Optimising kangaroo care to reduce neonatal severe infection/sepsis and resistant bacterial colonisation among high-risk infants in neonatal intensive care: a pragmatic, multicentre, parallel cluster randomised hybrid implementation–effectiveness trial (NeoDeco)

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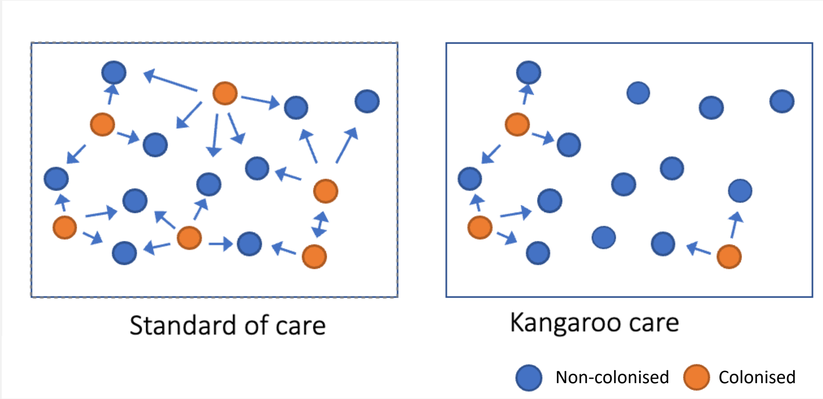
NeoIPC



Background & Rationale

Skin to skin contact (StSC) between an infant and carer has several beneficial effects. Early, regular and prolonged StSC as a unit-level strategy may decrease the risk of resistant bacterial colonisation in infants receiving neonatal intensive care, but this has not been investigated in a robust manner to date. When applied for its potential infection prevention and control (IPC) effects, it may therefore be beneficial to provide StSC to a wider range of infants than the preterm infants usually targeted. We aim to investigate such a strategy in the NeoDeco trial.

Trial Design

NeoDeco is a Horizon 2020-funded pragmatic, multicentre, parallel group, cluster randomised hybrid effectiveness-implementation trial investigating the effectiveness of increasing StSC sessions in high-technology neonatal units through applying a range of implementation strategies.

Study Population: High-risk infants born before 32 weeks' gestation admitted to participating neonatal intensive care units (NICU)

Setting: 24 Neonatal units routinely caring for extremely premature infants and with a minimum of 12 beds, will participate from Greece, Italy, Spain, Switzerland and the United Kingdom

The Study intervention will be implemented at the unit level and has two components:

Component 1: Skin-to-skin contact for optimised KC:

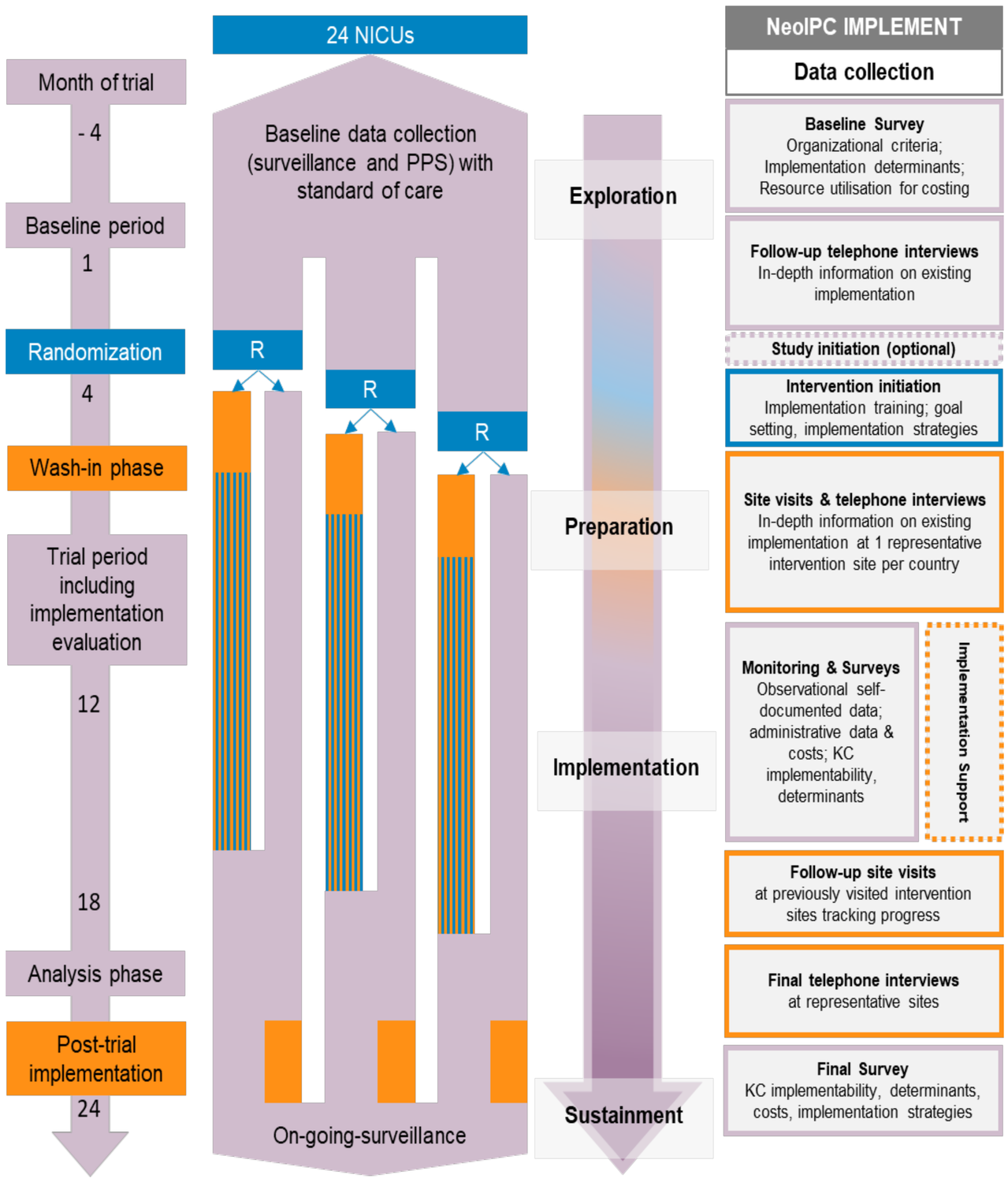
- All infants who are not breastfeeding on demand and can tolerate StSC should be offered it. The first session of StSC should take place as soon as possible after admission to the unit.
- At least two hours of StSC per day, optimum of ≥4 hours of StSC per day.
- At least one hour of StSC per session
- Suitability for transfer into StSC should be assessed at least every shift.

Component 2: Implementation support:

- Implementation strategies for achieving the desired level of StSC in the NICU, engaging clinical staff involved in implementing StSC.

Co-primary outcomes: The co-primary effectiveness outcomes are the cumulative incidence of hospital acquired neonatal severe infection among high-risk infants and unit-level resistant bacterial colonisation.

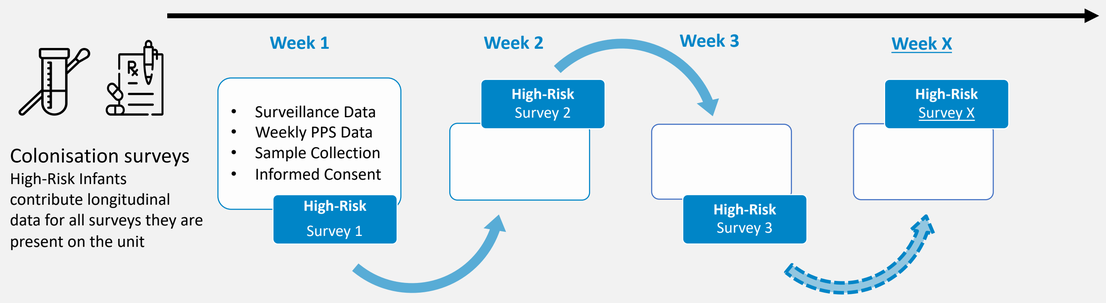
All other care is provided based on local practice, including sepsis treatment and IPC measures. All sites will be offered implementation support for increasing StSC provision; however, intervention sites will be randomised to immediate receipt of implementation support whereas standard care sites will be offered this after the study period.



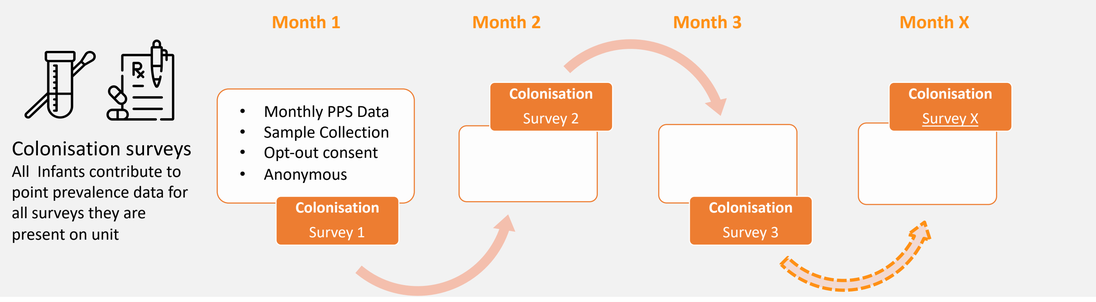
Note: At each randomisation (R), 8 NICUs are randomly allocated to the intervention (optimised KC) arm or the standard of care arm in a 1:1 manner. NICUs allocated to the control SOC arm will be given the opportunity for implementation of optimised KC in the post-trial period.

Sample and Data Collection

17 Month Study period – Weekly Surveys for High-risk infants on NICU



17 Month Study period – Monthly Surveys for all other infants on NICU



Expected impact

The NeoIPC Project brings together national neonatal networks and will be testing approaches for surveillance and monitoring of IPC activities and bacterial colonisation in NICUs as part of the wider project beyond the NeoDeco trial.
The NeoIPC project is supporting the creation of a platform for investigating best approaches for IPC in the neonatal intensive care setting.
NeoDeco will investigate the effect of optimised StSC as an Infection Prevention control measure in Neonatal units.

Learn more about the NeoIPC Project here!

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