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

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Reviewer: Marsha Campbell-Yeo

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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

This protocol outlines a proposed exploratory multi-site quasi-experimental study with the aim to compare usual FCC with mobile enhanced FICare (mFICare) on growth and clinical outcomes of preterm infants born at or before 33 weeks gestational age, as well as the stress, competence and self-efficacy of their parents. The study is focused primarily on the effectiveness of FICare within US hospital settings.

There are two primary aims of the study. Aim 1, to evaluate the feasibility and acceptability of using mobile technology to gather data about parent involvement in the care of preterm infants receiving FCC or mFICare as well as of the mFICare intervention. In addition, for Aim 2, the effect sizes for infant growth (primary outcome) and for secondary infant and parent outcomes at NICU discharge and three months after discharge will be estimated (Aim 2).

General comments:

Overall the protocol is well written and clear. There are some elements that if expanded would strengthen the submission.

Specific comments:
Please expand on the randomization process on page 11 - who will control the randomization process, who and how will it be accessed?

With respect to the sequential nature of the enrollment, please expand on how the sites will be allocated, by whom? Please include anticipated timeline.

Please provide brief rationale for excluding additional parents in primary outcome.
Please provide brief rationale for the difference in planned recruitment numbers between the two comparison groups for Phase 1 and Phase 2?

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

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?

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

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?

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?

How will you monitor intervention fidelity?

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.

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.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

No

**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.

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