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Supporting parents of premature infants transitioning from the NICU to home: A pilot randomized control trial of a smartphone application

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ABSTRACT

Objective: To determine whether parents of Very Low Birth Weight (VLBW) infants in the Neonatal Intensive Care Unit (NICU) transitioning home with the NICU-2-Home smartphone application have greater parenting self-efficacy, are better prepared for discharge and have shorter length of stay (LOS) than control parents.
Methods: A four-week pilot randomized controlled trial during the transition home with 90 VLBW parents randomized to usual care (n = 44) or usual care plus NICU-2-Home (n = 46), a smartphone application designed for VLBW parents. Parenting Sense of Competence Scale (PSOC) was assessed at baseline, day after discharge, and two weeks post-discharge. Preparedness for discharge and length of stay (LOS) were secondary outcomes. Analyses by usage were also included.
Results: While parents of VLBW infants in the intervention group did not show an improvement in PSOC during the transition when compared directly to controls, after accounting for actual mean app usage, PSOC improved 7% (2.71 points/time greater; 95% CI = 1.45, 6.27) for intervention versus controls. Compared to controls, above-average users increased their PSOC score by 14% (6.84 points/time; 95% CL = 5.02, 8.67), average users by 11% (4.58 points/time; 95% CL = 2.89, 6.27) and below-average users by 6% (2.41 points/time; 95% CL = 0.04, 4.79). Moderate evidence showed LOS was shorter for above-average users compared to the control group (β = 12.2. SE = 6.9, p = 0.085).
Conclusion: A smartphone application used by parents of VLBW infants during the transition home from the NICU can improve parenting self-efficacy, discharge preparedness, and LOS with improved benefits based on usage.

1. Introduction

Premature birth occurs in almost 12% of births (Hamilton et al., 2012) with Very Low Birth Weight infants (VLBW, birth weight < 1500 g) comprising 18% of the premature low births (Hamilton et al., 2014). VLBW infants' survival becomes directly proportional to gestational age and birth weight (Stephens et al., 2010), with parents providing all care after successful discharge. Among neonates, VLBW infants have the longest average length of hospital stay and the highest rates of morbidity and re-hospitalization in the first year (Escobar et al., 1999; Underwood et al., 2007).

While the admission experiences of parents of VLBW infants have been studied (Singer and Ryff, 1999; Singer et al., 1999; Singer et al., 2003; Singer et al., 2010), the needs of parents transitioning home has received less attention (Bruder and Cole, 1991; Fowlie and McHaffie, 2004). "Pervasive uncertainty" is how one study described the parents' feelings around the care of these medically vulnerable infants during the transition (Garfield et al., 2014). Despite efforts by NICU staff and the American Academy of Pediatrics' (AAP) policy statement on the importance of involving parents from admission through discharge (Committee on Fetus and Newborn, 2008), parents desire more information and frequently report feeling unprepared for discharge (Sneath, 2009; De Rouck and Leys, 2009; Brazy et al., 2001; Smith et al., 2012).

Technology is one novel approach for supporting parents making the transition from the NICU to home. Smartphones may be particularly useful for NICU parents because they are easy to transport between

Abbreviations: VLBW, Very Low Birth Weight; NICU, Neonatal Intensive Care Unit; PSOC, Parenting Sense of Competence Scale; LOS, length of stay; ITT, intention-to-treat; ICC, intraclass correlation; RCT, randomized control trial.

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home and the NICU, small enough to carry when caring for the baby, and almost 80% of adults in childrearing ages of 18–49 have a smartphone. While many applications (apps) are available for general newborn care, few were created with the NICU infant in mind and none have been scientifically evaluated for their efficacy in providing support to parents. Recent calls for evaluations of the utility of the growing number of health apps have been made. This article describes a pilot randomized controlled trial of a parent-empowering smartphone application called NICU-2-Home wherein we hypothesized as a primary outcome that the NICU-2-Home app would lead to improved parenting self-efficacy during the transition home with their VLBW infants compared to controls. Two secondary outcomes, preparedness of the VLBW infant's parents for discharge from the NICU and length-of-stay (LOS), were also investigated.

2. Material and methods

2.1. Study design, participants, and intervention

The NICU-2-Home study was a randomized controlled trial piloted with all parents of VLBW infants eligible who were ≥18 years old, English speaking, caring for a living infant together and willing to be randomized. The study period included the final two NICU weeks (beginning when the infant moved from an isolette to an open crib or 34 weeks, whichever came first), discharge, and two weeks at home; four-weeks in total. Once eligible parents were consented and baseline entry questionnaires were completed, parents were randomized to NICU-2-Home or control using a 1:1 blocked randomization using sealed and numbered envelopes. Couples were assigned to the same arm. The care team was not told (a) parents' decision to participate or (b) their assigned group. The study was registered at clinicaltrials.gov (NCT01987180) with the primary aim of examining parenting self-efficacy and secondary aims of analyzing collected salivary biomarkers currently under review. Our Institutional Review Board approved the study.

Control group parents received usual care including NICU care handouts and nurse education; those in the NICU-2-Home group received the same plus an Android smartphone with the NICU-2-Home application installed for the study period. All participants independently completed measurement tools and data collection via self-report surveys at three time points: baseline entry into study (T − 14), one day prior to discharge (T − 1), and 14 days after discharge (T + 14). Recruitment took place January 2013 through February 2014.

Each mother and father intervention parent was given a smartphone with the NICU-2-Home application, mobile phone service, a data plan and orientation to the app. NICU-2-Home was designed with a theoretical underpinning using Bandura's Self-Efficacy Theory (Bandura, 1995) and was developed with Motorola Mobility specifically for this project based on findings of the needs of VLBW parents who had transitioned home (Garfield et al., 2014). NICU-2-Home had four main features including: 1) Passport-2-Home—a selfguiding discharge checklist; 2) Education Center – curated, multimedia educational information on NICU infant care; 3) Baby Connect© – a commercially available app for tracking activities of daily living; and 4) Mood Tracker—synchronized updates of parents current mood (Supplemental Table S1: Components and Features; Supplemental Fig. S1: Thumbnail image of NICU-2-Home home page in Supplemental Information). Content was written and designed to be at a 7th grade reading level. Parents' phones were linked to share updates and only NICU-2-Home use was monitored and reported in time-stamped server logs.

2.2. Outcomes and measures

Our primary dependent variable of interest is parenting self-efficacy. Therefore, the *Parenting Sense of Competence Scale* (PSOC; $\alpha = 0.807$), a well-validated 17-item scale created to assess satisfaction of parenting and parental self-efficacy in a variety of populations (Johnston and Mash, 1989; Gilmore and Cuskelly, 2009). All items were summed with ranges from 17 to 102 (no norm exists); higher scores indicate a greater sense of parental self-efficacy. The PSOC was measured over three occasions: entry into study (T − 14), the day before discharge (T − 1), and the final day of the study (T + 14).

As a pilot study, exploratory secondary outcomes were examined including preparedness for discharge and length of stay (LOS). The *Press-Ganey discharge questionnaire* was administered to assess preparedness for discharge. This single question asks "How prepared do you feel about your baby's discharge?" (range: "not at all" to "very well"). LOS was measured as the number of NICU days from study enrollment through discharge (i.e. intervention period) in order to make LOS clinically meaningful as all babies would in theory be likely to be discharged within similar timeframes.

In addition to study arm and time point, independent variables were examined including: average use of the NICU-2-Home app (coined *mean app usage*), calculated as the average number of uses of the app per day from baseline to the end of the study and considered as measure of exposure; gender, age, race, marital status, education, employment status, income, insurance status, gestational age and weight were also examined. Our study was powered to find statistically significant results with 40 participants in the two groups assuring 80% power at 0.05 to detect an effect size of 0.63 standard deviations of change in PSOC, for a longitudinal analysis assuming a 0.5 within-subject correlation (ICC) (Horrigan, 2007).

2.3. Analyses

2.3.1. Primary analysis

Our primary analysis was based on the intent-to-treat (ITT) principle where all randomized participants were included individually in the analyses. Since the data were longitudinal (and thus correlated) in nature, a repeated measures linear mixed-effects model assuming a compound symmetric covariance pattern was used to examine the change in mean PSOC scores over the three measurement occasions (i.e. the time points T − 14, T − 1, and T + 14) while controlling for possible confounding covariates of self-efficacy and the mismatched randomization of parental race and age.

2.3.2. Supplementary analyses

A mean app usage variable and a mean app usage and time point interaction variable were added in supplementary analyses to evaluate how app usage may have affected mean PSOC scores and other outcomes. A *user level* variable was created categorizing three groups based on average app usage from baseline until discharge (T − 1): below average (<25th percentile), average (25th–75th percentile), and above average (>75th percentile). Control participants were categorized as nonusers. The user level variable was included in the model for a third analysis.

2.3.3. Statistical methods

The models included a random intercept and fixed effects for time (i.e., time point), study arm, parent gender, and demographic covariates. Since missing data can result in observations being excluded in the model, multiple imputations (N = 20) were used to account for missing data. The imputations were conditioned on all of the independent variables listed as well as two auxiliary variables: a *technology attitudes* summed score and a *technology for parenting attitudes* summed score (Horrigan, 2007). The technology for parenting attitudes questions were modified by adding "for parenting" to the various questions. All imputations were done in SAS 9.4 using **proc mi**. Estimates and 95% confidence limits were calculated using **proc mianalyze**. Chi-squared tests were conducted for the Press-Ganey questionnaire item comparing the percentage of each category's endorsement by study arm and user level. LOS was examined by study arm and by user level through