ClinicalTrials.gov registration title page

Official title of the study:

The effect of the Close Collaboration with Parents-training program and single-family room architecture on length of stay and growth parameters in Finland

Research group

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Background

In Europe, over 500,000 newborn infants are hospitalized each year. Infants are often separated from their parents during their hospitalization. One study showed that very preterm infants spent 80% of their time without any human contact (1). A European survey showed a large variation in parents' presence between hospitals, starting from 2.6 hours per day (unpublished data). Even when present, the parents are often just bystanders.(2,3) Separating the child from the parents places the socio-emotional and cognitive development at risk.(4,5) Studies have shown that parental involvement during hospitalization facilitates growth, socio-emotional, cognitive and linguistic development in preterm infants.(6-9)

An intervention directed at empowering parents shortened the length of stay by 3.9 days in preterm infants.(10) Vohr et al. showed that in settings with single-family room architecture, the infants of actively participating mothers had on average 15 days shorter length of stay compared to infants of non-active mothers. Interventions aimed at family-centered care are heterogeneous and their effects vary. In a meta-analysis comprising seven studies on family-centered care interventions, the length of stay was unaffected, but on the other hand e.g. preterm subpopulations were not considered.(11)

Parental presence can also be encouraged by hospital architecture. Even if modern hospitals nowadays include facilities also for parents based on the beneficial effects of single-family rooms (12,13), only 13.3% of 331 neonatal units provided parents with the facilities needed to stay with their infant throughout a 24-hour day.(14) Single-family rooms shortened the length of stay by 10 days among very preterm infants born before 30 gestational weeks in a randomized setting in Stockholm.(15) Also single-family room models are heterogeneous; according to a loose definition three solid walls suffices to qualify as single-family room, and does not necessarily include beds for the parents. A meta-analysis of 12 different single-family room studies did not show any significant benefit regarding length of stay compared to traditional hospital architecture.(16) However, in this meta-analysis most studies were observational studies without control groups; only one randomized study was included and no causal inferences could be drawn.

The Close Collaboration with Parents training program has been developed in Turku University Hospital, Finland. It is a structured and comprehensive training program for neonatal staff aiming to support parenthood and parental involvement in neonatal intensive care. The program addresses staff attitudes by reflection and exercises. The program has been shown to improve implementation of family-centered care in the varying contexts of neonatal intensive care units in both regional hospitals and university hospitals. After the completion of the training program, parents spent more time with their child during hospitalization.(17) Nurses reported that the training program strengthened the family-centered care culture and that the program enforced the role of the parents as primary caregivers.(18,19) Breast feeding was commenced on average three weeks earlier than before the training program, skin-to-skin care was commenced earlier and the amount of skin-to-skin care increased. The weight gain of premature infants improved by 44.5%, and the mothers of very preterm infants suffered from fewer depressive symptoms.(20,21)

It is imperative to study the economic impact of extensive, resource-demanding interventions that affect a whole neonatal unit. The Close Collaboration with Parents training program has so far been implemented in 11 neonatal units in Finland. In addition, four units have changed to single-family room architecture between 2014 and 2019. The national health care registers kept by the Institute for Health and Welfare contain a fully population-based dataset comprising all newborn infants (Medical Birth Register), hospitalizations and outpatient visits (Hospital

Discharge Register). These data are available since 1987, and enable retrospective research on the health and care of newborn infants. In Finland, we currently have a unique opportunity to study the effects of both a family-centered care intervention and single-family room architecture in more controlled circumstances than in previous studies: the interventions have been performed systematically throughout the country; societal support such as paid parental leave and universal access to health care grant all parents the same opportunities to participate; the register data are comparable for all units; and preterm infants can be studied as a separate group.

Research questions

- Does the Close Collaboration with Parents training program affect the length of stay in neonatal units?
- Does single-family room architecture affect the length of stay in neonatal units?
- Do the interventions affect the need for outpatient visits after discharge during the first year of life?
- Are the interventions cost-effective?
- Do the interventions affect early postnatal growth in preterm infants?

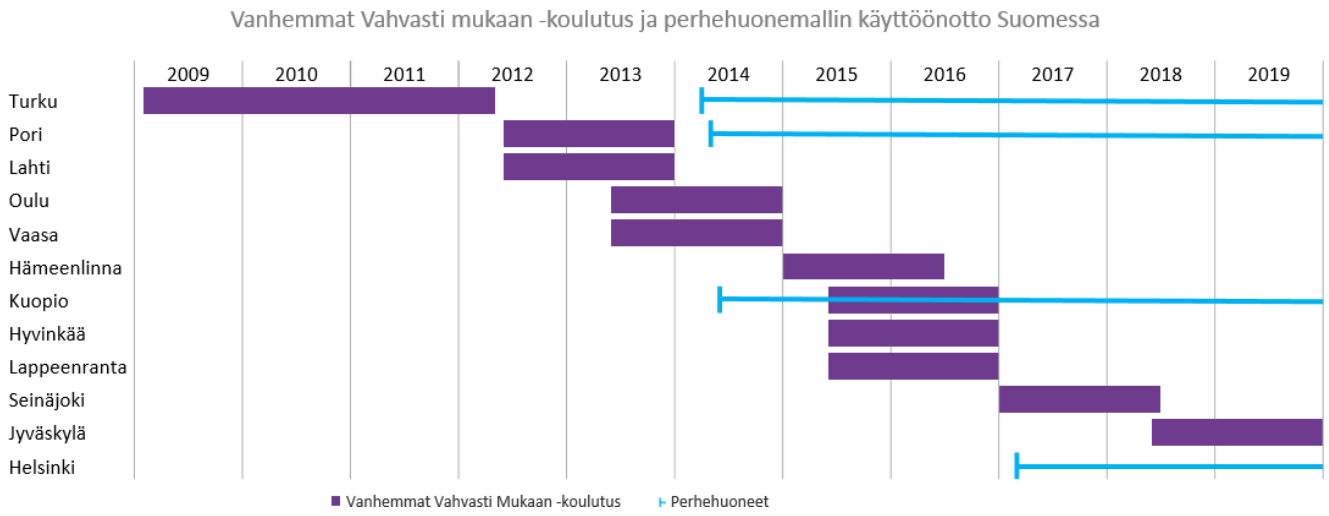
Our hypotheses are that the length of stay will be shorter, outpatient visits fewer and early postnatal growth better in units where either or both of these interventions have been implemented.

Methods

The study population will consist of all newborn infants born from January 1st 2006 to December 31st 2020, who have needed care in a neonatal unit immediately after birth. These infants will be identified from the Hospital Discharge Register. Data on vital background data, birth details, diagnoses, length of stay, growth parameters and outpatient visits will be obtained from the Hospital Discharge Register and the Medical Birth Register. These data will be linked through the infants' personal identification codes, which will be replaced by a pseudonymized ID-number before delivering the data to the research group. Planned subgroup analyses will be done for preterm infants and for infants with significant congenital anomalies.

Description of the interventions: Two interventions are studied (Figure 1)

- Close Collaboration with Parents-training program in 11 neonatal units
- Adoption of single-family room architecture in 4 neonatal units
- Control group: Infants cared for in the 10 neonatal units where neither of the interventions have been implemented.



Outcomes:

The *primary* outcome is the length of stay during the initial hospitalization to neonatal care. Comparisons will be made between infants cared for in intervention units and those cared for in non-intervention units.

Secondary outcomes are:

Corrected gestational age at discharge

The amount of outpatient visits after discharge during the first year of life

Growth parameters (weight, length, head circumference) at discharge compared to national standards

Change in growth parameters from birth to discharge

Cost effectiveness (according to hospitalization cost analyses carried out by the Institute for Health and Welfare)

Statistical analysis:

The planned analyses include a linear mixed model-approach to account for the effect of unit, degree of prematurity and intervention. Variables that will be considered for inclusion into the model are gestational age at birth, mode of delivery, birth weight z-score, plurality, neonatal morbidities, and receipt of antenatal steroids.

Timeline

During the year 2020 the research group has applied for funding, and research data permit from the Institute for Health and Welfare. Processing of the pseudonymized data will be initiated during the autumn of 2021. The analyses of the data and calculating of cost effectiveness will be done during 2021-2022. The manuscripts for scientific publishing will be drafted and submitted for publication during 2022-2023.

Members of the research group and roles

- *Ryo Itoshima*: Drafting of research plan, data application and analysis, drafting of research manuscripts
- *Suvi Lähteenmäki*: Funding, drafting of research plan, data analysis and drafting of research

manuscripts, reporting of funding

- *Kjell Helenius*: Drafting of research plan, data application and management, study supervision, editing of manuscripts
- *Anna Axelin:* Funding, study supervision, editing of manuscripts
- *Sari Ahlqvist-Björkroth*: Funding, study supervision, editing of manuscripts
- *Liisa Lehtonen:* Principal investigator, funding, study supervision, editing of manuscripts

Meaning and potential implications

Costly interventions are done in neonatal care to enable parental involvement. The effects of these interventions are important for future resource allocation, so that investments can be planned based on scientific evidence. Also other fields of medicine nationally and internationally, both in pediatrics and adult medicine, could benefit from interventions that advance care practices and family centered care culture.

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