Improving Preterm Infant Outcomes with Family Integrated Care and Mobile Technology

ID: 16-19542

Study Protocol and Statistical Analysis Plan

January 17, 2018

Study Protocol

Study staff at UCSF, UCLA, BCH-O, and CRMC will perform the following procedures.

Usual FCC Group:

Education: Parents will receive an orientation to the unit by a NICU nurse and will have access to the usual written and video materials provided by the NICU. Parents will receive all NICU-required individualized parent teaching and support, delivered at the bedside by nurses or the Discharge Coordinator.

Direct care: Parents will be encouraged by nurses to participate in infant care under nursing supervision for feeding, bathing, dressing, and holding skin-to-skin.

Social work and other support: Individualized support from social workers, lactation consultants and other specialists will be offered.

Documentation: Parents will not be asked to formally document any observations of their infant or their own skills acquisition. Nurses and Discharge Coordinators will complete the standard Discharge Teaching Checklist per usual hospital policies. Parents will be asked to track their time in the NICU, time learning from nurses and time spent in infant caregiving activities, and to keep a journal of their NICU experience (without any specific instructions about content). They will use the We3Health App for this, with only the data tracking and journal features activated. These data will not be shared with the clinical team.

mFI-Care Group:

mFI-Care clinical team and alumni parent training: After completion of the usual FCC group enrollment, nurses who volunteer to provide care to mFICare infants/parents and the volunteer alumni parents will receive in-person and online training from the study team. The nurse training will follow the Canadian FI-Care curriculum and cover topics such as the differences between FCC and mFI-Care, psychological implications of preterm birth for parents, infant development, parent-infant attachment, re-conceptualization of the nursing role, and parent coaching skills. Alumni parent training will follow the Canadian FI-Care curriculum. Physicians, therapists and and social workers will receive in-person and online inservice education specific to their roles. Once training and inservice education are complete, mFI-Care enrollment will commence.

Education: Parents will be oriented to the unit by a mFI-Care nurse who will introduce them to the program, explain the parent's role as primary caregiver for their infant, and orient them to the NICU and parent resources, including the We3Health App. Parents will be able to access the App in English. Parents will be provided the Canadian FI-Care Parent Education program, a 3-week rotating curriculum offered 3 afternoons per week (Appendix 2.B). The small group sessions will be facilitated by a member of the study team. Parents will participate in-person or access the content remotely at a time of their choosing via the We3Health App.

Direct care: mFI-Care parents will be treated as the infant's primary caregiver, with nurses serving as teachers and coaches. Parents will not be required to be in the NICU at specified hours as in the Canadian FI-Care program, but when in the NICU, they will be expected to provide as much infant care as they can, with support from mFI-Care-trained nurses. Parents will not provide ventilation management, intravenous fluid or intravenous medication administration.

Daily medical rounds: mFI-Care parents will be expected to participate in daily medical rounds either in-person or remotely by logging on to the HIPAA-compliant web-link via the We3Health App. Parents will report standardized data of their infant's status to the rounding care team, ask questions, and reach consensus with the clinicians on the infant's daily plan using the We3Health App. Nurses will provide role-modeling and coaching to prepare parents for this role.

Peer-Support: mFI-Care parents will receive peer support from alumni parents who will contact them remotely, by telephone, text or through the We3Health App, at least twice weekly and as desired. The

mFI-Care parents will also be able to 'meet' and share experiences and information with other mFI-Care parents through a secure online parent forum on the We3Health App.
Documentation: mFI-Care parents will be expected to document time spent with their infant and record infant activity, feeds and output using the We3Health App. They will also use the App to keep a journal of observations of their infant and their own NICU experience that they can share with family, friends and the clinical team if they wish. Parents will access the FI-Care skills checklist via the We3Health App and track their learning and skills acquisition. The infant observation data, parent-team communication and parent skills will be accessible to the clinical team and parents for rounds.
Parent Resources for both groups: All parents, regardless of group assignment, will be provided with similar resources to enable them to spend extended periods or stay overnight with their infant and to facilitate breastfeeding. Each single patient room in the study site provides a reclining chair, sofa bed, locked storage, wifi and a bedside tablet computer for parent use. There is also a nearby family lounge with kitchen, shower, and laundry facilities.

Statistical Analysis Plan:
Descriptive statistics will be provided for all study variables: means and standard deviations for quantitative variables and frequencies and percents for categorical variables. Data analysis will be based on an intention-to-treat strategy with all participants enrolled in the usual FCC or mFI-Care groups at UCSF analyzed within their respective groups regardless of compliance with the group assignment. Outcomes will be compared between the usual FCC and mFI-Care groups using t-tests for continuous variables, Wilcoxon tests for ordinal variables, and chi-square tests for categorical variables. We expect 225 eligible ICN admissions during the study period and anticipate enrolling 50 parent-infant pairs in each group (usual FCC and mFI-Care) at UCSF. Assuming 20% attrition, we will have complete data on 40 infants per group. Enrollment at the UCLA site is exploratory to further assess feasibility and acceptability thus statisitcal power is based on the UCSF sample. The primary outcome, change in weight Z-score, typically has a standard deviation of between 0.44-0.47 (data from Toronto pilot and Canada-led cRCT). With a 0.05 null-hypothesis rejection threshold (alpha) for the two-tailed t-test, we will have 80% power to identify a group difference of 0.28-0.29. Differences among the groups in potential confounding variables (e.g., GA, birth weight) will be examined. Variables that differ among the groups may be considered as covariates when examining group differences in the primary and secondary outcomes.The covariate-adjusted scores may provide more precise estimates of the effect sizes. We will calculate confidence intervals around the differences because this will give a better idea of the range of values around the true means for the population and guide the sampling strategy for the future US cRCT. We will compare participation rates in specific aspects of usual FCC and mFI-Care such as caregiving activities, education, time spent with the infant or holding skin-to-skin or the primary and secondary outcome variables to see if they differ for parents and infants with different characteristics (e.g., sex, race/ethnicity or distance between hospital and home). We will compare attitudes and perceived practices of nurses and physicians during the FCC and mFI-Care conditions.