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Abstract: Abstract
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Objective: The purpose of this pilot study was to determine feasibility and design for the development of a larger multi-centered study.
Results: Study findings were used to: estimate effect size; determine staff and bed side care organization; to evaluate feasibility of data collection measures; and issues related to recruitment and follow-up. Results were incorporated in the development of a larger multi-centered trial grant proposal.
Discussion: Pilot studies can play an important role in the development of a competitive grant proposal and efficient conduct of a research trial. This article will provide an overview of the study design with emphasis on the implications of study findings for the development of a larger multi-site trial.
Key Words: Co-bedding, co-regulation, parental self-efficacy, feasibility study

Check List for Initial Revision (Journal Office use Only)

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*** Title Page & Acknowledgements**

Co-bedding twins: Utilization of Pilot findings to Improve Funding Success

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Celeste Johnston for her ongoing mentorship through out development of this pilot study and the larger multi-site trial.

Abstract

Background: Co-bedding, a developmental care practice for twins and multiples, has been theorized as a strategy to decrease the adverse neurodevelopmental effects that may be associated with hospitalization.

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Discussion: Pilot studies can play an important role in the development of a competitive grant proposal and efficient conduct of a research trial. This article will provide an overview of the study design with emphasis on the implications of study findings for the development of a larger multi-site trial.

Co-bedding twins: Utilization of Pilot findings to Improve Funding Success

Introduction

Approximately 50% of twins and 90% of triplets are born prematurely, often facing medical and developmental challenges. Co-bedding of twins and multiples is a developmental initiative. Its purpose is to minimize neurodevelopmental sequelae (Lutes & Altimier, 2001). Co-bedding is believed to enhance twin co-regulation, improve respiratory status, decrease oxygen requirements, increase weight gain, and facilitate mutuality in their circadian rhythms and sleep/awake patterns (Fowler-Byers, Yoviaish, Lowman, & Francis, 2003; Hayward, 2003; Lutes & Altimier, 2001; Nyquist & Lutes, 1998). In 1998, Nyquist and Lutes proposed that the synactive theory of development (Als, 1986) could provide an explanatory model for understanding how co-bedding may assist preterm twins in coping with the extrauterine environment. . Maintaining continued physical contact by swaddling twins in the same blanket, and boundary, provides them with the opportunity to co-regulate and to continue to progress in their unique interactive development (Fowler,-Byers et al. 2003; Hayward, 2003; Lutes & Altimier, 2001; Nyquist & Lutes, 1998).Despite the theorized benefits, due to a paucity of research on the practice of cobedding, neonatal care providers do not have adequate information to make evidence based policy decisions.

Importance of pilot studies

The purpose of this pilot study was to determine feasibility of study design, methods, and the measurement of desired outcomes for the development of a larger multi-centered study to examine the effects of co-bedding on twins and their parents. Polit, Beck and Hungler (2001, p 467) define a pilot study as, “a small scale version, or trial run, done in preparation for a major study.” A pilot study provides an opportunity for the researcher to obtain valuable information related to the actual conduct of the trial and to assess the adequacy of the data collection plan (Polit & Hungler, 1999). It is not unusual for problems to arise in the course of a project which result in a delay in the study while changes are made to the research

design. In quantitatively designed studies, data collected prior to implementation of any major alterations in the protocol often has to be discarded from the final analysis (Polit et al. 2001). “A pilot study is critical in determining the feasibility of subject enrollment, the intervention, the protocol or data collection plan for the study, and the likelihood that subjects will complete follow-up measures” (Melnyk & Fineout-Overholdt, 2005, p266). In a pilot study the basic mechanics of the trial can be assessed for their ease of administration within the clinical environment.

Properly conducted randomized control trials can be quite lengthy and expensive. Funding agencies generally include feasibility as part of their scoring template prior to the allocation of any funding. Scores reflect the agency’s level of assurance that the study can be completed in the proposed timeframe and that all conditions ensuring minimal loss of data has been addressed (Lancaster, Dodd, & Williamson, 2004). A pilot study strengthens a proposal by providing: essential baseline information related to the development and justification of the trial; data to determine an appropriate power analysis; and, an opportunity to carry out a dry run of the study to work out any kinks in the proposal (Lancaster et al 2004). “A well-conducted pilot study, giving a clear list of aims and objectives within a formal framework will encourage methodological rigor, ensure that the work is scientifically valid and publishable, and will lead to higher quality RCT’s” (Lancaster et al. 2004, p 307). A high quality clinical trial proposal increases the likelihood of success from funding agencies.

The design of a pilot project does not negate the need for scientific rigor or ethical protocol. Adherence to research standards is just as important in a pilot study as it is in a larger trial. Maintaining accuracy within a pilot project ensures the likelihood that any weaknesses/inadequacies intrinsic to the proposed larger trial will be uncovered (Polit & Hungler, 1999). Within a pilot project, subjects should be representative of the proposed population for the larger trial. This will provide the researchers the ability to

assess the acceptability of the trial to potential research subjects (Wittes & Brittain, 1990). Furthermore, ethical approval and informed consent is required for any research involving human subjects.

Pilot Project – Methods

Design

A randomized control design was utilized in this pilot study to compare parental self-efficacy, parental anxiety, infant co-regulation and physiological measures of the infants (heart rate, respirations, temperature, oxygen saturation) when twins are co-bedded (cared for in the same incubator) versus standard care (cared for in separate incubators). Twins were randomized into two groups. Stratification of eligible twins less than 2000 grams and greater than and equal to 2000 grams was the initial plan for the larger study. Given the increased risks associated with the lower weight group, enrolment was limited to twins weighing less than 2000 grams. This ensured that all safety issues for the smaller infants at the greatest risk would be addressed. Dyads in the experimental group were placed in a common twin (Giraffe ™) incubator for care. Twins in the control group received standard neonatal care in separate incubators. To decrease possible bias related to nursing care practices, twin dyads, regardless of group allocation, were each assigned to be cared for by the same nurse.

Sample

Sample size was time specific as opposed to number specific. The study took place over a three-month span of time and recruited eligible sets of twins being cared for in a tertiary level neonatal intensive care unit. It was anticipated that 6-12 twin dyads would meet inclusion criteria. Following ethical approval, parents of twins who met the inclusion criteria (<2000g, stable as defined as no endotracheal tubes, no umbilical lines, no symptoms of sepsis, and no chest tubes) were approached by a research assistant. The study was explained and consent was obtained for participation. Group allocation was randomly assigned

using opaque envelopes. During the study period eight sets of twins were admitted to the neonatal intensive care and met the study inclusion criteria. Six families were recruited.

The purpose of the pilot study is to examine the effects of co-bedding on parental self-efficacy. The primary hypothesis states that co-bedding has a positive effect on parental self-efficacy. The secondary hypothesis addresses possible differences between groups with relation to infant co-regulatory behavior, parental anxiety, incidents of infection, frequency of caregiver errors, and physiological measures of the infants (heart rate, respirations, temperature, oxygen saturation). When completing a pilot study it is important to have clearly identified outcome measures, with reliable methods of measurement for each outcome.

Data Collection

Parents were given the Infant Care Survey (ICS) (Froman & Owen, 1989; 1990) and the Spielberger State-Trait-Anxiety Inventory (STAI) (Speilberger, Gorsuch, Lushene, Vagg, & Jacobbs, 1983) to complete upon entry to the study, before discharge and at one month post discharge. The ICS was developed by Froman and Owen (1989) and has been shown to have reliability (alpha internal consistency 0.975) and validity (multiple regression analysis F = 9.069, $p<0.001$, $df = 5,136$) for measurement of self-efficacy in maternal knowledge and skills related to infant care**.** The STAI is a proven tool (Chronbach's alpha 0.93 for State and 0.92 for Trait) for measuring anxiety and has been used extensively in research and clinical practice (Speilberger et al, 1983). The tool has demonstrated high test-retest reliability with a Pearson coefficient of 0.96 for the State subscale and 0.98 for Trait subscale (Speilberger et al, 1983).

A minimum of eight, five-hour Nursing Child Assessment Sleep/Activity Records (NCASAR) were completed by the research assistant on each set of twins, on a bi-weekly basis (Barnard, 1999). All activities, i.e. feedings, blood work, x-rays, etc. and the infant's state were tracked on the form. The NCASAR's for each dyad was compared for synchrony of activity (co-regulatory behavior) by looking at

infant state, heart rate, temperature, respirations, and oxygen saturation. Inter-rater reliability was assessed by having both the research assistant and a certified NCAST provider assess the infant state simultaneously for the first two five-hour observation periods. Inter-rater reliability was scored using Cronbach alpha at 0.98.

The research assistant, using ongoing chart review, collected data on heart rate, respirations, temperature, oxygen saturation, infection rates, care giver error, infant feeding, and infant demographics using two separate data collection tools developed for this study. Infection rate was determined by three separate measures; incidence of septic work-up, treatment with antibiotics, and actual confirmed incidence of sepsis. Caregiver errors were collected from readily available quarterly reports. All data collected was kept confidential and individual identities were protected throughout the analysis process.

Staff and Bedside Issues

The clinical application of any research protocol is paramount to its success. Plans for the set up of the site had to be organized ahead of time and well thought out. A single twin incubator was set up between two infant care sites. The Giraffe™ incubator (GE Medical, Ohmeda Products) has a large mattress surface and permits access from both sides. To facilitate safety, each twin and their equipment were assigned a side of the incubator and a specific color code. All cables, and tubing for each infant exited on their assigned side. Color-coding decreased the risk of treatment errors and cross contamination from shared equipment (i.e. soother, temperature probe, etc.) by providing an easily distinguishable marker for infant identification. A second incubator was readily available for separation of the twins if necessary.

Implications for Larger Multi-site Trial

Through the provision of information for the planning and justification of randomized controlled trials, pilot studies play a key role in health research (Anderson & Prentice, 1999). Findings from this pilot study proved to be essential in the development of a larger research proposal. Alterations to the methods

sections, sources of potential bias, data collection and recruitment and follow-up were incorporated into the design of a larger multi-site trial which was successful in receiving provincial funding.

Rationale for revised protocol

Revisions to Methods

Sample

The pilot study was a 3-month time specific study. Based on co-regulatory data collected in the pilot study (specifically, time spent in quiet sleep), the population effect was set at 0.05. For the multi-site trial significance was set at 0.05 and power was set at 0.80, resulting in a sample size of 152 sets of twins (76 sets co-bedding and 76 sets receiving standard care). As the effect size was based on co-regulatory data, the primary hypothesis in the multi-site trial was changed to 'co-bedding twins will increase twin co-regulatory behavior.'

Inclusion criteria for the pilot study was based on weight (< or = 2000g). Weight was initially believed to be an important factor as it generally directed whether infants would be cared for in incubators or open cribs. Standard unit practice transition infants to cribs upon reaching 2000g. It is believed that an infant's ability to alter state and physiological status is correlated more closely to gestational age and maturation than infant weight (Anders, Keener, & Kraemer, 1985; Holditch-Davis, Scher, Schwatz, & Hudson-Barr, 2004). Co-regulation is defined as newborn twins' activities for supporting one another in the physiologic transition to postnatal life and in the achievement of stable sleep/awake states through activities mediated by physical contact (Als, H., 1986). With the change in our primary hypothesis, it was believed that the inclusion criteria should reflect gestational age as opposed to infant weight**.** Therefore in the larger study, infants will be stratified by gestational age (<31 6/7 weeks or $\geq$32 weeks) and site location.

Exclusion criteria for the pilot study included a weight less than 1000grams, ventilatory assistance, sepsis, chest tubes, umbilical lines, and congenital anomalies. When one twin of a set was placed on

phototherapy, questions related to the unnecessary treatment for the second twin arose. Given that a moderate level of unconjugated bilirubin is not considered to be harmful and given that the antioxidant properties of bilirubin may actually provide some protective qualities, it was determined that "current treatment with phototherapy" be added as an exclusion criteria for the larger study.

Protecting against possible bias

The research assistant's awareness of the randomization allocation provided the opportunity for bias. In order to eliminate any potential bias related to randomization, a 24-hour accessible computer generated randomization site will be utilized for the larger study. The larger study was also strengthened by blinding the data collection procedure. This was accomplished by using video-taped data collection for infant state, and continuous recording using Somte™ sleep screen for collection of physiological parameters. One research nurse will approach the parents to introduce the study, obtain consent, and film the infants for coding. Two separate research assistants, blinded off-site, and who would not have access to the unit or familiarity with the study, will code either the study group or the control group for infant state.

Data collection

As baseline data was collected after randomization, it was believed that knowledge of randomization allocation may have affected the results of the questionnaires and, although the data was collected on the twins within 24 hours, there appeared to be a possible effect on their states. It was determined that baseline data needed to be collected on all twins and parents prior to randomization.

At the time of data entry, it was determined that a portion of the data was redundant. The data collection procedure was simplified for the larger study. Eight 5-hour data collection periods, were reduced to three 3-hour data collection sets on study days one, three, and seven. Data was analyzed using repeated measure ANOVA and Pearson's *r.* This remained unchanged for the larger study.

Recruitment and follow-up

The pilot study yielded a poor parental questionnaire response, 100% completion of questionnaires at enrolment, 37.5% at discharge, and 0% at one month. This low-level rate of return is believed to be due to the busy schedule of parents of multiples (Holditch-Davis et al. 1999). Follow-up is important to determine infant sleep practices after discharge and to assess the impact of sleep decisions on parental self-efficacy and stress. As a result, the budget was adjusted to include a small compensation to be mailed with the final questionnaires. In addition, the research nurse will conduct a one month discharge phone interview to complete questionnaires and to assess current infant sleep arrangements. A community partnership was established with POMBA, the Parents of Multiple Birth Association. It is believed that this collaboration would promote awareness of the study prior to birth and encourage ownership of the study by the study participants, which will hopefully encourage completion of the questionnaires. Including key stake holders was anticipated to improve follow-up as well as dissemination of findings.

Determining the recruitment rate is an important aspect of the pilot study as it permits the researchers to accurately assess an enrollment rate for the larger study and to determine yearly budget breakdown when applying for funding (Lancaster et al 2004). The pilot study had a 70% recruitment rate. Based on this rate, the multi-site trial is anticipated to take two and a half years to complete data collection.

Anticipated outcomes and significance

This pilot study was developed to assess the feasibility of conducting a multi-centre trial examining parental self-efficacy, parental stress, infant co-regulation, infant safety, and infant stress to compare sets of twins who are randomly assigned to an experimental group who are co-bedding and to a control group of twins who are receiving standard care. The pilot assessed the use of the three chosen data collection techniques for examining the relationship between these variables. The information obtained during this pilot was used to develop a proposal that was successful in securing external grant support for a larger multi-site trial. This paper demonstrates

the considerable benefits of conducting a pilot study prior to developing a proposal for a larger multi-site trial. Information derived from pilot studies can determine feasibility, strengthen project design, improve funding success and ultimately enhance the outcomes of a larger study. The authors hope that other researchers will recognize the important role pilot studies play in health research and consider the use of a pilot study in preparation for larger trials.

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Co-bedding twins receiving phototherapy in incubator

Co-bedding twins in crib

Co-bedding site using twin Giraffe™ incubator

Table

Variable	Study Group	Mean	SD	SE Mean	Minimum	Maximum
Quiet sleep	Co-bedding care	5.357	2.33	0.359	1.000	12.000
	Standard care	0.780	1.27	0.199	0.000	4.000
Crying	Co-bedding care	5.341	2.352	0.367	1.000	12.000
	Standard care	0.1944	0.4672	0.078	0.000	2.000
Co-regulated	Co-bedding care	14.895	3.315	0.760	10.000	20.000
	Standard care	13.941	2.045	0.496	9.000	19.000

July 4, 2006

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Dear Ms Dougherty:

Please accept my manuscript 'Co-bedding twins: Utilization of Pilot findings to Improve Funding Success' f'or your perusal. The authors include the following: Kathryn Hayward, RN, BScN, IBCLC, Marsha Campbell-Yeo, RN, NNP, Sheri Price, RN, MN, Della Morrison, RN, NNP, Robin Whyte, MB, Heather Cake, MA, and Jocelyn Vine, RN, MN. There are no conflicts of interest for any of the above stated authors.

Ethical approval for the pilot study and for the larger multi-site trial was obtained through the Research Ethics Board at the IWK Health Centre. Ethical approval will be obtained from the Research Ethics Board for the St. John's Health Care corporation prior to data collection at the second site.

We look forward to hearing back from you in the near future.

Yours truly

Kathryn Hayward