Media Intervention with Parents To Support the Development of Preterm Newborns

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Abstract

Objectives. Evaluate a media intervention *No Matter How Small,* about development in infants born preterm.

Design. Controlled clinical trial, randomized by site.

Setting. Four hospital-based Level III Neonatal Intensive Care Units (NICUs)

Participants. 107 parents of preterm newborns being cared for in the NICU

Methods. Surveys measured parents' knowledge of preterm infant development, and favorable attitudes toward Developmentally Supportive Care (DSC), at baseline (enrollment). After the intervention at two sites, follow-up surveys at 1 and 4 months later.

Results. DVD program increased parental knowledge of fetal and neonatal brain development, reduced stress and increased confidence in applying DSC.

BACKGROUND

In 2004 there were 508,356 infants born preterm, or 12.5% of all births. (Martin et al. 2006) Between the time newborn intensive care began in the 1970s and 2000, the mortality rate of VLBW babies decreased from 50% to less than 20% (Westrup et al. 2000). However, between 2000 and 2005, the mortality rate rose again from 34.6 % in 2000 to 36.5% in 2005 (Mathews & MacDorman 2008). Advances in medicine have yet to reduce morbidity for premature infants in similarly striking ways, especially in terms of neurofunctional outcomes including behavior and learning problems. Existing scientific and clinical insight into the neurobehavioral development of premature newborns needs to be communicated to clinicians and parents who provide direct care to preterm newborns in the early days and weeks of life. The application of current neurobehavioral science to the care of premature newborns requires changes in the practices of clinicians and parents.

Scientific and clinical attention to the neurobehavioral development of premature newborns is the new, relatively uncharted frontier of NICU care. The urgency of exploring that frontier is becoming more evident as the population of very early-born preterm children reaching school age is on the rise. A 2002 meta-analysis concluded that gestational age at birth is proportional to their average cognitive test scores at school age, thus children born preterm are at risk for reduced cognitive test scores. Furthermore preterm and low birth weight children are 50% more likely to be enrolled in special education services (Bhutta et al. 2002). Even in cases where preterm children have a generally normal IQ, they are at risk of exhibiting subnormal levels of executive functioning (Bohm, Smedler, & Forssberg 2004). Additionally, prematurity and low birth weight double the risk of behavior problems; these problems show stability over time, measured by a study examining children at 3, 5, and 8 years of age (Gray, Indurkhya, & McCormick 2004). The neurological and educational sequelae to preterm birth are dramatic evidence that more must be done to support the developing brains of infants during the time spent in the NICU. Also, concern is growing about increasing costs of: ongoing physical, occupational and speech therapy; early intervention (EI) caseloads; grade repetition; and special education directly proportionate to the rise in the population of NICU graduates. Costs incurred by parents in their child's ongoing rehabilitation and education have not been fully explored. (Zupanic et al. 2000)

The research of Heidelise Als, Ph.D., and her colleagues at Harvard Medical School, shows that the unexpected experiences of life in the NICU may inhibit developing neuronal pathways and interfere with full differentiation (Duffy, Als, & McAnulty 1990). In addition, their work shows that the sounds, lights and constant activities in a typical NICU influence infants' arterial oxygen saturation directly (Als et al. 1994). Als' seminal 1994 RCT study of the Newborn Individualized Developmental Care and Assessment Program (NIDCAP) in the *Journal of the American Medical Association* demonstrated improved medical and neurodevelopmental outcomes for preterm infants receiving individualized developmental care. NIDCAP presents an approach to intensive care that is geared to support each individual infant's strengths and efforts toward self-regulation and competent functioning. The model was shown to result in medical, neurodevelopmental and cost-saving benefits.

After surfactant replacement therapy became available in NICUs to treat respiratory distress syndrome (RDS) in the mid 1990s, two studies confirmed Als' initial findings and suggest that individualized, developmentally supportive care (IDC) contributes to significant reduction in major morbidities including intraventricular hemorrhage (bleeding into the brain), chronic lung disease, need for respirator assistance and tube feedings. (Fleisher, VanderBerg & Constantinou 1995) and 2000 (Westrup). Additionally, IDC was shown to be connected to improvements in self-regulatory abilities, weight gain, and mental and psychomotor development at nine months of age, corrected for prematurity (Als et al. 1994). Infants who received IDC also had shorter hospital stays (between 64 and 91 fewer days) and savings in hospitalization charges of over $91,000 per infant.

Developmentally supportive care has been connected to improvement in self-regulation, weight gain, and mental and psychomotor development at nine months corrected age.

Als has contributed longer-term outcome data to the discussion around individualized developmental care with results from cognitive, motor and neuro-organizational assessments (at ages 3 and 7) of children who had participated in Als' initial 1986 study (Als in Guralnick 1996). Infants who had received IDC in the NICU demonstrated advantages in verbal, motor, memory and general cognitive indices of the McCarthy Scales. They also showed better expressive language abilities, less perseveration, better sentence complexity, enhanced behavioral organization, and improvement in visual and spatial measures suggestive of better frontal lobe functioning. Developmental care in a NICU, could be associated with improved cortical and frontal lobe development lasting into school age.

In addition to Als' research supporting the benefits of developmental care, a systematic review was conducted of 31 eligible RCTs involving developmental care interventions clinical outcomes (Symington & Pinelli 2000). While the review called for more evidence demonstrating short and long-term effects, it also pointed to proven benefits of developmental care including: improved short-term growth outcomes, decreased respiratory support, decreased length and cost of stay, improved neurobehavioral outcomes to 24 months of corrected age. Another systematic review also itemizes long-lasting advantages to developmental care (Bowden et al. 2000).

In the practice of developmentally supportive care, a central premise is that careful, trained observation, documentation and interpretation of infant behavior by caregivers constitute the best basis for developing clinical care plans and the amelioration of stress behaviors. The focus is always on enhancement of each infant's unique repertoire of self-regulation strategies and emerging competencies.

In 2004, the National Institute on Child Health and Human Development (NICHD) funded Vida Health Communications, Inc. of Cambridge, Massachusetts to produce, evaluate and distribute two DVDs for the distinct audiences of parents and clinicians. The resulting integrated set of multimedia programs consists of "No Matter How Small" – for parents and "Focus on the Brain" for clinicians. In ways that are appropriate for their different audiences and by using visual media's potential to magnify, slow-down, freeze and repeat hard-to-identify behaviors, the programs teach about fetal and preterm infant brain development, the neurobehavioral competencies of newborns, and specific care strategies now known to support the growth and development of premature infants in NICUs.

This article reports on findings from the evaluation of the program *No Matter How Small,* which targets parents of infants in NICUs. The media sought to increase the knowledge and understanding of the parent, and to affect their stress levels and their confidence in applying Developmentally Supportive Care (DSC). The researchers hypothesized that:

1. Parents of infants in the NICU who received the DVD program would exhibit significantly greater increase in knowledge of and positive attitudes about preterm brain development from enrollment to one month later, than parents who received the usual education and training.

2. These changes would persist three months following the intervention.

METHOD

Overview

This research design combined randomization of study sites with a quasi-experimental pre/post study design (Campbell and Stanley, 1963), using survey instruments designed specifically for these purposes. Additional analysis explored the potential compounding interaction of the use of both DVD programs with their intended populations in the same NICU.

To evaluate the media program, this study compared knowledge, confidence, and stress among parents who were given the parent DVD program to parents who did not have access to it. Baseline and short-term follow-up surveys were administered to all parents approximately one week apart, with parents at intervention site viewing the media program during the interim. To test persistence of the intervention effect, the first twenty parents recruited at each of the four study sites were asked to complete a mailed follow-up test approximately three months after the second administration.

Participants

Four NICU sites agreed to take part in the study:

Site 1: a Level III NICU, had 46 bassinettes, 180 NICU staff, 8,000 live births/year, and 800 births before 37 weeks.

Site 2: a Level III NICU, had 55 bassinettes, 100 NICU staff, 4,200 live births/year, and 370 births before 37 weeks.

Site 3: a Level III NICU, had 43 bassinettes, 110 NICU staff, and 4,300 live births/year.

Site 4: a Level III NICU, had 30 bassinettes, 30 NICU staff, 1,300 live births/year, and 250 births before 37 weeks.

The sites were randomly assigned to either the intervention or control condition. The same research team at each of the four sites coordinated both the parent and the staff aspects of the study. At each site, trained study staff approached potential participants individually, explained the study, answered questions and screened for eligibility.

Eligibility criteria were as follows:

- The baby's medical team agreed that the baby is not experiencing an acute medical crisis at the time of recruitment;
- Less than a week had transpired since the baby's NICU admission
- Only one parent of an infant could be admitted to the study.

Individuals who were eligible and wished to enroll completed written informed consents (all appropriate human subject protections were implemented under supervision by each institution's Institutional Review Board).

Procedures

Baseline. Parents were asked to complete the baseline survey immediately upon enrollment, or to return it to the on-site study staff at their earliest convenience. Upon completion of the first survey, parents received an incentive payment of $20.

Intervention. For participants at the intervention sites, the DVD program was made available for viewing privately in a quiet location in or by the NICU. Some parents chose to watch the media program at home, while others viewed it on a DVD player and TV provided by the study in a nearby quiet or family room.

Follow-up. Parents completed a second survey approximately one week after the first. Again, it was completed on-site or at home and then returned to study staff. Because parent visiting and research staff schedules were highly variable staff did not pressure participants for timely completion of surveys; instead, completion times were recorded in the surveys to permit analysis for potential time bias. Upon completion of the second survey, parents received incentive payments of $20 (for early enrollees who were asked to complete a total of three surveys) or $30 (for those completing only the first two surveys). At the expiration of the recruitment period, 20 parents had completed a 3-month follow-up survey.

Measures

Instrument Development. The survey instrument was developed specifically for use in this study. Researchers articulated five domains of outcomes, generated measurement items for each. Eight experts rated the suitability of each item ("Poor," "Fair," "Good," or "Excellent"), suggested wording changes to

improved clarity and consistency without raising the reading level, additional questions, and reversing valence of some true/false items to improve the distribution.

Thirty-six clinical staff at a NICU not in the study anonymously tested the survey. The level of item non-response was low and acceptable. Three true-false questions had even distributions of responses, so the language was clarified to avoid possible confusion or misinterpretation. With a mean of 2.5 incorrect true/false responses per individual and median and mode of 2 incorrect, these questions appeared to be at the correct level of difficulty. Because ten of the thirty-six test respondents s answered all 8 Likert questions the same, the valences of two questions were reversed in the hope of prompting future respondents to think about and answer these questions individually.

Table 1 sets forth outcome domains and items that were included in the survey that was administered at all three time points:

Table 1. Outcome Domains, Scales, Sample Items, and Number of Items

Outcome Domain	Scale	Sample Item	Number of Items
1. Knowledge of fetal & neonatal brain development	T/F	A preterm infant's brain develops most rapidly when s/he is sleeping.	8
2. Knowledge of a premature infant's expressions, behaviors and needs.	T/F	Normally, a preterm infant will spend as much time awake as asleep.	12
3. How to care for preterm infants.	T/F	Preterm infants often find skin-to-skin contact (for example, between the infant's cheek and its mother's bare breast) to be comforting.	21
4. Confidence in applying developmentally supportive care concepts.	T/F	I am good at helping my infant avoid stress.	9
5. Parental stress.(experience & amount)*	5-point Likert-type scale	[How stressful is:] Not being able to hold my baby when I want.	10

* Cronbach's alpha = .75

Demographic characteristics and contact information were collected as part of the baseline survey only.

Knowledge was assessed in total and across three specific domains. Answers on the True/False tests were scored using a sum of points, with one point awarded for each correct answer, zero points for blanks, and minus one point for each incorrect answer. Each parent's change in knowledge score from baseline to follow-up was calculated.

Confidence in applying DSC concepts was assessed in a single domain. Scores were based upon one point for each item where the respondent expressed confidence (T) and no points where respondent did not confirm confidence (F or missing). Changes in confidence scores from baseline to follow-up were calculated.

Stress was assessed using the 10-item *NICU Parental Role Alteration Stress Scale.* This is a targeted sub-scale of the original 34-item Parental Stressor Scale (Miles, Funk & Carlson 1993). Due to experts' concern that the initial questions to parents about parental experiences would, in themselves, trigger stress, evaluators opted instead to use only a psychometrically validated instrument (described later) for measuring parental stress. It measures parental stress as a single domain; questions use a Likert-type scale. Changes in stress scores from baseline to follow-up were calculated.

Optional user feedback. The short-term follow-up survey included a 1-page "Optional Viewer Evaluation" to elicit users' reactions to the DVD. Seven questions inquired about the usefulness of the

information, its relevance, level of organization, level of complexity, overall quality, length, and whether the user would recommend it to others.

Analyses

Except as specified, our analyses focused on the 107 parents who responded to both the baseline and the short-term follow-up surveys. Responses to the optional user feedback questions were compiled for review but not used in the quantitative analyses.

Preliminary analyses. As a check on randomization, bivariate analyses (chi-square and t-tests) were used to check for significant differences in demographic characteristics between the control and intervention groups, and for differences in baseline outcomes**,** both overall and by domain (knowledge, confidence, or stress).

Data were analyzed for potential time bias, i.e., differences in baseline outcomes attributable to the date each survey was completed. Correlations between date and outcomes were examined first overall and then separately by group (control and intervention).

Next, to check for potential consequences of attrition, and for bias of model estimates, participant characteristics and baseline outcomes were compared between dropouts and completing participants.

Bivariate analyses. T-Tests were performed to determine the apparent effect of the intervention without accounting for other factors. These t-tests used either a pooled standard error or the Satterthwaite method depending on results of a Folded F test of equivalence of variance. In each t-test, the null was tested against a one-sided alternative of greater improvement in the treatment group, using alpha=.05 to assess the level of significance.

Multivariate analyses. Multivariate analyses, which adjust for other possible explanatory variables, provide fairer estimates of the effects of intervention and represent the principal results of the study. Multivariate analyses consisted of modeling outcomes in three domains knowledge, confidence, and stress under two specifications: using main effects only, and including selected demographic covariates and their interactions with the experimental variable. Covariates were selected because the underlying characteristic was significant in several of the main effect models. The interaction models, which employ close to the maximum number of independent variables, are best construed as sensitivity tests of the main effects model to indicate how much the estimate of treatment is influenced by model specification. Selection of the characteristics to interact with the treatment effect was based on demonstrated significance in main effect models.

Longitudinal repeated measure models were also constructed to examine the effects of the treatment over time, from baseline to short-term follow-up, and from baseline to longer-term (3-month) follow-up. The specification of the model included a treatment indicator, two time indicators (for follow-ups), and two "treatment by time" interactions. The treatment indicator adjusts for baseline differences between the treatment and comparison groups, the two time indicators adjust for temporal differences occurring simultaneously to both groups, and the coefficients of the two interactions represent the effects of treatment at the two respective times.

Few parents completed the longer-term follow-up survey. Because of the need to include additional time and interaction variables in the longitudinal model, the demographic variables were omitted. Given the relatively small sample size, and the variability of the variables representing difference between the baseline and long-term follow-up survey responses, the power to detect significant estimates in these models would be limited to identifying large effects..

RESULTS

Participants

Overall, 68% of parents approached agreed to participate in the study. A higher rate would be preferred, but this is a common response rate for a general population. Table 2 provides demographic characteristics

of the study participants. The study design of randomizing at the level of the site resulted in two study groups that were well balanced on measured demographic characteristics.

Table 2. Participant Characteristics (n=107)

Characteristic	n	Percent
Condition		
Control	61	57.0
Intervention	46	43.0
Sex		
Male	12	11.2
Female	95	88.8
Single Parent		
Yes	25	23.4
No	82	76.6
Race/Ethnicity		
Hispanic / Latino	19	17.8
Black / African American	11	10.3
Asian	0	0
White	77	72.0
Age		
15-19	4	3.8
20-24	16	15.2
25-29	26	24.8
30-39	49	46.7
40-49	10	8.6
50-59	0	0
60-69	0	0
Income		
$10,000/year or less	36	34
$10,001 – $30,000/year	44	41
Over $30,000/year	27	25
Education		
Less than HS	11	12.2
HS Grad (or equivalent)	94	87.9

Note: Percentiles may not total to 100% due to rounding errors.

Preliminary Analyses

No significant differences in demographic characteristics were found between the control and intervention groups. Parents in the control group completed the survey, on average, a month later (mean difference = 34. 4 days) than parents in the intervention group. Since no evidence was found of correlation between test date and any of the baseline scores (knowledge, confidence, or stress), this should have no significant effect on the outcomes. Furthermore, differential attrition between study groups did not demonstrate any

negative consequences. Compared with completing participants, the group of dropouts did not have significantly different baseline scores, overall or within domain. In addition, the multivariate models including additional demographic characteristics did not point to any significant association. These results indicate that those who completed the study adequately resembled all parents originally enrolled in the study.

The difference in attrition rate between treatment enrollees and controls was small (e.g., 10.3% and 8.0%, respectively, at short-term follow-up). Regression analyses modeling baseline scores as a function of treatment/control status, dropout status, and their interaction found no significant association between the treatment/attrition interaction and the baseline score, overall or in any domain.

Effects of Program

Bivariate Comparisons of Intervention and Control Groups

Preliminary bivariate analyses indicated significant group differences in the hypothesized direction in three of the domains (Table 3): Parents in the treatment group exhibited greater improvement than parents in the control group in knowledge of fetal and neonatal development ($p<.001$), confidence in applying DSC concepts ($p<.001$), and lowering stress ($p<.05$).

Table 3. Group Differences in Change Scores

Outcome	Mean Change[1]		t	P (<t)
	Intervention Site	Control Site		
Knowledge (three domains combined)	4.43	2.92	1.41	0.08
1. Knowledge of fetal and neonatal brain development	**2.11**	**.59**	**3.57**	**0.0003**
2. Knowledge of premature infant's expressions, behaviors and needs	.56	1.13	-0.79	0.78
3. Knowledge of how to care for preterm infants	1.63	1.13	0.86	0.20
Confidence in applying DSC concepts	**1.54**	**.53**	**3.28**	**0.0008**
Stress	**.17**	**-.12**	**1.91**	**0.03**

Note: Percentiles may not total to 100% due to rounding errors.

[1] positive indicates improvement

For the overall knowledge score the group difference was not significant, but it did indicate a trend ($p<.10$). Intervention effects on the other two knowledge domains were not significant.

These bivariate analyses indicate a likely significant intervention effect; however, multivariate analyses adjusting for other possible explanatory variables will provide more accurate, adjusted estimates of intervention effects.

Multivariate Analyses

Main Effects Models. The main effects models, with demographic characteristics included as covariates (Table 4), affirm the findings of the bivariate analyses. Treatment had a statistically significant effect on scores for the domain involving knowledge of fetal and neonatal development ($p=.003$), increasing treatment respondents' knowledge by 1.22 points (.61 questions) more than

controls. This domain demonstrates the greatest difference in improvement – in the hypothesized direction – between the treatment and control sites.

Treatment also showed a statistically significant effect on parents' confidence in applying DSC concepts. Treatment subjects improved their positive responses to this domain's questions (assertions of confidence) by about 1.04 questions more than control subjects (p<.001).

Finally, in the stress domain, treatment subjects reduced their average stress response by .32 more than control subjects (p=.025). The entire sample actually had no net change in stress response. That is, while the intervention parents' stress was reduced, the control parents' stress actually increased to a similar degree.

For **While stress levels decreased over three months for parents who received the DVD intervention, stress levels increased for parents in the control group.**

overall knowledge combining all three domains, group differences were not statistically significant. Treatment effects on other individual knowledge domains were not significant.

Interaction Models. Estimates of treatment impact in these models, which include interaction terms for males and for subjects under 21 years of age (not displayed), are similar to estimates of treatment in the main effect models. This confirms that results are robust against a small change in model specification.

Longitudinal Models Examining Persistence

By the time of the 3-month follow-up (Table 5), the treatment group's differential improvement in knowledge of fetal and neonatal brain development was no longer significant. Overall, the difference in knowledge between groups was about 1/3 of what it was immediately post-intervention.

Table 4. Effect of Program, Controlling for Covariates

Outcome	Effect	t	P (>|t|)
Knowledge (three domains combined)	0.88	.86	0.39
1. Knowledge of fetal and neonatal brain development	**1.22**	**3.05**	**0.003**
2. Knowledge of premature infants' expressions, behaviors and needs	-1.10	-1.56	0.12
3. Knowledge of how to care for preterm infants	0.56	.97	0.34
Confidence in applying DSC concepts	**1.04**	**3.41**	**0.001**
Stress	**0.32**	**2.28**	**0.03**

Improvement in parent's confidence post-intervention was significant at immediate follow-up (change=.95, one-sided p<.001), and fell back only slightly at 3-month follow-up (change=.82, one-sided p=.04). Given that confidence scores represent the number of questions for which the parent can confirm adequate confidence, a difference of .95 (or .82) reflects an average increase of almost one more positive response among the treatment group. No significant group difference in parental stress score was detected in this model, either at short-term or longer-term follow-up.

Table 5. Effect of Program in Longitudinal Models (Interaction of Timex Treatment)

	Immediate (1 week) Follow-Up			Long-Term (3-month) Follow-Up		
Outcome	**Effect**	**t**	**P (>|t|)**	**Effect**	**t**	**P (>|t|)**
Knowledge (three domains combined)	1.64	-1.56	0.12	0.55	-0.33	0.74
1. Knowledge of fetal & neonatal brain development	**1.50**	**-3.53**	**0.001**	0.80	-1.18	0.24
2. Knowledge of premature infants' expressions, behaviors and needs	-0.47	0.68	0.50	-0.05	0.05	0.96
3. Knowledge of how to care for preterm infants	0.61	-0.99	0.32	-0.34	0.34	0.73
Confidence in applying DSC concepts	**0.95**	**-3.17**	**0.002**	**0.82**	**-1.76**	**0.08**
Stress	0.26	-1.85	0.07	-0.11	0.48	0.63

Optional User Feedback

The program was assessed favorably by the 44 parents who rated it (Table 6). All would recommend it to other parents of infants in NICU. The percent who rated the usefulness, relevance, organization, clarity and quality as "good" or "excellent" ranged from 88% to 96%.

Table 6. Responses to Optional User Evaluation Questions (n=44)

Item	**Percent giving Rating**				
Please rate the program on the following traits:	**Poor**	**Fair**	**Average**	**Good**	**Excellent**
Usefulness of information	0	2	2	48	48
Relevance to what I'm going through	0	5	7	44	44
Organization of information	0	0	7	49	44
Level of understanding / complexity	0	0	5	50	46
Overall quality of the program	0	0	7	41	52
	Too long	**Too short**	**The right length**		
The program was…	0	5	95		
	Yes	**No**			
Would you recommend this program for use by other NICU parents?	100	0			

DISCUSSION

Clearly the DVD program had a significant effect in improving parents' knowledge of fetal and neonatal brain development, and reducing parents' levels of stress and increasing confidence in applying the

concepts of developmentally supportive care (DSC). Moreover, these findings were robust, in that treatment effects were not limited to a single domain, and were similar across multiple variations of the multivariate model. It is particularly noteworthy that while parents in the intervention group experienced a decrease in stress, parents in the control group showed a nearly equivalent increase in stress. That is, not only was the intervention successful at decreasing intervention parents' stress (among other things), but also, absent the intervention, stress can be expected to grow during the first weeks of parents' NICU experience. The dissipation of treatment effects after three months is difficult to interpret, as this may be attributable to the small sample size for the longer-term follow-up survey.

The DVD offers an effective, standardized, cost-effective tool for improving parents' knowledge of newborn brain development, and their confidence in implementing developmentally supportive care.

Apart from the intervention's effectiveness, it is noteworthy that NICUs are very specialized environments rife with life-and-death pressures and a host of social, medical, financial, and organizational factors at play. Although the quasi-experimental aspect of the design was added to counterbalance limitations of randomizing only four sites, these other factors each had the potential to confound the study findings or frustrate its conclusions – thus, these results are all the more remarkable. The DVD program for parents will be a useful tool in today's health care environment where dollars for patient education and support are always under pressure – particularly as a self-administered tool because the DVD program can be repeated or reviewed non-sequentially, and at the parent's convenience.

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