Reviewer’s report

Title: Comparison of Family Centered Care with Family Integrated Care and mobile technology (mFICare) on preterm infant and family outcomes: A multi-site quasi-experimental clinical trial protocol

Version: 0 Date: 31 Aug 2019

Reviewer: Karen Benzies

Reviewer's report:

Thank you for the opportunity to review this interesting manuscript. Overall, it is very well-written and easy to follow the arguments despite the complexity of the interventions proposed. Regardless, the manuscript raises a few questions.

Is FCC really a philosophy of care rather than a framework? If so, it is understandable that implementation and evaluation have been problematic. Is FICare also a philosophy of care or an intervention program? The lack of clarity about effective components of FICare suggests that perhaps it is a philosophy of care. If so, will this project be fraught with challenges to multi-site implementation and evaluation similar to implementation of FCC? With these questions in mind, it seems that the aim of this proposed study is to evaluate the mobile app for parental engagement and evaluation. If the components of the interventions (i.e., FCC and FICare) are unclear, how can this study help to understand the mechanisms underlying FICare and its effects on infant and parental outcomes?

The 25-site international cRCT outcome was "high frequency breastfeeding" defined as greater than 6 attempts or successful feedings per day. Have the authors considered that this is not the effect of FICare, but rather is associated simply with parental presence in the NICU? There were no significant group differences in the absolute rates of breastfeeding after 21 days in the international FICare cRCT.

Stress is an ethereal concept. While the gold standard, the PSS-NICU is problematic because the factor structure of various iterations has not been well-established because of multiple adaptations. The abandoned sub-scale related to parent-health care provider interactions warrants renewed consideration given the importance of parent-HCP relationships to infant outcomes.

It is impossible to have multiple "primary" hypotheses.

It is laudable that parents and staff have been included in the design of the proposed trial. Perhaps respiratory therapists should be included as they too interact with families.
One of the challenges (cost driven) of the international cRCT was the inability to measure fidelity to core components of FiCare across sites. What is the plan to capture fidelity as designed for your study to inform future iterations of FiCare in the US context?

Under Study Design, do you mean "impact" or effect?

Under "Recruitment" do you mean "is" approved, or "will be approved" at each site? If already approved, what proportion of participants have already been recruited?

Please add information about recruitment and consent of the clinical team participants.

It is laudable that primary and secondary parents will be included; a major gap in this literature is lack of evidence for fathers.

How much time will elapse between the FCC and mFiCare phases?

What is the plan to ensure that data collection/entry by clinical staff meets study requirements?

Given the very large response burden for parents and clinical demands for staff, what are the expectations for completeness of data collection?

Is there an enrollment window for the study after admission to NICU?

It is unclear how the investigators will capture infant weight at 3 months post-discharge. Parental report may be insufficiently accurate to demonstrate group differences.

Please use either "trial" or "study" to refer to this protocol; it helps the reviewer.

The citations for data collection platforms seem to be incomplete (i.e., missing citations).

What are the plans for data management beyond the investigator manuscripts? Rather than destroying these data, will it be reposed for access by other qualified researchers?
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

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