 (32.2-57.2)		50.7 (43.5 - 58.0)		50.8 (26.3-66.6)		50.5 (31.2-58.0)	
Group B Full- born group	Responders=58		Responders=46		Responders=39		Responders=31		Responders =30		Responders=31	
	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI	n (%)	95% CI
Insomnia	31 (53.4)	[39.9 - 66.6]	20 (43.5)	[28.9-58.9]	27 (69.2)	[52.4-83.0]	13 (41.9)	[24.5 - 60.9]	20 (66.7)	[47.2 - 82.7]	13 (41.9)	[24.5 - 60.9]
HRQOL (median, min/max)												
Physical well being (PCS)	50.0 (25.0 - 65.5)		53.7 (37.0 - 61.3)		52.6 (50.6 - 55.8)		54.0 (30.7 - 65.2)		51.9 (24.1-62.7)		52.7 (40.1- 65.5)	
Mental well being (MCS)	50.0 (32.0 - 59.2)		51.5 (23.8 - 59.5)		52.3 (21.9 - 60.0)		52.4 (24.2 - 59.6)		50.2 (18.8-61.5)		50.5 (18.7- 60.6)	

*Including non- birthgiving mothers
CI= Confidence interval, 95%
HRQoL; Health-related quality of life

Table 4. Changes over time in physical (PCS) and mental (MCS) HRQoL analysed with linear mixed model for repeated measures

PCS- Physical HRQOL			
	B	**95%CI**	**p-value**
Time			
2 months postpartum (Baseline) (ref)			
6 months postpartum	1.21	[-0.14 to 2.57]	0.08
12 months postpartum	0.60	[-0.80 to 1.10]	0.40
Gender			
Mother (ref)			
Father	1.70	[-0.39 to 3.80]	0.11
Insomni yes/no			
No (ref)			
Yes	**-3.64**	**[-6.04 to -1.25]**	**0.03***
MCS- Mental HRQOL			
	B	**95%CI**	**p-value**
Time			
2 months postpartum (Baseline) (ref)			
6 months postpartum	- 0.43	[-2.52 to 1.65]	0.68
12 months postpartum	- 2.04	[-4.20 to 0.11]	0.06
Gender			
Mother (ref)			
Father	- 0.17	[-3.12 to 2.78]	0.90
Insomni yes/no			
No (ref)			
Yes	**- 6.93**	**[-10.31 to -3.55]**	**0.00***

Abbreviations: CI: Confidence interval, B: Regression coefficient, HRQoL: health- related quality of life

* $P \leq 0.05$

Additional file 1. The association between physical (PCS) HRQoL and total sleep time at follow up using linear mixed model for repeated measure.

PCS- Physical HRQoL- total sleep time (sleep diary)			
	B	**95% CI**	**p-value**
Time			
2 months postpartum (Baseline) (ref)			
6 months postpartum	1.31	[-0.10 to 2.74]	0.07
12 months postpartum	0.68	[-0.80 to 2.16]	0.37
Gender			
Mother (ref)			
Father	2.45	[0.17 to 4.73]	0.04
Total sleep time (sleep diary)	0.10	[-0.07 to 0.29]	0.25
PCS- Physical HRQoL- total sleep time (actigraphy)			
	B	**95% CI**	**p-value**
Time			
2 months postpartum (Baseline) (ref)			
6 months postpartum	1.39	[-0.76 to 2.80]	0.06
12 months postpartum	0.52	[-0.98 to 2.01]	0.50
Gender			
Mother (ref)			
Father	3.10	[0.66 to 5.55]	0.01
Total sleep time (actigraphy)	0.06	[-0.01 to 0.02]	0.58

Abbreviations: CI: Confidence interval, B: Regression coefficient, HRQoL: Health-related quality of life

Additional file 2. The association between physical (PCS) HRQoL and sleep efficiency at follow up using linear mixed model for repeated measure.

PCS- Physical HRQOL- sleep efficiency (sleep diary)			
	B	**95%CI**	**p-value**
Time			
2 months postpartum (Baseline) (ref)			
6 months postpartum	1.34	[-0.88 to 2.77]	0.07
12 months postpartum	0.69	[-0.79 to 2.18]	0.36
Gender			
Mother (ref)			
Father	1.60	[-1.29 to 4.49]	0.28
Sleep efficiency (sleep diary)	0.69	[-0.075 to 0.21]	0.35
PCS- Physical HRQOL- sleep efficiency (actigraphy)			
	B	95%CI	p-value
Time			
2 months postpartum (Baseline) (ref)			
6 months postpartum	1.40	[-0.06 to 2.87]	0.06
12 months postpartum	0.52	[-0.98 to 2.01]	0.50
Gender			
Mother (ref)			
Father	2.53	[0.11 to 4.96]	0.04
Sleep efficiency (actigraphy)	0.06	[-0.14 to 0.28]	0.53

Abbreviations: CI: Confidence interval, B: Regression coefficient, HRQoL: Health- related quality of life

Additional file 3. The association between mental (MCS) HRQoL and total sleep time at follow up using linear mixed model for repeated measure.

MCS- Mental HRQOL- total sleep time (sleep diary)			
	B	**95%CI**	**p-value**
Time			
2 months postpartum (Baseline) (ref)			
6 months postpartum	-0.45	[-2.66 to 1.76]	0.69
12 months postpartum	-1.85	[-4.14 to 0.44]	0.11
Gender			
Mother (ref)			
Father	0.93	[-2.26 to 4.12]	0.57
Total sleep time (sleep diary)	0.15	[-0.01 to 0.04]	0.25
MCS- Mental HRQOL- total sleep time (actigraphy)			
	B	**95%CI**	**p-value**
Time			
2 months postpartum (Baseline)			
6 months postpartum	-0.86	[-3.07 to 1.35]	0.46
12 months postpartum	-2.45	[-4.70 to 0.20]	0.03
Gender			
Mother (ref)			
Father	2.10	[-1.59 to 5.78]	0.26
Total sleep time (actigraphy)	0.18	[0.01 to 0.52]	0.31

Abbreviations: CI: Confidence interval, B: Regression coefficient, HRQoL: Health- related quality of life

Additional file 4. The association between mental (MCS) HRQoL and sleep efficiency at follow up using linear mixed model for repeated measure.

MCS- Mental HRQOL- sleep efficiency (sleep diary)			
	B	**95%CI**	**p-value**
Time			
2 months postpartum (Baseline)			
6 months postpartum	-0.37	[-2.58 to 1.83]	0.74
12 months postpartum	-1.80	[-4.09 to 0.49]	0.12
Gender			
Mother (ref)			
Father	-0.97	[-5.01 to 3.08]	0.63
Sleep efficiency (sleep diary)	0.15	[-0.04 to 0.36]	0.14
MCS- Mental HRQOL- sleep efficiency (actigraphy)			
	B	**95%CI**	**p-value**
Time			
2 months postpartum (Baseline) (ref)			
6 months postpartum	-0.84	[-3.04 to 1.37]	0.46
12 months postpartum	-2.44	[-4.69 to -0.19]	0.03
Gender			
Mother (ref)			
Father	0.44	[-3.20 to 4.08]	0.81
Sleep efficiency (actigraphy)	0.20	[-0.12 to 0.51]	0.22

Abbreviations: CI: Confidence interval, B: Regression coefficient, HRQoL: Health- related quality of life