

Jun 18, 2007

RE: NRES-D-07-00065, entitled "Maternal Anxiety and Depression Following a Premature Infants' Discharge from the NICU: An Integrative Model of the COPE Program"

Dear Dr. Melnyk,

Recently you sent your manuscript for consideration by Nursing Research. The review of your manuscript is complete and the comments of the reviewers are listed below along with a checklist for style. You may revise your manuscript based on the reviews and resubmit the manuscript to Nursing Research for further consideration. I will verify that this has been done upon receipt of the revised manuscript.

Please include with your revised submission an itemized, point-by-point response to the comments of the reviewers. The revisions should be completed by Sep 16, 2007 to avoid being considered as a new submission.

To submit a revision, go to <http://nres.edmgr.com/> and log in as an Author. You will see a menu item called "Submission Needing Revision." Please click on this item to obtain your submission record and begin the revision process.

With Kind Regards,

Molly C. Dougherty, PhD, RN, FAAN
Editor
Nursing Research

Reviewer Comments:

Reviewer #1: This paper provides an important analysis exploring the processes underlying the impact of an intervention with mothers of low-birth-weight preterm infants. Data from a previously published and effective intervention are used for this secondary analysis. While, the overall purpose and much of the methodology are sound, there are a number of needs for revision and some questions that need to be addressed.

The introduction to the paper need strengthened. The logic and rationale for the study is not clear prior to the purpose statement. The focus needs to be made on the need to understand processes through which interventions work (eg., page 4, line 15 to 20 plus more). The second paragraph focused on "one iatrogenic effect of preterm birth" appears out of context before the reader has a full understanding of the study. Therefore, it is not clear why this paragraph is mentioned. Furthermore, the support (research) for this aspect of the model is not strong. Given the weak evidence for premature infant stereotyping, calling it an iatrogenic effect seems strong. This section should be imbedded in the later section describing the framework for the study.

The purpose sentence is too long, making the reader have to reread it several times. The section in this sentence about the original study should be pulled out and made into the second sentence.

The inclusion of extensive data on infant outcomes for the intervention does not seem relevant to this article (p. 4, line 8 to 14).

The theoretical framework guides the reader in understanding the original intervention. It would make the purpose and data analysis clearer if the last paragraph tied the framework to the hypotheses being tested for THIS paper, that is, those related to understanding the processes underlying the intervention. As written, it is not clear whether the hypotheses listed are for the original paper analyzing outcomes or for this paper exploring processes. Much of this is found later in the Formulation of the Integrative Model on page 11-12.

Under "Methods," drop the subheading "Design" and just describe the design. A brief description of the design is needed (not just that it is a secondary analysis).

The sample size is wonderful. Congratulations on collecting data on such a rich sample of mothers.

The description of the maternal participants could be greatly shortened. Refer to the table and point out key differences between the groups rather than repeating the table. Some aspects of the table might also be shortened (ie., categories of marital status, yearly income, educational level). A table depicting the characteristics of the infant might also be used with the narrative simply summarizing key issues or differences.

In the organization of the methods, it would be more appropriate to describe the "Intervention"

prior to presenting the "Measures". Likewise, the "Procedures" section should follow the intervention and measures section (before data analysis) and needs to include IRB approval (found on p. 6, line 20), recruitment, consent procedures (I couldn't find mention of this), data collection patterns (now on p. 8, line 7 to 14) were included.

The section on measures needs to be organized conceptually with an introduction that briefly describes the constructs for the study (ie., maternal distress measures, maternal belief measure, and mother-infant interaction measures plus demographics and medical record data?). The narrative then should be organized in this same order. Brief statements about the validity of measures are needed. This is especially important for the Index of Parental Behavior in the NICU which is a new tool and a rating instrument. Rating instruments for measuring maternal-infant behavior have limitations. In this study, one limitation that must be addressed in the discussion is the lack of data on validity (unless there is some), the short time frame for the observation, and the fact that the observations were not repeated to establish some reliability of the evaluations. The Parental Stressor Scale:NICU included in analysis the construct staff behaviors and communication which was dropped from the instrument after factor analysis. Further, it is not clear how the subscales were used in the analysis. It is likely that pathways for the parental role alteration scale would be stronger than other subscales based on new research with the scale. Validity of the Parental Belief Scale is also needed.

The findings section was clearly written. The data analysis methods need to be reviewed by a statistician. The figure for the analysis was hard to read (print size and copied lightly) and thus to follow.

It is hoped that these recommendations can help guide the revision and resubmission of this important paper. Thanks for your hard work in conceptualizing and studying interventions for mothers of preterm infants.

Reviewer #2: MS NR-D-07-00065

Maternal Anxiety and Depression following a Premature Infants' Discharge from the NICU: An Integrative Model of the COPE Program

The manuscript proposes and tests a theoretical model of an intervention to affect anxiety and depression in mothers of preterm infants. In prior studies, the COPE behavioral-education intervention has been found to be effective for parents whose children were hospitalized in the NICU and PICU. The maternal outcomes of this study are relevant given the national concern for maternal health, especially for depression and its impact on child development. Since the theoretical model proposes the processes by which interventions affect infant and parent outcomes, the findings can inform intervention approaches in specific ways for specific outcomes.

The theoretical model is based on control and self regulation theories suggesting that the event of the premature birth places parents at a disadvantage due to lack of control and information. It seems to assume that parent(s) have a certain cognitive level and capacity to learn from the COPE program information and activities. Demographically, 86% of the sample are high school graduates and all mothers were able read and write English per inclusion criteria. Since the risk for premature birth is higher for women who are socioeconomically disadvantaged, it would be helpful to address the utility of the intervention in a broader context in the discussion. Is it possible that the theoretical processes supported in this study would not be applicable for mothers who are disadvantaged?

The sample was recruited from two hospitals. Details are not provided as to the sample size from each and whether there were hospital-specific differences tested. Medical and nursing practice styles are likely to differ between institutions. How was this considered in the present study? It is not stated whether mothers of multiples (twins, triplets) were included.

While other studies of the COPE program include fathers, this study reports on mothers only. The terms are not consistent throughout the manuscript where parent and mother seems to be used interchangeably, thus clouding the report. For example, on page 6, it is hypothesized that COPE would 'strengthen parental beliefs about infants and their (whose?- mother/father/both) role,decrease maternal stress, ...'. Is the pathway of the proposed processes that COPE influences both parents, which in turn affects the mother? Or is the pathway maternal beliefs influencing maternal stress, depression and anxiety? The term 'parental beliefs' is used in the measures

section (pages 8, 10), but a limitation cited on page 19 of the Discussion was that almost all measures were completed by mothers. The relationship between maternal stress and depression and anxiety in the NICU is not clear in the theoretical description or in the model figure. Later in the manuscript on page 12, the variables of SES and maternal trait anxiety (the biggest predictor) are inserted. Though these seem logical, they do not appear to be supported in the background or theoretical framework.

There are questions about the Parental Beliefs Scale: NICU where two factors are derived. The theoretical basis of the measure and subscales is not described and few psychometrics are reported or referenced. Additional validity information would increase confidence in this mediating variable.

There are incomplete sentences and group comparison data is not clear. For example, on page 7 (paragraph 1, last sentence) no differences are reported for some demographic variables, but differences between whom/what are not described. A mean CRIB score and discharge weight are given, but not by intervention and control group. The birth weight categories describing the sample are unconventional as opposed to LBW, VLBW, ELBW. The size of the < 1000 gram group is of interest in studies of prematurity. On page 20, future research is suggested for 'important parenting variables' which are not explored or expanded in the discussion. More detail is needed for the 'manipulation checks' for the women in the control program (page 11). The structural results are well presented and follow the model in Figure 2.

There are some smaller scale concerns. Attention is needed to the correct referencing in the reference list and in the manuscript. For example, the initials in the Anthony et al reference are incorrect and Gil is misspelled on page 3. Some references are missing: Johnson & Leventhal (cited on page 4); Carver & Sheier (page 4). The Anthony et al reference concerns parents of children aged 7-14 who have chronic illness from pediatric rheumatology and pulmonary clinics. It is unclear how this reference supports the statement on page 3.

A timeline of the intervention and measurement assessments would help clarify the sequence of the study. APA style needs attention.

Reviewer #3: NRES D 07 00065

Statistical Review

This is a report of a complex model with a fairly small sample. The complexity of the model causes two difficulties: 1. the report is difficult to read and understand, and 2. the model may be unstable because the sample is too small for the number of parameters, so the results do not provide strong evidence. Some suggestions follow for revising to address both these points.

The writing and organization is generally very good. The analysis appears to have been correctly done. The tables and figures are not correctly numbered and figure legends have been omitted.

The difficulty in understanding the results of this study comes mainly from the large number of variables reported. Selecting a smaller number of variables for the model would enhance understanding of the results. One possibility to simplify the model might be to create a construct for maternal psychosocial issues in NICU and include indicators of anxiety, depression, and stress, thus reducing the number of parameters in the model. Though this is a "cruder" measure, the size of the model may be more in keeping with the sample size (and the text will be easier for the reader to understand) and later studies can sort out the exact effects of specific psychosocial issues. If authors are unwilling to test a more parsimonious model, they will have to direct considerable attention to clarifying the text so readers can understand what they are reporting, and draw some conclusions that are generally useful to people other than the designers of COPE.

Comments regarding the measurement and statistical analysis

The Chi square statistic for the full model fit has a p value of .004. This is a negative finding, as it indicates a very poor model fit. In SEM, the desired finding is a non-significant chi square (which shows there is no significant difference between the data and the model). The authors have not addressed this in their text and appear to think a significant finding indicates good model fit. This is

a serious weakness of this manuscript.

Authors should justify the sample size in terms of the large number of parameters estimated in the model (especially when the large number of non-significant paths (described in legend for figure 1, (which is not really figure 1) are included, as they must be). The sample size in relation to the complexity of the model should be acknowledged in the discussion at the very least. This is a serious weakness of this analysis, but a good rationale with citations may mitigate it if addressed well in the text.

Usually, alternative models are estimated and/or modified models are tested. If this was done, it should be reported, even if the models themselves are not presented.

In Measures section, state for each measure what a high score indicates. This was done for some measures and not for others. To clarify the constructs in the model (of which there are many), list the construct name first, then state what the measurement tool is. This will enable the reader to refer back to find the construct easily when reading the results. The two measures of mother-infant interaction are obviously highly collinear (two ratings by same observers) and they are very significantly associated in the correlation table. This should be acknowledged in the text, or the construct should be measured with just one indicator. It is not necessary to repeat the income categories that are readily apparent in the demographic table, nor any of the other demographic descriptions.

On page 11, text states that there are three exogenous variables. They are not named here (and they should be), but are named on next page. These variables should be shown in the conceptual model figure as well.

The full table of parameter measurements for the measurement model is unusual. These are not usually presented in full. However, it is acceptable to include them.

Page 15 of text repeats the results presented in Figure (2 (or 3 if correctly numbered)). The text does not need to repeat the parameters shown in the figure. Eliminate all text that does this. Parameters can be presented in a table if authors feel they want more clarity of presentation (see APA style book).

In analysis section, provide a brief rationale for the selection of the fit indices for this study, from among the many available.

Discussion. The discussion in regards to interpretation of the model is weak. There are so many variables, that it is difficult to obtain a take-home message from this. Authors should clearly state why it is helpful to know that COPE works through beliefs and anxiety. Perhaps there are other applications for COPE with other populations, or perhaps certain program components could be dropped if they don't aid these processes, or some such value to knowing how COPE works.

The conclusion that COPE works through parental beliefs and then through reduction in anxiety to finally affect anxiety later needs to be more clearly argued, in terms of statistical analysis. There are both direct and indirect effects of multiple variables in this model and the authors have not differentiated the effects of the preceding variables. For example, the fact that maternal distress in NICU is related to maternal distress after NICU is so intuitive that it seems logical that that parameter would be strong, which it is. Thus the fact that COPE affects parental beliefs and parental beliefs affect distress in the NICU does not mean that COPE is part of the direct effect of distress in the NICU and distress after. It may be that the relationship is entirely due to distress earlier and distress later. One way to clarify this is by calculating the total direct and indirect total effects of COPE on the final outcome variable, as compared to the total direct and indirect effects of other variables, such as parental beliefs and anxiety in NICU. Another is by showing a preliminary model in which all variables are exogenous and then showing how the parameters and fit indices improve when mediation models are tried. For example, if the path coefficient from anxiety in the NICU to anxiety after NICU is similar when the former is an exogenous variable as when it is in full mediation model, then it is difficult to make the argument that COPE is accounting for any variance in that path in the full model.

Comments regarding clarity of the text of the manuscript

The tables in the text are misnumbered and do not match the actual numbers of the tables.

The figures are misnumbered and only one figure legend was provided (that legend states that it is for figure 1, but figure 1 is labelled as the CONSORT flow chart)

Title: Use CONSORT guidelines to write the entire text. Title should state :A randomized controlled trial", as per those guidelines

Abstract: Background sentence is too vague. Revise with a sentence that addresses the background for this particular study

In Tables, the name of the variables and the name of the measures are mixed in the presentation of results in tables. It would help the reader if the variables are always called by the same name and the variable name is presented in the tables (an alternative is to call all variables by the measure name, but it should be one or the other, so all variables are consistently named in all tables, and within tables). For example, the parent interaction variable is called IPBNM7T and INTACT1M. The reader does not know what these mean without intense searching in the measures section, and even there the measures are not called by this name.

Statements such as "Thus, the COPE intervention appears to prevent later anxiety..." (page 14, last line) belong in the discussion, not results.

CHECKLIST FOR STYLE

Title Page

Please include the title page with the manuscript file.

Abstract

Only 2-3 keywords are required - please delete four.

Text

Reduce # of pages (i.e. 14-16 pages , regular article)- there are currently 18 text pages.

References

Reduce number of references to 40 - there are presently 55 references.

For 6 or more authors, use only the first author's name with et al. (e.g., Melnyk...).

Add in-text citations of the following references to the reference list:

Melnyk (2001); Melnyk & Finecount... (2005).

Update "in press" references (ie, Melnyk).

Misc. --

Check spelling for Bierman or Behrman?

Check publication date for Lorion ref/cit.

The following references are not cited in the text. Remove from reference list or add to text:

Fan& Chen (2001)

Joreskog...

Melnyk, Alpert-Gillis... (1997)

Miles... (1993)

Reynolds (1994)

Tables

Define all abbreviations used in the tables in a note below each table.

Figures - they are not clear enough for print. Please provide the original file, not one that is embedded.