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Filename: 450169

2016 PAS Annual Meeting

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QUESTIONNAIRE INFORMATION**Research Type:** Clinical**Reason why the November deadline could not be met:**

The data collection for this study was only completed in Dec 2015.

Title: Evaluation of Family Integrated Care (FICare): A Cluster Randomized Controlled Trial (RCT) in Canada and Australia

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Background: Today's neonatal intensive care units (NICUs) are highly technical places where infants are physically, emotionally and psychologically separated from their parents. Family Integrated Care (FICare) is a model of care that supports and facilitates the integration of parents into their infant's care in the NICU.

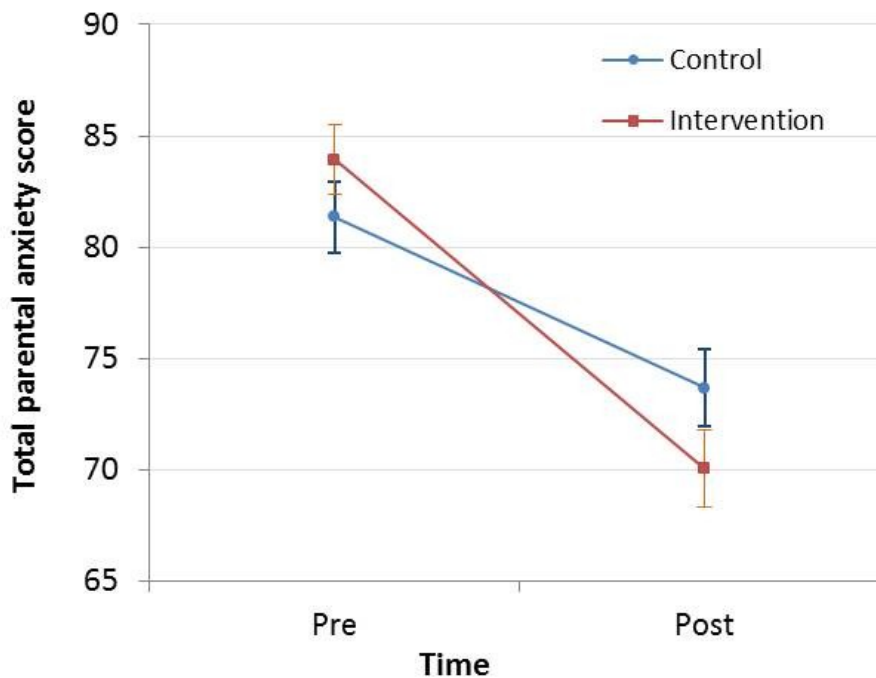
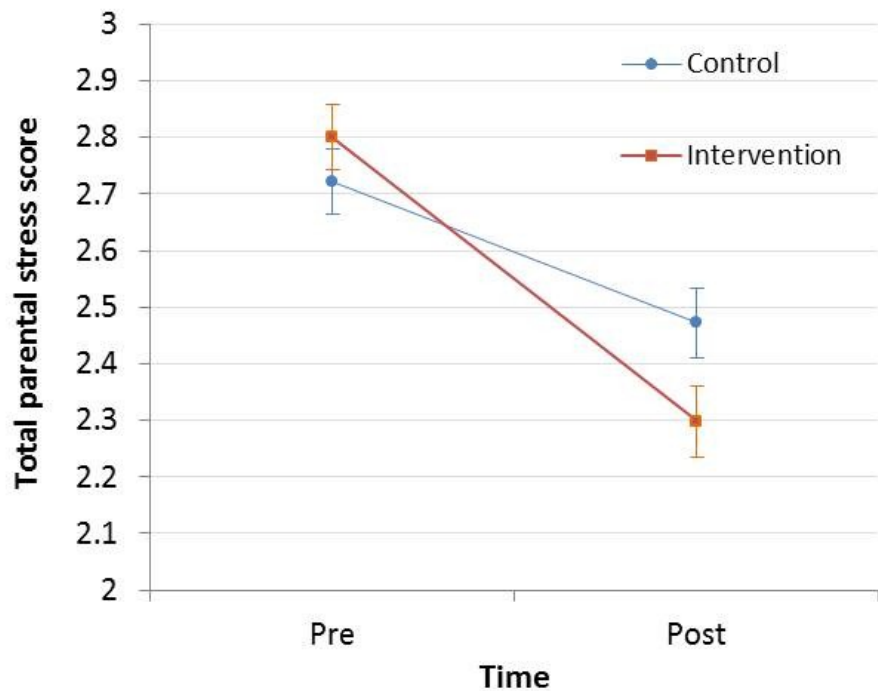
Objective: To evaluate the impact of FICare on infants and their parents in NICU's.

Design/Methods: A cluster RCT was performed in 25 Level 3 NICUs across Canada and Australia; 13 were randomized to the intervention (FICare) and 12 to the control (standard care). Parents and staff at the intervention sites were trained, educated and supported during the implementation of the model. Patient consent was obtained from all participants. Outcomes were compared based on intention to treat principle, using multilevel models to account for clustering.

Results: Infant characteristics are presented in the following table:

	Control	Intervention
# infants (#sites)	873(12)	827(13)
Gender %	M 54	M 54
Birthweight g mean(sd)	1263(419)	1210(411)
Age an enrolment days, median(IQ range)	12(6-23)	15(8-28)
Apgar score <7 at 5 min, %	26.8	27.75
Small for Gestational Age,%	11.6	9.8

As measured by the change in z-scores, infants demonstrated greater weight gain in FICare sites (1.58), than those in the control sites (1.46), over the 21 days of enrollment (p <0.001). Meanwhile, a significant decrease in stress and anxiety scores were observed among parents of infants at FICare sites compared to those in the control groups as illustrated below (p<0.01).



Conclusions: FICare had a positive impact on both infant and parent outcomes in NICU. Future efforts should focus on sustaining the model and exploring its use in different contexts.

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