Author’s response to reviews

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

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Version: 1 Date: 21 Oct 2019

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Response to Reviewers

We thank the reviewers for their positive comments about the study and are grateful for their constructive feedback. We have addressed all of the comments as detailed below and noted the changes are highlighted in the revised manuscript in red text.

Editor Comments:

1) In the ethics approval and consent to participate statement, please confirm whether the consent you obtained from study participants was written or verbal. If verbal consent was obtained, please clearly state this and if this was approved by the ethics committee.

Written informed consent will be obtained from all participants. This has been added to the Recruitment section and Ethics Approval and Consent to Participate statement.
Karen Benzies (Reviewer 1):

1) 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?

We appreciate these thought provoking question that have challenged the field for some time. After this manuscript was submitted, we published a review paper addressing some of these issues (philosophy vs models; specifying components of FICare). This has been added to the Background section. While the general implementation of FCC is variable, in this study, we will – with the addition of mobile technology – be able to precisely measure the degree of implementation of parent support and parent involvement in their infant’s care. This is described in the study Methods.

2) 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.

FICare is intended to maximize parental presence, as well as involvement in their infant’s care, so we agree that parental presence likely contributed to greater rates of high frequency breast feeding and more infants receiving breastmilk through breastfeeding rather than by bottle feeding at discharge in the Canadian FiCare trial.

3) 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.

We agree. We retained the Staff Behaviors and Communication subscale from the original PSS:NICU. Please see corrected references in Table 1.

4) It is impossible to have multiple "primary" hypotheses.

This has been corrected.
5) 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.

Thank you for pointing this out. In fact, respiratory therapists participated in the planning for the study and were inadvertently omitted from the list of team members. They have been included in the Preliminary Work section.

6) 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?

This is a main goal of the addition of the mobile technology to FICare (See Aims and Methods). If determined to be feasible and acceptable, we should be able to measure fidelity to the core components across sites.

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

Thanks for pointing this out. We mean ‘effect’.

8) 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?

We have written the protocol primarily in future tense (although the trial is already underway). However, we have indicated that the protocol has been approved at all sites to pre-empt any concerns by reviewers or readers that the protocol might not be approved.

9) Please add information about recruitment and consenting of the clinical team participants.

This information has been added to the Recruitment section.

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

Thank you.

11) How much time will elapse between the FCC and mFICare phases?

Approximately 2 months (see first paragraph under Intervention).

12) 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?

There are no data collection/data entry requirements of clinical staff other than required for usual patient care. All study-related data are collected or abstracted from the medical records by trained research staff (see Clinical Data section). Our preliminary work suggests that parents are
motivated to participate in data collection. Nonetheless, the primary aim is to determine the feasibility and acceptability of mobile application technology to gather data about parent involvement in the care of NICU infants in the usual FCC and in the mFICare parent intervention.

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

Parents will be approached after infants have been admitted to the NICU for more than 72 hours. They may request to defer enrollment to a later date, as long as the infant is expected to remain in the NCU for a minimum of 21 days. This has been added to the Recruitment section.

14) 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.

In our experience, parents of preterm infants closely track their baby’s weight once at home. Nonetheless, there may be differences in scales and other sources of inaccuracy that may affect this particular self-reported measure. We will learn if this measure is useful or not.

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

We are unclear about what the reviewer is referring to. Please clarify.

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

If the reviewer is referring to Table 1, we have added a footnote to clarify the measures that were developed specifically for this study. If the reviewer is referring to elsewhere in the manuscript, please provide details.

17) What are the plans for data management beyond the investigator manuscripts? Rather than destroying these data, will it be reposited for access by other qualified researchers?

Unfortunately, we do not have the resources to store the data and manage access for other researchers, nor do we have access to repositories for such data.

Marsha Campbell-Yeo (Reviewer 2):

1) Please expand on the randomization process on p11 - who will control the randomization process, who and how will it be accessed?

The following randomization details have been added to the Recruitment section: Statistical staff from the university have prepared computer-generated random number schemes for twin and triplet births and placed the assignments in opaque envelopes numbered sequentially. Study site staff are blinded to the randomization scheme. Once a parent has signed the consent form, the study staff will retrieve the appropriate envelope in the sequence and open it to reveal which of the infants will be the primary infant for the study.
2) With respect to the sequential nature of the enrollment, please expand on how the sites will be allocated, by whom? Please include anticipated timeline.

All sites begin with the FCC phase and then progress to the mFICare phase, as noted in the manuscript. We have moved this statement to a more prominent position under the mFICare intervention section. The anticipated timeline is not known because of wide variations in NICU preterm birth admission rates at the sites. As stated in the Intervention section, we anticipate a 2 month interval between the FCC and mFICare phases.

3) Please provide brief rationale for excluding additional parents in primary outcome.

Additional parent-infant pairs from the same family are non-independent and therefore are excluded from the primary analyses. This has been added to the Recruitment section.

4) Please provide brief rationale for the difference in planned recruitment numbers between the two comparison groups for Phase 1 and Phase 2?

One site only committed to participating in the FCC phase of the study.

5) Please expand on how the primary parent will be selected and by whom if both parents are eligible?

The parent who expects to spend the most time with the infant will be considered the “primary” parent for analysis. This has been added to the Recruitment section.

6) Given the primary infant outcome is growth - please provide further details on how you will control for alternative feeding practices which may impact growth and how this will be controlled for in the analysis? E.g. NG feedings, use of fortification, parental nutrition, use of human donor milk?

As per the prior Canadian FICare trial and the recent study from the UK (see references 46, 50), feeding practices are not controlled for in the analyses. The parental presence/involvement are hypothesized to have an effect on growth above and beyond particular feeding practices.

7) Will potential site differences , which may reflect variation in feeding practices, be taken into consideration during analysis of the primary outcome?

Yes. Site has been added to the example of potential confounding variable to be considered in the analyses.

8) Please expand on the provision of peer support - is this peer support based on a standardized program? How will it be monitored? How will peer support providers be chosen?

Additional detail has been added to the description of Peer Support. Sites have several options for providing peer support to parents in the study: Each site will build upon their existing peer support program or will be assisted by the study team to establish a new program. The sites will
determine their selection criteria. Alumni training follows the Canadian FiCARE curriculum as stated in the Clinical Team and Alumni Parent Training section. See response regarding intervention fidelity below.

9) Please clarify the FiCARE intervention group - it is unclear what content will be included and what will be provided in person and what via the mHealth platform? Will this be standardized?

We have added additional text to the mFiCARE Group section to clarify that all elements of the FiCARE model are provided in-person. Additionally, education, daily medical rounds, peer support and documentation are supported by the We3healthTM so that parents may access these components of the intervention at other times than when offered in person or when they are away from the NICU.

10) How will you monitor intervention fidelity?

Additional text has been added to elaborate that we will conduct regular site visits that will involve auditing of study recruitment procedures, intervention implementation and data collection. Site staff will also participate in monthly calls to discuss study progress, address any questions about study operating procedures, address any concerns about protocol implementation, and share best practices.

11) Please address the feasibility of the study recruitment beyond the first study site. An anticipated timeline of the project would be helpful including anticipated on boarding of the additional sites.

We understand the reviewer’s interest in the study timeline. However, this is very difficult to predict because of uncertainties with institutional approvals and variability in preterm birth and NICU admission rates and therefore we do not wish to publish a study timeline as part of the protocol.

12) Please expand on the processes related to the 3 month follow-up as well as any potential limitations and planned interventions to reduce loss to followup.

The procedures are described in the Parent Survey Data section. We have added details about compensation to the Recruitment section.