Collaborating to improve neonatale care: Parental participation on the neonatal ward - the neoPartner study

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To investigate the effect of FCR during hospital stay, accompanied by FICare, on parental stress at discharge in parents of preterm (born before 37 weeks of gestational age) or ill (for instance with sepsis or small for gestational age) infants...

Ethical review	Approved WMO
Status	Completed
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON55894

Source
ToetsingOnline

Brief title
The neoPARTNER study

Condition

- Neonatal and perinatal conditions
- Adjustment disorders (incl subtypes)
- Family issues

Synonym
neonatal care

Research involving
Human

Sponsors and support

Primary sponsor: OLVG

Source(s) of monetary or material Support: Nederlandse Vereniging van de Kindergeneeskunde

Intervention

Keyword: Family Centred Rounds, Family Integrated Care, Parent participation, Shared Decision Making

Outcome measures

Primary outcome

The main outcome is parental stress at discharge, as defined by the total score on the Parental Stress Scale (PSS:NICU). The PSS:NICU is a three-dimensional tool, in which parents express the amount of stress they experienced by rating 26 items on a 5-point Likert scale (*not stressful at all* to *extremely stressful*).

Secondary outcome

Secondary outcome measures on the individual level will be parent participation in neonatal care, parent-infant bonding and experiences in shared decision making. The longitudinal course of parental mental health (anxiety, depression, posttraumatic stress) will be analyzed, as well as biomarkers of stress (in saliva, hair and breastmilk) and breastmilk composition. Also, neonatal secondary outcome measures will be taken into account, specifically length of stay, breastfeeding rates at discharge, biomarkers of stress in saliva, methylation rate of glucocorticoid receptors (from buccal mucosa) and growth. On the cluster level we will study professional secondary outcome measures such as work engagement and autonomy.

Study description

Background summary

Parents are often appointed a passive role during the admission of their preterm (born before 37 weeks of gestational age) or ill infant. Multiple studies have demonstrated that information and communication are crucial for families of intensive care patients. However, common practice in neonatal wards regarding daily rounds is that the medical rounds are only attended by the physician and nurse without presence and participation of the parents. Parents are usually updated by the nurse afterwards. Family Centred Rounds (FCR) include parents on daily rounds (digital or physical presence), involving them in the process of patient management, allowing them to hear their infants* conditions first-hand, to provide information on their child*s general wellbeing themselves and to ask questions and participate in shared decision making. Family Integrated Care (FICare) comprises a framework to implement FCR by bringing parents, medical and nursing staff together and involving parents as equal partners, minimizing separation, and supporting parent-infant closeness. FICare consists of a collaborative program of psychological, educational, communication, and environmental strategies to support parents to cope with neonatatal environment and to prepare them to be able to emotionally, cognitively, and physically care for their infant.

Study objective

To investigate the effect of FCR during hospital stay, accompanied by FICare, on parental stress at discharge in parents of preterm (born before 37 weeks of gestational age) or ill (for instance with sepsis or small for gestational age) infants admitted to the neonatal ward for >7 days as compared to standard daily rounds (SDR) without parents with SNC. We primarily hypothesize that FCR and FICare are superior to SNC with regard to parental stress at discharge. Secondary outcomes in parents include participation in neonatal care, experience in shared decision making, parent-infant bonding, biomarkers of stress (in hair and saliva), breastmilk composition and the longitudinal course of parent mental health after infant discharge. Infant outcomes include breastfeeding at discharge, growth, biomarkers of stress in saliva and length of hospital stay. For healthcare professionals outcomes such as work engagement and autonomy will be analysed at the cluster level. Cost-effectiveness analysis will be done as well at the level of parents and healthcare professionals.

Study design

A multicentre stepped wedge cluster randomised trial will be conducted. A total of 10 hospitals with a level 2 neonatal ward in the Netherlands will participate. Timing of start of intervention will be randomised between sites.

Intervention

The intervention will consist of parental participation in medical rounds (FCR). Parents and healthcare professionals will be supported by the four pillars of FICare: parent education, education of healthcare professionals, psychosocial support and environment of the neonatal ward.

Study burden and risks

Due to the nature of this study and the risk of cross-contamination, randomization on the individual level is not possible. It concerns hospitalized neonates that are treated with FICare or SNC for at least 1 week and are followed until the (corrected) age of 12 months. They are minor and thereby incapacitated subjects. The risk for SAEs is negligible. Regarding the CCMO guidelines in minors the risk must be negligible and the objections must be minimal.
The burden of participation for parents is low and consists of (digital or physical) participation in medical rounds, participating in care, filling out questionnaires at different time points and the collection of hair-, saliva- and breastmilk samples. Hence, the burden is mainly time-related and is non-invasive. The total amount of time required to fill out the questionnaires will be approximately 20-30 minutes every time.
The burden for the infants is none, since all studied parameters are part of the routine clinical care and are noted in the clinical chart and the collection of saliva and buccal mucosa is non-invasive. Moreover, the infants cared for according to the FICare with involvement of parents could have better breastfeeding and growth rates. Parents could experience less stress, and healthcare professionals could feel more engaged and autonomous at work.
Concluding, the risks are negligible, the burden is minimal and this study might show equal or better outcomes in infants treated with FICare. This implicates that the research question is group-related and can only be performed in this group of infants.

Contacts

Public
OLVG

Oosterpark 9
AC 1091
NL
Scientific
OLVG

Oosterpark 9
AC 1091
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Babies and toddlers (28 days-23 months)
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

- infant requiring hospital admission directly (within 24 hours) after birth
- parents of 18 years or older

Exclusion criteria

- Infant*s hospital stay shorter than 7 days;
- Infant with severe congenital or syndromal anomaly;
- Infant with critical illness who is unlikely to survive;
- Parent with current psychosocial problems (such as posttraumatic stress disorder, schizophrenia or psychotic disorders) with or without medication which have not been stable over the past year;
- Involvement of child protective services in the family;
- Parent not able or not willing to fill out questionnaires in English or Dutch.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-03-2022
Enrollment:	1800
Type:	Actual

Ethics review

Approved WMO Date:	06-12-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-02-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-11-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-10-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	07-11-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78176.100.21