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Correction to: Family Integrated Care (FICare) in Level II Neonatal Intensive Care Units: study protocol for a cluster randomized controlled trial



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After publication of our article [1], the authors have reported mathematical errors made in the sample size calculation for this cluster randomized controlled trial (cRCT) (Benzies et al. 2017). Independent statistician Peter Faris (PhD; Director, Research Facilitation, Analytics, Alberta Health Services) reviewed the sample size calculation for this cRCT and concluded that the statistician responsible for the original sample size calculation made a mathematical error when translating the absolute difference in length of stay (LOS) to a relative effect when estimating sample size using log-transformed LOS. As a consequence, the calculations were based on a 60% relative decrease in LOS rather than a 10% decrease. Additionally, we are unable to verify the intra-cluster correlation (ICC = 0.18) and standard deviation (SD = 0.235 in natural log scale) reported by the original statistician as the dataset used for these calculations is no longer available.

Retrospectively, using parameters from the cRCT (SD = 8, ICC = 0.085, mean LOS = 19 days, 10 sites, 65 mother participants per site), an absolute difference of 4.46 days in LOS (a 23.5% relative change in LOS) would have been

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required for the trial to achieve 80% power. Detailed calculations are available upon request from the first author. With only 10 available clusters in the province, a cRCT design was not feasible to achieve sufficient power to demonstrate a 10% difference between groups in LOS while adjusting for clustering. Moreover, the 10 clusters included all sites within the province, rather than a random selection of sites. Therefore, the analysis approach was modified to (1) assess the impact of the intervention within the province, and (2) account for site size, patient variation, and differences in mother and infant characteristics across the sites.

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