

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A systematic review of effective interventions for communicating with, supporting and providing information to parents of pre-term infants
AUTHORS	Brett, Jo; Staniszewska, Sophie; Newburn, Mary; Jones, Nicola; Taylor, Lesley

VERSION 1 - REVIEW

REVIEWER	<i>Krista L. Oswalt, PhD</i> Post Doctoral Research Associate Arizona State University United States I have no competing interests.
REVIEW RETURNED	14-Dec-2010

THE STUDY	There is inconsistency between the abstract and the manuscript in terms of the number of studies included in the systematic review.
GENERAL COMMENTS	<p>This is an important area for a systematic review of the literature to be performed. I commend the authors for attempting this project. Thank you for the opportunity to review this manuscript. Overall, the manuscript is well-written and of great significance and interest to healthcare professionals. It is clear that a great deal of effort was put into the preparation of this manuscript. The organization of the results into 7 categories was particularly helpful. Please see below for specific constructive criticism to enhance this manuscript.</p> <p>Introduction:</p> <ul style="list-style-type: none">• Although the introduction is relatively well-written, the focus is on infant outcomes. However, the results of the 77 studies primarily focus on parental outcomes (i.e. stress, confidence, etc.) If information about parent and child outcomes is going to be reviewed, both of these should be included in the introduction. <p>Methods:</p> <ul style="list-style-type: none">• Despite the explanation for inclusion of all study designs, I am concerned about the varying degrees of rigor associated with non-randomized control studies. The Cochrane Handbook (www.cochrane-handbook.org) (specifically sections 13.1.2 & 13.1.3) confirms my concerns. This large number of studies limits the authors' ability to provide quality descriptions/critiques of these studies.

- Additional details regarding the evaluation of study quality is requested. It is unclear whether the table labeled "SIGN Level of Evidence" will be included in the article. It is not referred in the text and I was quite confused about this column in Table 1.

Discussion:

- There is limited discussion of methodological issues associated with the included studies and potential solutions for future studies (i.e. POPPY). A key component of a systematic review includes the assessment of each study along with a synthesis of the finding. The authors need to enhance their assessment of each study and the appraisal of the evidence. Readers are not looking for a simple restatement of what is already known, but rather clarification of studies (often contradictory) in order to solve the clinical problem of interest.
- The authors talk about family-centered care in the discussion. Was this a conclusion based on the outcomes of the systematic review or could it be used as part of the inclusion study criteria to further limit the large number of studies included in this systematic review?

Minor Suggestions

Introduction:

- The second paragraph of the introduction is confusing. Upon initially reading this paragraph, I thought it was beginning to describe one of the studies in the systematic review. This paragraph could benefit from some rewording and reorganization to clarify the relationship between POPPY and this systematic review.

Methods:

- Study selection criteria should be more specific, perhaps in bulleted form. A good example is : Hough, J.P., Boyd, R. N., & Keating, J. L. (2010). Systematic Review of Interventions for Low Bone Mineral Density in Children With Cerebral Palsy. *Pediatrics*, 125 (3): e670-e678.

Search Results Figure 1:

- The number of papers reported in Figure 1 and the text (n=77) does not correspond to the number of papers reported in the abstract (n=74).

Table 1 Data extraction tables:

- I suggest that the studies be organized in order to publication year rather than alphabetical by author name. I think this is especially important because of the large range

	<p>of publication years (1980-2009) and the probability of improvement of studies over time.</p> <ul style="list-style-type: none"> The formatting of the table needs to be revised. Words in a number of the columns (i.e. intervention, outcome measure, no. of controls, and statistically significant) are not legible. <p>Results:</p> <ul style="list-style-type: none"> The authors are inconsistent in citation. Some include numeric references as well as author and year. This seems unnecessary. One convention should be chosen and used throughout the manuscript. <p>Discussion:</p> <ul style="list-style-type: none"> The paragraph beginning on line 33 of page 31 is somewhat confusing. Again, the relationship between this systematic review and the POPPY studies needs be further clarified. <p style="text-align: center;"><u>Recommendations</u></p> <p>I recommend that this paper be considered for publication after major revisions are made.</p>
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REVIEWER	<i>Dr Mark Davies</i> Senior Staff Specialist in Neonatology Associate Professor of Neonatology Dept of Neonatology Royal Brisbane & Women's Hospital Australia
REVIEW RETURNED	20-Dec-2010

THE STUDY	<p>The authors report a systematic review of interventions for communicating with, supporting and providing information to parents of pre-term infants.</p> <p>Whilst the intention of the authors seems clear, and a summary of the evidence of these interventions is laudable, the results of their endeavours cannot support their conclusions.</p> <p>In the introduction there is no explicit delineation of the problem/s that the "effective interventions" sought are meant to solve. Without an adequate description of the problem and no rationale for any proposed intervention the rationale for the review is unclear.</p> <p>The main problem is that the review lacks focus. There is no explicitly stated aim. There is no testable hypothesis or hypotheses stated.</p> <p>There is no adequate description of the inclusion and exclusion criteria for studies. Hence the population of infants to which the intended included studies would be generalisable is not clear. The interventions to be included are not stated, and nor are the</p>
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	outcomes which the authors deem clinically relevant. There is no description of how studies screened for inclusion are to be assessed for validity. As a result of these problems we cannot be assured that all relevant studies have been included and that only irrelevant studies have been excluded. A good example of this problem is the inclusion of the RCT of infant massage – how is this intervention interpreted as an intervention "... relating to information, communication, and/or support for parents of preterm infants ...".
RESULTS & CONCLUSIONS	The results are unreliable because of the methodological problems described above.
REPORTING & ETHICS	The QUOROM guidelines are an example of suitable guidelines that have not been followed. There are others that would be appropriate for non-randomised studies.

REVIEWER	Professor Jane Sandall Professor of Women's Health Programme Director (Innovations) NIHR King's Patient Safety and Service Quality Research Centre Department of Primary Care and Public Health Sciences, King's College London School of Medicine, King's College, London,
REVIEW RETURNED	01-Jan-2011

GENERAL COMMENTS	<p>This paper reports the results of the first phase of the POPPY study, which takes the form of a systematic review to identify effective interventions for communicating with, supporting and providing information for parents of pre-term babies.</p> <p>The review synthesises information from a large number of study designs, and it would be helpful if more focused points were made regarding added value to what is already known, level of evidence for key findings and pointers for a range of stakeholders such as policy makers and service providers, parents and researchers.</p> <p>The authors have not identified whether they followed any reporting guidelines for the review. If they did, so it is helpful to the reader to know this. It would be helpful if the abstract also includes the study appraisal and synthesis methods, limitations and systematic review registration number if available.</p> <p>Review points Further details should be provided of the POPPY study including the study web site. It would be helpful to include the search strategy for at least one data base in an Appendix, so the search can be repeated. Need to clarify what countries were included in the search. Could the authors clarify the rationale for guidelines chosen i.e. SIGN. Is it possible to give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram? I.e. How were original hits reduced to 434 ordered papers to 77 included.</p> <p>The section on Supporting parents through individualised developmental and behavioural Care programmes includes outcomes for babies and parents. Can the findings for parents would be better presented in the section on parental stress, as it is confusing to present these findings in two</p>
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	<p>sections, even though they are cross-referenced.</p> <p>On p39 the authors state that research on ethnic minorities and teenagers are underrepresented in the review, yet these groups are over represented in parents of babies in NICU. Can the authors provide data on this? As, this potentially affects the relevance of the review findings to a significant group of parents of pre-term babies.</p> <p>The review covers a wide range of study designs and it is not clear how the results which are mixed inform the discussion. For example, the results from trials seem unclear re benefit but abstract emphasises beneficial impact. As such, the findings are presented in a confusing manner. It would be helpful to summarise the main findings including the strength of evidence for each main outcome, and consider their relevance to key groups as noted above. (E.g. healthcare providers, users, and policy makers).</p> <p>Could the authors discuss the limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).</p> <p>Could the authors provide a general interpretation of the results in the context of other evidence, and implications for future research?</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewers 1:

A. Major changes

1. Introduction:

Although the introduction is relatively well-written, the focus is on infant outcomes. However, the results of the 77 studies primarily focus on parental outcomes (i.e. stress, confidence, etc.) If information about parent and child outcomes is going to be reviewed, both of these should be included in the introduction.

The introduction has now been re-written to give a more parent-focussed introduction

2. Methods:

Despite the explanation for inclusion of all study designs, I am concerned about the varying degrees of rigor associated with non-randomized control studies. The Cochrane Handbook (www.cochrane-handbook.org) (specifically sections 13.1.2 & 13.1.3) confirms my concerns. This large number of studies limits the authors' ability to provide quality descriptions/critiques of these studies.

While we understand the reviewers concerns regarding the large number of non-randomised controlled trials in this study, we feel their inclusion is important in giving a breadth of knowledge in an area which is not easily studied using randomised controlled trials. We set out to cover the complete pathway of the parent through the neonatal unit and home, and therefore the broadness of the review necessitates a wider evidence base than if we were just assessing a single intervention. We have stratified the review into RCTs and non-RCTs, and then stratified the non-RCT studies by intervention (cohort and quasi experimental) and non-intervention (cross-sectional, case series, cross-sectional) to help address this issue. We have also quality assessed the evidence using the Scottish Intercollegiate Guideline Network (SIGN) quality assessment, which was chosen for its similarities of assessing across a broad area of research (for guideline development). See comment below on SIGN. If a study was fatally flawed it was excluded from the study.

We have discussed this issue further in the discussion, and we have included the data extraction tables for the non-intervention studies (which we did not submit in the first submission). We have re-read the section of the Cochrane Handbook and also sought further advice from Dr Gill Gyte, a Research associate at Cochrane Pregnancy & Childbirth Group and also a member of our advisory group, and feel the use of non-RCTs in this review is appropriate.

3 Additional details regarding the evaluation of study quality is requested. It is unclear whether the table labeled "SIGN Level of Evidence" will be included in the article. It is not referred in the text and I was quite confused about this column in Table 1.

Additional text has been added to the discussion explaining the SIGN level of evidence and is also now reported in a separate figure (figure 4).

4. There is limited discussion of methodological issues associated with the included studies and potential solutions for future studies (i.e. POPPY). A key component of a systematic review includes the assessment of each study along with a synthesis of the finding. The authors need to enhance their assessment of each study and the appraisal of the evidence. Readers are not looking for a simple restatement of what is already known, but rather clarification of studies (often contradictory) in order to solve the clinical problem of interest.

We have added more information about methodological issues of the studies and summarised the outcomes of each level of evidence in the discussion in order to clarify the levels evidence presented, and suggested future research. Because this review set out to map out the evidence for potential interventions to assist parents who have had a premature infant, there is no one solution to the problems they encounter. We hope that neonatal units will take the evidence provided and adapt the pathway suggested in figure 2 to fit their own environment and policies to create a less stressful and informative experience for parents who have had a premature infant.

5. The authors talk about family-centered care in the discussion. Was this a conclusion based on the outcomes of the systematic review or could it be used as part of the inclusion study criteria to further limit the large number of studies included in this systematic review?

We discuss family centred care as a conclusion of the evidence. The interventions reported are similar to the family-centred care pathways that have been used and reported on in USA (Hamilton etc). While it is clear the medical needs of the infant are the priority for the neonatal unit, evidence suggests that caring for the parents and the baby as a unit, improves outcomes for the infant and the neonatal unit as well as the parents themselves.

Family centred care references:

Michael S. Dunn, Maureen C. Reilly, Anne M. Johnston, Robert D. Hoopes, Jr, and Marie R. Abraham Development and Dissemination of Potentially Better Practices for the Provision of Family-Centered Care in Neonatology: The Family-Centered Care Map. *Pediatrics*, Nov 2006; 118: S95 - S107

Anne M. Johnston, Candice E. Bullock, Jean E. Graham, Maureen C. Reilly, Colleen Rocha, Robert D. Hoopes, Jr, Vanessa Van Der Meid, Susan Gutierrez, and Marie R. Abraham Implementation and Case-Study Results of Potentially Better Practices for Family-Centered Care: The Family-Centered Care Map. *Pediatrics*, Nov 2006; 118: S108 - S114.

Roger P. Saunders, Marie R. Abraham, Mary Jo Crosby, Karen Thomas, and William H. Edwards Evaluation and Development of Potentially Better Practices for Improving Family-Centered Care in Neonatal Intensive Care Units

Pediatrics, Apr 2003; 111: e437 - e449.

Kimberly A. Cisneros Moore, Kara Coker, Allison B. DuBuisson, Betsy Swett, and William H. Edwards Implementing Potentially Better Practices for Improving Family-Centered Care in Neonatal Intensive Care Units: Successes and Challenges. Pediatrics, Apr 2003; 111: e450 - e460.

Helen Harrison The Principles for Family-Centered Neonatal Care. Pediatrics, Nov 1993; 92: 643 - 650.

The references 5,6, and 7 in the paper also report the benefits of family-centred care at the neonatal unit.

B. Minor corrections:

6. Methods:

Study selection criteria should be more specific, perhaps in bulleted form. A good example is :Hough, J.P., Boyd, R. N., & Keating, J. L. (2010). Systematic Review of Interventions for Low Bone Mineral Density in Children With Cerebral Palsy. Pediatrics, 125 (3): e670-e678.

The study selection criteria has been made more specific and bullet pointed.

7. Search Results Figure 1:

The number of papers reported in Figure 1 and the text (n=77) does not correspond to the number of papers reported in the abstract (n=74).

Many apologies for this mistake. The number was 74, but on numerous re-counts 72 is the correct number. This has been corrected in the text and figure.

8.

9. Table 1 Data extraction tables:

I suggest that the studies be organized in order to publication year rather than alphabetical by author name. I think this is especially important because of the large range of publication years(1980-2009) and the probability of improvement of studies over time.

The studies are now in date order.

The formatting of the table needs to be revised. Words in a number of the columns (i.e. intervention, outcome measure, no. of controls, and statistically significant) are not legible.

This has been corrected. The formatting issues arose in the attempt to paste the tables into the main part of the paper. They have been e-mailed separately to ensure this doesn't happen again.

10. The authors are inconsistent in citation. Some include numeric references as well as author and year. This seems unnecessary. One convention should be chosen and used throughout the manuscript.

This has now been changed to number referencing only

11. The paragraph beginning on line 33 of page 31 is somewhat confusing. Again, the relationship between this systematic review and the POPPY studies needs be further clarified.

This paragraph has now been clarified.

Response to Reviewer 2:

Overall, the reviewer is concerned with how this review fits with the traditional systematic reviews methodology. We did not set out to conduct a Cochrane style systematic review, as the issue under research does not fit into an experimental proposition under test (e.g. is treatment effective). We set out to conduct a more realist review. This has now been made clear in the methods of the paper. Realist review is not a method or formula, but a logic of enquiry that is inherently pluralist and flexible, encompassing all types of study types. It seeks not to judge but to explain, and is driven by the question 'What works for whom in what circumstances and in what respects?' We wanted to identify what works for parents who have had a premature infant and at what part of their experience at the neonatal unit and after returning home. In practical terms, the realist reviewer identifies and evaluate the programme theories that implicitly or explicitly underlie families of interventions (Mays and Pope 2005).

The quote below highlights the differences between a traditional systematic review which has one hypothesis and reaches a conclusion, with the realist systematic review that aims to provide a more indepth description of how interventions may fit a complex pathway to provide health managers and health policy makers to make decisions:

"The experimental propositions under test relate to whether the treatment (and the treatment alone) is effective. As well as random allocation of participants, safeguards such as the use of placebos and double blinding are utilized to protect this causal inference. The idea is to remove any shred of human intentionality from the investigation. Active programmes, by contrast, only work through the stakeholders' reasoning and knowledge of that reasoning is integral to understanding its outcomes. Broadly speaking, we should expect that, in tracking the successes and failures of interventions, reviewers will find at least part of the explanation in terms of the reasoning and personal choices of different actors and participants" Pawson 2005

Please see references below for more information on this type of review.

Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review – a new method of systematic review designed for complex policy interventions. *Journal of Health Services Research & Policy* Vol 10 Suppl 1, 2005: 21–34

Mays N, Pope C, Popay J. Systematically reviewing qualitative and quantitative evidence to inform management and policy making in the health field. *J Health Serv Res Policy* 2005;10(Suppl 1):6–20

Greenhalgh T. Meta-narrative mapping: a new approach to the synthesis of complex evidence. In: Hurwitz B, Greenhalgh T, Skultans V, eds. *Narrative Research in Health and Illness*. London: BMJ Publications, 2004

Whilst the intention of the authors seems clear, and a summary of the evidence of these interventions is laudable, the results of their endeavours cannot support their conclusions.

We have reviewed our conclusions carefully and given the type of systematic review this is (as clarified above) believe our conclusions are supported by our results.

In the introduction there is no explicit delineation of the problem/s that the "effective interventions"

sought are meant to solve. Without an adequate description of the problem and no rationale for any proposed intervention the rationale for the review is unclear.

The introduction has been rewritten to highlight the problem more clearly.

The main problem is that the review lacks focus. There is no explicitly stated aim. There is no testable hypothesis or hypotheses stated.

This review is not a Cochrane style review that has a testable hypothesis, this is a realist review with a logic enquiry about interventions that parents have found useful in supporting and informing them throughout their time at the neonatal unit and after discharge. The aim was to identify and evaluate from the parent perspective a family of interventions which were useful along their pathway through the neonatal care of their infant.

This has now been made clearer in the methods section of the paper.

There is no adequate description of the inclusion and exclusion criteria for studies. Hence the population of infants to which the intended included studies would be generalisable is not clear. These criteria are now clearly identified in the text.

The interventions to be included are not stated, and nor are the outcomes which the authors deem clinically relevant.

A realist review sets out to map out the interventions along the pathway in order to assist managers and policy makers in their decisions when developing care pathways for these parents. The review is not intended to have direct clinical outcomes. The review identifies parent-reported outcome studies. There is no description of how studies screened for inclusion are to be assessed for validity. As a result of these problems we cannot be assured that all relevant studies have been included and that only irrelevant studies have been excluded. A good example of this problem is the inclusion of the RCT of infant massage – how is this intervention interpreted as an intervention “... relating to information, communication, and/or support for parents of preterm infants ...”.

We have now clearly stated our inclusion and exclusion criteria.

Baby massage programmes, from the parent point of view, is a supportive programme in that it helps them to interact with their fragile infant, to feel closer to their infant, and therefore build their confidence in handling and caring for their infant. The searches were broad, and therefore there is a lower risk of missing relevant studies than in the narrow searches so often conducted for systematic reviews. We also received advice from a very experienced advisory panel of experts in the field, including neonatal consultants, neonatal nurses, and head of the National Perinatal Epidemiology Unit at Oxford University (Peter Beresford, Chair) and a representative from the Cochrane group (Gill Gyte), to help identify all types of studies in all areas of the parents' pathway.

The results are unreliable because of the methodological problems described above.

We would like to reassure the reviewer that having considered this point carefully, we are confident that strict methodological guidance was followed. The literature base is not strong, which we discuss in the paper, which reduces the ability to provide definitive answers. However, this is a complex issue which is difficult to assess using randomized controlled trials that provide definitive answers.

However, the review provides an in-depth knowledge base with which policy makers can use as guidance in developing family-centred care policies at the neonatal units.

The QUOROM guidelines are an example of suitable guidelines that have not been followed. There are others that would be appropriate for non-randomised studies.

We followed the York Centre for Reviews and Dissemination (CRD), which we state in the methods of the paper and reference in the reference list. The Centre for Reviews and Dissemination is a department of the University of York and is part of the National Institute for Health Research in the UK

CRD undertakes high quality systematic reviews that evaluate the effects of health and social care

interventions and the delivery and organisation of health care.
The CRD provides clear, concise methodology for systematic reviews.

Reviewer 3

This paper reports the results of the first phase of the POPPY study, which takes the form of a systematic review to identify effective interventions for communicating with, supporting and providing information for parents of pre-term babies.

The review synthesises information from a large number of study designs, and it would be helpful if more focused points were made regarding added value to what is already known, level of evidence for key findings and pointers for a range of stakeholders such as policy makers and service providers, parents and researchers.

Although a variety of published findings are available, this review brings this evidence together, to show how it fits together in a logical pathway to provide support, information and clear communication through the parents pathway through the neonatal unit and after discharge of their infant.

The aim of the review was also to focus on the parent reported outcomes – what works best for them, and to put this forward to the neonatal units

The authors have not identified whether they followed any reporting guidelines for the review. If they did, so it is helpful to the reader to know this. It would be helpful if the abstract also includes the study appraisal and synthesis methods, limitations and systematic review registration number if available. We followed the York Centre for Reviews and Dissemination (CRD), which we state in the methods of the paper and reference in the reference list. The Centre for Reviews and Dissemination is a department of the University of York and is part of the National Institute for Health Research in the UK

CRD undertakes high quality systematic reviews that evaluate the effects of health and social care interventions and the delivery and organisation of health care

The CRD provides clear, concise methodology for systematic reviews.

The study appraisal and synthesis methods are now reported in the design section of the abstract, and the limitations of the evidence is now reported in the conclusion section of the abstract.

The systematic review does not have a registration number.

Review points

Further details should be provided of the POPPY study including the study web site. It would be helpful to include the search strategy for at least one data base in an Appendix, so the search can be repeated.

The website has now been added to the author page

The search strategy for medline has been added as table 1. The data extraction tables are now table 2a,b,c.

Need to clarify what countries were included in the search.

All developed countries – now included in inclusion criteria (which has been bullet pointed to make it clearer).

Could the authors clarify the rationale for guidelines chosen i.e. SIGN.

We have quality assessed the evidence using the Scottish Intercollegiate Guideline Network (SIGN) quality assessment, which was chosen for its similarities of assessing across a broad area of research (for guideline development). A paragraph about the SIGN levels of evidence has now been added to the discussion with a rationale for why we have used it.

Is it possible to give numbers of studies screened, assessed for eligibility, and included in the review,

with reasons for exclusions at each stage, ideally with a flow diagram? i.e. How were original hits reduced to 434 ordered papers to 77 included.

All but one of the excluded papers (from 434 papers) were excluded because they did not report parent reported outcomes of the interventions (i.e. reported baby outcomes or parent outcomes as reported by health professionals). 1 paper was excluded because at first glance it was obvious it was fatally flawed.

The section on supporting parents through individualised Developmental and Behavioural Care programmes includes outcomes for babies and parents. Can the findings for parents be better presented in the section on parental stress, as it is confusing to present these findings in two sections, even though they are cross-referenced.

Having re-read this section I have not identified where the reviewer feels baby outcomes are reported. It might be that the reporting of improved mother-baby interaction, or improved confidence in caring for their baby could be construed as baby outcomes, but are intended as parent outcomes in this instance (helping the parents to feel more empowered to care for and love their infant). I am also aware that the developmental and behavioural programmes are intended to improve infant outcomes, but in the evidence reported they identify the parent outcomes only, as these programmes also (as secondary outcomes) facilitate parents.

I also feel that the individualized developmental and behavioural care programmes are a critical intervention in supporting and informing parents, and should not be grouped with interventions that only relieve stress. They report other parental outcomes too, such as improved knowledge and greater confidence. We hope that the figure 3 will provide a clear overview of how the interventions fit into the parent pathway at the neonatal unit.

On p39 the authors state that research on ethnic minorities and teenagers are underrepresented in the review, yet these groups are over represented in parents of babies in NICU. Can the authors provide data on this? As, this potentially affects the relevance of the review findings to a significant group of parents of pre-term babies.

The review did not find evidence that was specific to these groups. They may have been included in the studies, but were not identified as teenagers or ethnic minorities. We know from the interview section of the POPPY study that both ethnic minorities and teenagers are difficult to recruit. The ethnic minorities were difficult to recruit for interview for two reasons: cultural reasons (e.g. suspicion of research, and issues of gaining permission from other family members) and language barriers. This is definitely an area where more research needs to be done, for the reasons you have identified and we have stated this in the discussion.

The review covers a wide range of study designs and it is not clear how the results which are mixed inform the discussion. For example, the results from trials seem unclear re benefit but abstract emphasises beneficial impact. As such, the findings are presented in a confusing manner. It would be helpful to summarise the main findings including the strength of evidence for each main outcome, and consider their relevance to key groups as noted above. (E.g. healthcare providers, users, and policy makers).

Could the authors discuss the limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).

Could the authors provide a general interpretation of the results in the context of other evidence, and implications for future research?

We have now re-written the discussion, which makes it clearer, and discusses the weakness of the literature base. The aim of the review was to report parent outcomes only, and so relevance to healthcare providers and policy-makers is not identified in the evidence. This would be an interesting study to conduct though, particularly in the current economic climate.

We have collaborated with users (parent representatives, National Childbirth Trust and Bliss, the

premature baby charity – authors on this paper) throughout all aspects of the POPPY study, and they have disseminated the results to neonatal units throughout the UK. We have also had the results reported in the latest Government Neonatal Task Force. Evaluating this process is a possible future research study.

The following reference reports the impact of users (parents) in the development of this study:
 Staniszewska S, Jones, N., Marshall, S., Newburn, M., (2007) 'User involvement in the development of a research bid: barriers, enablers and impacts' Health Expectations 10 (2), 173 - 183 (1369-6513)

VERSION 2 - REVIEW

REVIEWER	<i>Krista L. Oswalt</i>
REVIEW RETURNED	17-Feb-2011

THE STUDY	There is still concern about the number of studies being reviewed in this systematic review. Additionally, the main outcome measure is described vaguely as "parent-reported outcomes". Specific outcome measures are described in the results section.
RESULTS & CONCLUSIONS	The results are not clearly evaluated. The mixture of RCTs and other study designs make it difficult to interpret the results.
GENERAL COMMENTS	I commend the authors for the great deal of effort put into this manuscript. Unfortunately, I feel that a number of issues brought up by all 3 reviewers still remain. I would suggest that the authors consider breaking this manuscript into several manuscripts that could provide more indepth evaluation of the studies and implementation guidance for healthcare workers and policy makers.

REVIEWER	<i>Jane Sandall</i>
REVIEW RETURNED	13-Mar-2011

GENERAL COMMENTS	The paper is much improved following revision. I have one comment and it is related to the tables. The paper provides an overview of the evidence base section by section (9 in all). Each section summarise the study designs and strength of evidence. However this is not matched by the data extraction tables which is ordered by study design rather than the nine topics. This is not helpful to the reader who will wish to see what studies relate to each section. I would suggest that this table is re-ordered.
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VERSION 2 – AUTHOR RESPONSE

Response to reviewers:

Reviewer 1:

Reviewer(s)' Comments to Author:

Reviewer: Krista L. Oswalt
 Post Doctoral Research Associate
 Arizona State University
 USA

Comment: There is still concern about the number of studies being reviewed in this systematic review.

Response: We set out to cover the complete pathway of the parent through the neonatal unit and home, and therefore the broadness of the review necessitates a wider evidence base than if we were just assessing a singular intervention. We have stratified the review into RCTs and non-RCTs, and then stratified the non-RCT studies by intervention (cohort and quasi experimental) and non-intervention (cross-sectional, case series, cross-sectional) to help address this issue. We feel that offering a broad range of evidence provides the reader with the opportunity to select the level of evidence that they see appropriate, but hope that the reader appreciates that only including quantitative studies in this review would have limited the outcome of the review, and perhaps provided a skewed set of single interventions rather than providing a more complete pathway of interventions. We hope that neonatal units will take the evidence provided and adapt the pathway suggested in figure 2 to fit their own environment and policies to create a less stressful and informative experience for parents who have had a premature infant.

Comment: Additionally, the main outcome measure is described vaguely as "parent-reported outcomes". Specific outcome measures are described in the results section.

Response: By parent reported outcomes we mean any outcome that is reported by the parent themselves, and not outcomes that are reported by health professional assessment or observation. For example, there were more papers that reported the benefits of breast feeding and kangaroo care for parents of premature infants that were excluded because the study reported this from the health professionals perspective and not from the parent's perspective. In line with the extensive evidence on the importance of patient reported outcomes, we felt it was important that the outcomes reported were from the parents' perspective.

Comment: The results are not clearly evaluated. The mixture of RCTs and other study designs make it difficult to interpret the results.

Response: As we have stated above, we defend our decision to include a broad evidence base in order to provide the bigger picture in this complex pathway of interventions to help improve parents' support needs, information needs and communication needs.

We have attempted to show a clear division between the RCT evidence and observational evidence. However, we are not sure that further evaluation is justified, as it is questionable as to whether RCTs are an appropriate method of evaluating the parents' experiences of interventions over and above, say, a qualitative study. It is therefore very difficult to evaluate the results to say that one study method is better than another. If studies were fatally flawed they were excluded from the review.

While the RCT studies are more objective, they often fail to provide a more indepth empirical reality of parents' experiences of having a premature infant. A well conducted RCT may not provide a true reflection of improved self-esteem or empowerment, for example. Whereas a qualitative study, provides an understanding of the experiences. Furthermore, evaluation of such complex interventions is challenging because of the various interconnecting parts of the pathway reported in figure 2.

Again, there is a expansive evidence base on the shifting paradigm of how interventions that involve human agency are viewed- namely as complex interventions.

Comment: I commend the authors for the great deal of effort put into this manuscript. Unfortunately, I feel that a number of issues brought up by all 3 reviewers still remain. I would suggest that the

authors consider breaking this manuscript into several manuscripts that could provide more indepth evaluation of the studies and implementation guidance for healthcare workers and policy makers.

Response: While we accept the reviewers still have issues regarding the lack of Cochrane style review, we feel we have extracted as much data as possible from the evidence provided, and splitting the evidence up into several manuscripts would not add more to the results reported. Indeed, we feel splitting the data would disrupt the continuity of interventions reported in the pathway, and therefore weaken the strength of this paper. This paper gives an overview of interventions that may be helpful to parents who have had a premature infant, and provides insight in a way that a Cochrane style review may not be able to do with parents' experiences of support, information and communication after having a premature infant. Perhaps more significantly, reporting a broader evidence base in systematic reviews may also throw light on the reason why there is a lack of association between variables and outcomes seen in quantitative (Cochrane-type).

Reviewer 2

Reviewer: Jane Sandall
Professor of Women's Health
King's College, London

Comment: The paper is much improved following revision. I have one comment and it is related to the tables. The paper provides an overview of the evidence base section by section (9 in all). Each section summarise the study designs and strength of evidence. However this is not matched by the data extraction tables which is ordered by study design rather than the nine topics. This is not helpful to the reader who will wish to see what studies relate to each section. I would suggest that this table is re-ordered

Response: Thank-you for this comment. We agree that it is confusing, and have changed the order of the studies in data extraction form to match the 9 sections reported in the paper.