Family-centred care for hospitalised children aged 0-12 years
(Review)


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Family-centred care for hospitalised children aged 0-12 years

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ABSTRACT

Background

This is an update of the Cochrane systematic review of family-centred care published in 2007 (Shields 2007). Family-centred care (FCC) is a widely used model in paediatrics, is thought to be the best way to provide care to children in hospital and is ubiquitous as a way of delivering care. When a child is admitted, the whole family is affected. In giving care, nurses, doctors and others must consider the impact of the child’s admission on all family members. However, the effectiveness of family-centred care as a model of care has not been measured systematically.

Objectives

To assess the effects of family-centred models of care for hospitalised children aged from birth (unlike the previous version of the review, this update excludes premature neonates) to 12 years, when compared to standard models of care, on child, family and health service outcomes.

Search methods

In the original review, we searched up until 2004. For this update, we searched: the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library, Issue 12 2011); MEDLINE (Ovid SP); EMBASE (Ovid SP); PsycINFO (Ovid SP); CINAHL (EBSCO Host); and Sociological Abstracts (CSA). We did not search three that were included in the original review: Social Work Abstracts, the Australian Medical Index and ERIC. We searched EMBASE in this update only and searched from 2004 onwards. There was no limitation by language. We performed literature searches in May and June 2009 and updated them again in December 2011.

Selection criteria

We searched for randomised controlled trials (RCTs) including cluster randomised trials in which family-centred care models are compared with standard models of care for hospitalised children (0 to 12 years, but excluding premature neonates). Studies had to meet criteria for family-centredness. In order to assess the degree of family-centredness, we used a modified rating scale based on a validated instrument, (same instrument used in the initial review), however, we decreased the family-centredness score for inclusion from 80% to 50% in this update. We also changed several other selection criteria in this update: eligible study designs are now limited to randomised controlled trials (RCTs) only; single interventions not reflecting a FCC model of care have been excluded; and the selection criterion whereby studies with inadequate or unclear blinding of outcome assessment were excluded from the review has been removed.
Data collection and analysis

Two review authors undertook searches, and four authors independently assessed studies against the review criteria, while two were assigned to extract data. We contacted study authors for additional information.

Main results

Six studies found since 2004 were originally viewed as possible inclusions, but when the family-centred score assessment was tested, only one met the minimum score of family-centredness and was included in this review. This was an unpublished RCT involving 288 children post-tonsillectomy in a care-by-parent unit (CBPU) compared with standard inpatient care. The study used a range of behavioural, economic and physical measures. It showed that children in the CBPU were significantly less likely to receive inadequate care compared with standard inpatient admission, and there were no significant differences for their behavioural outcomes or other physical outcomes. Parents were significantly more satisfied with CBPU care than standard care, assessed both before discharge and at 7 days after discharge. Costs were lower for CPBU care compared with standard inpatient care. No other outcomes were reported. The study was rated as being at low to unclear risk of bias.

Authors’ conclusions

This update of a review has found limited, moderate-quality evidence that suggests some benefit of a family-centred care intervention for children’s clinical care, parental satisfaction, and costs, but this is based on a small dataset and needs confirmation in larger RCTs. There is no evidence of harms. Overall, there continues to be little high-quality quantitative research available about the effects of family-centred care. Further rigorous research on the use of family-centred care as a model for care delivery to children and families in hospitals is needed. This research should implement well-developed family-centred care interventions, ideally in randomised trials. It should investigate diverse participant groups and clinical settings, and should assess a wide range of outcomes for children, parents, staff and health services.

Plain Language Summary

Family-centred care for hospitalised children aged 0-12 years - an update

This is an update of the Cochrane systematic review of family-centred care published in 2007 (Shields 2007). For this update, we have changed the title to show that it is about children aged 0 to 12 years only. We have now excluded premature neonates, and we have changed several other selection criteria: study designs are now limited to randomised controlled trials only; the way in which family-centredness of interventions is assessed for inclusion has changed; single interventions not reflecting a FCC model of care have been excluded; and the selection criterion whereby studies with less than adequate blinding of outcome assessment were excluded from the review has been removed.

When a child comes into hospital, the whole family is affected. In giving care, nurses, doctors and those caring for the child must consider the impact of the child’s admission on all family members. ‘Family-centred care’ is one way of caring for children in hospital. It is “a way of caring for children and their families within health services which ensures that care is planned around the whole family, not just the individual child/person, and in which all the family members are recognised as care recipients” (Shields 2006, p. 1318). However, with changes in family structures, for example, development of the single parent family, questions arise about how care is best delivered. To ensure that children are cared for in ways that minimise emotional trauma and assist in recovery, it is important that such ways of delivering care are measured to see if they are effective.

This review has tried to do that by examining research about family-centred care. We looked for randomised trials of family-centred care interventions for children aged 0-12 years, in hospitals. We assessed potentially-relevant studies against criteria that identify important parts of family-centred care. Despite extensive searching we identified only one moderate-quality study (Bolton 2004) for inclusion. This study, from a doctoral thesis, showed that the family-centred care model had a positive effect on the adequacy of children’s care, parental satisfaction, and costs. For other indicators such as clinical outcomes and children’s behaviour there was no significant difference between the family-centred care model and standard inpatient care. There were no harms reported.

In this searches for this update, we also found 25 qualitative studies which described aspects of family-centred care, and a review of these will be published by the Joanna Briggs Institute. Our main conclusion from this Cochrane review update, however, is that further, rigorous research is needed to assess the effects of family-centred care on children’s experience of hospitalisation, as well as on their parents, hospital staff, and service delivery outcomes such as costs.

Family-centred care for hospitalised children aged 0-12 years (Review)

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BACKGROUND

While this is an update of a previously published review (Shields 2007), this background about the development of family-centred care has changed little. Until at least the late 1950s, hospitals worldwide tended to be bleak places for children. It was believed that visits from parents would inhibit effective care (Nethercott 1993) and were detrimental to the child, who would become distressed when the parents left (Johnson 1990; Shields 1999). Researchers began to suggest, however, that children whose parents did not visit them suffered acute emotional trauma which may have long-term psychological consequences in adolescence and adulthood (Bowlby 1971; Bowlby 1973).

In 1956, the British government commissioned a report into the welfare of children in hospital. The resulting report, the Platt Report (Platt 1959), recommended that visiting be unrestricted, that mothers stay in hospital with their child, and that training of medical and nursing staff should promote understanding of the emotional needs of children. The process of change has resulted in a humanisation of paediatrics (Darbyshire 1994; Jolley 2009), although the movement away from traditional approaches to health service delivery to the involvement of families in all aspects of the planning, delivery, and evaluation of health care has been slow (Coyne 2007a; Palmer 1993). The foundation for a family-centred approach to paediatric health care is the belief that a child's emotional and developmental needs, and overall family wellbeing, are best achieved when the service system supports diligently the ability of the family to meet the needs of their child, by involving families in the planning and delivery of care (Allen 1998; Neff 2003).

Much of the literature concerning family-centred care has originated from the UK and USA, which are developed and culturally distinctive (predominately Anglo-Saxon) societies (Irlam 2002). In low and middle income countries with fewer technological, economic and human resources, specific information about the psychosocial care of children in hospital is limited (Irlam 2002; Shields 2001c). Shields found that in some developing countries, parents were encouraged to stay with their hospitalised child only if it fitted with hospital rules (Shields 2001c). Stanford reported that in Central America where children's health is poor, some hospitals allowed parents to stay when their child was acutely ill, while some restricted parental visiting to one hour per day (Stanford 1986). These restrictions on parental visiting were thought to be the result of space limitations and lack of facilities rather than a philosophical objection to parents being present. A study in Tanzania found that mothers were concerned about environmental conditions such as overcrowding and lack of food while their children in hospital, while staff's concerns included lack of trained staff, overwork and low pay (Mwangi 2008), and a study from Iran has also highlighted problems with the implementation of family-centre care models (Aein 2007).

Family-centred care in high-income countries has been explored as care that is led by parents, with the health professional acting as a consultant, encouraging open and honest dialogue with the family (Hutchfield 1999; Irlam 2002). The family is acknowledged as expert in the care of their child, and the perspectives and information provided by the family have been described as important to clinical decision-making (Irlam 2002; Neff 2003; Webster 1999).

In the UK, the importance of promoting the role of families in the care of the hospitalised child has been acknowledged (DOH 2003). A number of related terms has been used to describe the attributes of family-centred care (Hutchfield 1999); these include partnership-in-care (Coyne 1996), parental involvement (Hurst 1993), nurse-parent partnership (Hill 1996), parental participation (K-Hallstrom 1999), and care-by-parent (Costello 1998; Evans 1994).

In 1992, the Institute for Patient- and Family-Centered Care was established in the USA, taking over the role of the Association for the Care of Children's Health, whose task it had been to develop a nationwide program to enhance the implementation of a family-centred approach to the care of infants, children, and adolescents. Much of the family-centred care literature from the USA refers to the seminal work of Shelton (Shelton 1987), who developed a framework for offering family-centred care to children. Within this framework, Shetlon and colleagues delineated eight elements which characterise health services which are family-centred (Trinette 1993). Subsequently, a ninth element was included (Johnson 1996). The nine elements of family-centred care include:

- recognising the family as a constant in the child's life;
- facilitating parent-professional collaboration at all levels of health care;
- honouring the racial, ethnic, cultural, and socio-economic diversity of families;
- recognising family strengths and individuality and respecting different methods of coping;
- sharing complete and unbiased information with families on a continuous basis;
- encouraging and facilitating family-to-family support and networking;
- responding to child and family developmental needs as part of healthcare practices;
- adopting policies and practices that provide families with emotional and financial support; and
- designing health care that is flexible, culturally competent, and responsive to family needs.

According to the Institute for Patient- and Family-Centered Care's definition:
“Family-centered care is an approach to the planning, delivery, and evaluation of health care that is grounded in mutually beneficial partnerships among health care providers, patients, and families. It redefines the relationships between and among consumers and health providers. Family-centered practitioners recognize the vital role that families play in ensuring the health and well being of infants, children, adolescents, and family members of all ages. They acknowledge that emotional, social, and developmental supports are integral components of health care. They promote the health and well being of individuals and families and restore dignity and control to them. Family-centered care is an approach to health care that shapes policies, programs, facility design, and staff day-to-day interactions. It leads to better health outcomes and wiser allocation of resources, and greater patient and family satisfaction” (Webster 1999, IPFCC 2010).

It has been suggested that to practice in a family-centred manner requires a shift in the orientation of health services from a standard model to a collaborative model which recognizes family involvement as central to their child’s care. Within this view, the healthcare provider is an equal partner and facilitator of care, and families are invited to participate actively in the decision-making, planning and provision of their child’s care to the extent they choose (Ahmann 1998; Ahmann 2001).

Potential advantages and disadvantages of family-centred care

There is a range of potential benefits and difficulties associated with the provision of family-centred care. For instance, in one study, the stress levels of parents whose children were intensive care unit inpatients were reduced (Melynky 2004). However, researchers have also reported challenges when trying to implement changes which would result in meaningful family involvement in the care of their hospitalised child. Healthcare providers have reported a lack of adequate education in relation to understanding and implementing the concept of family-centred care in a practice situation, as well a lack of shared understanding of, and commitment to, family-centred care among all health professionals and families (Bruce 1997; Bruce 2002; Coyne 2007a; MacKean 2005; Roden 2009). In addition, the hospitalisation of a child, whether planned or unplanned, is stressful for even the most well-organised and functional family (Melynky 2000). The significant adjustments to both parent and healthcare provider roles when a child is hospitalised may result in understandable levels of stress (Callery 1997). Potential disadvantages of family-centred care may be that families feel that they are expected to provide input into the care of their child beyond their expectations or capabilities, or are given more information than either the child or the family is ready to hear. This may cause additional stress or anxiety for both the parents and child. In summary, in 1994, Darbyshire (Darbyshire 1994) suggested that family-centred care was a wonderful idea, but difficult to implement effectively, and some authors are beginning to agree, questioning family-centred care as a model of care (MacKean 2005; Sarajarvi 2006). Also, questions are being raised as to the ethics of continuing to use a model for which no rigorous evidence of effectiveness exists (Shields 2010).

Other models of health care for children

Family-centred care, which involves participation of, or partnering with parents (or family-members) is described as different to the standard models of care used in paediatric health services. In these, often, the healthcare provider plays a major role in assessing and formulating a plan of care, based upon the perceived needs of the child and/or family. In the medical or standard model of health care, the healthcare worker plans care around the child’s illness and treatment needs, and the family is generally expected to comply with treatment recommendations (Ahmann 1998).

Implementation of family-centred care

It is expected that the development, implementation and outcomes of family-centred models of care may differ according to the population and setting in which the models are applied. For example, the needs and outcomes for families of a child with a chronic condition who experience long hospital stays may differ from those of families of a previously healthy young child who is admitted for a treatment procedure. Also, older children may have a greater awareness and understanding of the reasons for their hospitalisation. Therefore, models of care may reflect increased participation of the child in their hospital care. However, even if the family-centred care models are seen as making a difference and are advantageous in their own right, reliable reassurance that they result in more good than harm should be sought. The previous Cochrane review (Shields 2007) of which this current review is an update found that no studies met the inclusion criteria for either family-centredness of the intervention under study, or were excluded because they did not meet key methodological quality criteria as pre-specified by the review authors. That said, there were 11 studies at that time which used qualitative methods to examine the implementation of family-centred care, and which met the criteria for family-centredness, and we published a review of these (Shields 2006).

OBJECTIVES

To assess the effects of family-centred models of care for hospitalised children aged birth to 12 years (but excluding premature neonates), when compared to standard models of care, on child, family and health service outcomes.
METHODS

Criteria for considering studies for this review

Types of studies
In this update, we have included only randomised controlled trials (RCTs) including cluster randomised trials in which family-centred care models are compared with standard models of care. In Shields 2007, we took a broader approach, including quasi-RCTs and controlled before and after (CBA) studies. We decided that in the interest of rigour, and to try to definitively say whether or not family-centred care is effective in delivering care to children and families, we would seek the highest level of evidence possible for this update of the review. However, we have assessed quasi-experimental studies e.g. quasi-RCTs and controlled before-and-after studies, in a separate review for the Joanna Briggs Institute (Shields 2012). Another and separate review for the Joanna Briggs Institute which will also be linked to this update will be a review of the qualitative studies which met the family-centredness score. In this way we will be able to provide a rounded, and highly rigorous statement about the effectiveness or otherwise of family-centred care for hospitalized children aged 0 to 12 years.

Types of interventions
We included any intervention that aimed to promote the family-centred model of care during a child’s hospitalisation. Only studies that provide clear evidence that the family and/or child were actively involved in the planning and/or delivery of health care during the child’s hospitalisation were considered for inclusion. For the purposes of the review, the minimum criteria for active involvement included evidence of collaboration between health care providers and the family and/or child in the planning and/or delivery of care as soon as possible after admission or during the preadmission period. Included studies must also have compared family-centred models with standard models of care. In the original review, we included “professionally-centred” models of care, but it became apparent to us that these are the same as “standard models” so we deleted the words “professionally-centred” as redundant for this update.

Types of participants
Child/children: throughout this review, the term ‘child’ or ‘children’ is used to include all newborn infants, babies and children up to the age of 12 years being cared for in hospital; and all parts of hospitals that provide a service to children. The definitions of childhood can vary, and age limits are arbitrary. For the purpose of this review the National Library of Medicine’s medical subject headings (NLM 2004) were used to define the age cut-off of 12 years. However, we have excluded neonates born prematurely and who are patients in a neonatal intensive or special care nursery, as their requirements for family-centred care, and the ethics and philosophies of care around this particular group, are different to those in a ward/unit where full term infants and children are nursed (Brophy 2006).

Families: throughout the review the following definition of the family was applied:

The family is a basic social unit having as its nucleus two or more persons, irrespective of age, in which each of the following conditions are present:

1. the members are related by blood, or marriage, or adoption, or by a contract which is either explicit or implied;
2. the members communicate with each other in terms of defined social roles such as mother, father, wife, husband, daughter, son, brother, sister, grandfather, grandmother, uncle, aunt; and
3. they adopt or create and maintain common customs and traditions.

This definition has been modified from Nixon’s original definition (Nixon 1988) to allow for inclusion of significant others who do not usually cohabit with the family.

Healthcare providers involved in caring for hospitalised children.
Family support interventions such as flexible charging schemes for poor families, referrals to other hospital or community services (such as, social workers, chaplains, patient representatives, mental health professionals, home health care, rehabilitation services), facilitating parent-to-parent support.

In Shields 2007, we tried to identify several interventions as family-centred. On reflection for this update, we viewed this as a deficiency in the original review, where, at times, it required a deal of discussion and deliberation about the possibility of inclusion of various studies. We have tried to avoid such problems in this update by taking a more direct and simple approach. Consequently, it is important, for this update, to describe what we considered did not constitute an holistic model of family-centred care. We excluded studies where there was no clear evidence of collaboration between the family and/or child and healthcare provider in the planning and/or delivery of care. Such studies could include parental presence during healthcare procedures such as routine examinations, anaesthetic induction, venipuncture and post-anaesthetic recovery, parental education packages, and bereavement team/protocols; because singular interventions such as parental presence without any collaboration or communication does not meet the holism of family-centredness. As an example, parental presence for anaesthesia induction might occur in the operating room, but this does not mean that the same hospital will allow parental involvement in any other aspect of the child’s care. In other words, if one intervention was the focus of a study, without recourse to a total family-centred care model, it was excluded.

The assessment of family-centredness is described in detail later, but in brief, we used the same scoring system as we used in the original review (Trivette 1993), as it worked effectively in the first instance, and also provided us with a way of quantifying what family-centred care is about. It has been used in the assessment of research and literature before, and is well tested. See Data collection and analysis - ‘Assessment of the family-centredness of the intervention’, and Appendix 1 for details.

Types of outcome measures
A number of processes and outcomes might be affected by models of care which aim to incorporate families in the decision making, planning, provision and evaluation of care when their child is hospitalised. Where possible, when assessing study quality we considered the use of validated research tools to measure satisfaction with care and psychological outcomes.

Child
- Psychosocial outcomes including psychological health (such as anxiety, confidence, sense of control, coping, adjustment, stress, upset, crying, insomnia, fears, behavioural regression), attitudes towards caregivers and attitudes towards rehospitalization.

- Behaviour (such as level of co-operation, compliance with care, and appetite).
- Physical health including physiological measures such as blood pressure and pulse rate; pain assessment or control such as use of medication or other means to reduce pain; length of hospital admission, readmission.
- Developmental outcomes including weight gain, developmental milestones.
- Knowledge and understanding including knowledge of condition, treatment, knowledge about personnel or procedure.
- Satisfaction: for example, with involvement in decision making, with level of communication.
- Attitudes: for example, views of cultural appropriateness, flexibility.

Parent
- Psychological health (for example, stress, anxiety, perceptions of coping, sense of control) and satisfaction (for example, involvement in decision making, level of communication).
- Attitudes (such as complaints, evaluations of cultural appropriateness, flexibility and responsiveness of the intervention).

Staff
- Psychological health (for example, stress, responsiveness to patient’s needs, confidence) and satisfaction (for example with the intervention, with care provided, with the level of education provided about family-centred care).

Health services
- Health-service provision outcomes, such as staffing requirements, costs of the intervention, time needed for the intervention, use of other hospital department services, litigation claims

All adverse outcomes, such as an increase in anxiety after receiving the intervention, were also sought.

Search methods for identification of studies

Electronic searches
For the original review (Shields 2007) we conducted the following searches in February 2004:
- MEDLINE (PubMed) (1966 to February 2004);
- The Cochrane Central Register of Controlled Trials (CENTRAL), (The Cochrane Library, Issue 2, 2004);
- CINAHL (1982 to February 2004);
family-centred care for hospitalised children aged 0-12 years (Review)

Appendix 1

Search strategies for the 2004 searches are available from the authors upon request.

For this update, we identified relevant studies by electronically searching the following databases:

- MEDLINE (Ovid SP), 2004 to 10 December 2011 (Appendix 2);
- The Cochrane Central Register of Controlled Trials (CENTRAL), The Cochrane Library, Issue 12, 2011 (Appendix 3);
- EMBASE (Ovid SP), 2004 to 10 December 2011 (Appendix 4);
- PsycINFO (Ovid SP) 2004 to 21 December 2011 (Appendix 5);
- CINAHL (EBSCO Host) 2004 to 22 December 2011 (Appendix 6); and

A search strategy was developed for MEDLINE (Ovid SP) (Appendix 2), using the search filter for RCTs, quasi-RCTs and CBA studies developed by the Cochrane Consumers and Communication Review Group. The search strategy was then adapted for the other databases, specified above. The updated search was limited to papers from 2004 onwards. We conducted searches in May-June 2009, and reran them in December 2011 (except for Sociological Abstracts which was updated in January 2011).

In this update, there were several changes to the databases searched. We searched EMBASE from 2004 onwards, and several which were included in the original review were not used: ERIC was not searched as it was not considered relevant, the Social Work Abstracts database was not available for searching at the range of libraries available to us. Any relevant articles that may have appeared in those databases we were confident we had identified from the other databases searched. Similarly, AMI was available but not searched as relevant references were indexed in other databases searched.

In this update, as in the original review, RCTS, quasi-RCTs and CBA studies were all included in the searches to ensure consistency with the original review, but we then screened them by hand, by which time we had decided, in the interests of rigour, to include only RCTs. The quasi-experimental studies are included in a separate review for the Joanna Briggs Institute (Shields 2012).

Searching other resources

For the updated review we also searched Web of Science Conference Proceedings, Australian Research Online, Clinical Trials Registry, Current Controlled Trials, UK Clinical Research Network: Portfolio Database, Bandolier and Google, using keyword search "family centred care" or family centred care". Of these, only Google produced any relevant results with links to two conference web sites. We searched the abstracts of the following conferences: The 4th International Conference on Patient- and Family Centered Care (2009); The 3rd International Conference on Patient- and Family-Centered Care (2007); Family Centred Care in Context Conference (2009).

We cross referenced relevant literature including identified trials, existing review articles, published conference and symposia proceedings, dissertations, hospital policy documents and other key informants. We searched reference lists of relevant articles. There was no limitation by publication language, and we found no relevant papers in a language other than English. Landry 2007 was published in English, and when we contacted the author for further clarification of the age group and intervention, we found that the data reports were in French. These were interpreted and we were able to ascertain that the study did not meet the required 50% cut-off in the score for family-centredness, and so was not included.

Data collection and analysis

Selection of studies

Two review authors (LS and MT) screened the outputs of the searches literature search independently and compared results. They screened the outputs from the database searches based on title and abstract, and assessed them according to the selection criteria.

Four review authors (HZ, JP, JH and LS) independently screened the full texts of possible papers according to the inclusion criteria of the review, including an assessment of the intervention in terms of the degree of family-centredness, as described below (see also Appendix 1). We discarded those references which clearly did not fulfil inclusion criteria, and retrieved potentially relevant articles, and undertook full-text assessments using the specifically developed and piloted assessment form (see Appendix 1). Discrepancies were resolved through discussion with all review authors. The full-text studies that were excluded are listed in the Characteristics of excluded studies table, with reasons for exclusion.

Assessment of the family-centredness of the intervention

For this update, as in Shields 2007, in order to assess relevant studies for the degree of family-centredness, we used a rating scale modified from the scale developed by Trivette and colleagues (Trivette 1993). These authors used the 9 elements of family-centred care, as described by the Association for the Care of Children's Health (now the Institute for Patient- and Family-Centered Care), to develop 13 evaluation items that describe the features of family-
centred care. We present the 9 Association for the Care of Children’s Health elements and the 13 corresponding sub-elements in Table 1. These sub-elements are further grouped into three cluster groups (that is, Cluster 1: family as a constant; Cluster 2: culturally responsive; Cluster 3: supporting family individuality) derived from an original cluster analysis by Trivette and colleagues (Trivette 1993). The clusters were designed to be used to help describe the model of family-centred care in individual trials.

We applied a rating of 0 to 4 to each of the 13 sub-elements of family-centred care, from 0 indicating the article included no evidence that the intervention either implicitly or explicitly was based upon the elements of family-centred care, to 4 indicating the article included numerous instances of explicit evidence that the intervention was based upon the elements of family-centred care (see Appendix 1).

We considered that an element of family-centred care was implicitly addressed if it could be inferred that the author(s)’ descriptions, arguments etc. were consistent with the intent of the elements of family-centred care, whereas if an element of family-centred care was clearly stated and distinctly expressed it ought to underscore health practice and we therefore considered it to have been explicitly addressed or endorsed (Trivette 1993).

Independently, each review author scored the evaluation items from 0 to 4 for each study, and final scores were resolved by consensus among authors. We added the scores together to give an overall rating of the intensity of family-centredness for each study. The maximum possible score was 52, and scores of 42 (or 80% of total score) (see below) or greater would have indicated a high degree of family-centredness. The results of the study rating were compared amongst review authors and also by an independent expert in the field. The reliability and validity of the scoring system had been tested by Trivette, Dunst and colleagues (Trivette 1993).

Our scoring sheet, of which the scoring system was an integral part, was tested by the review authors, and others who were independent of the review, by repeatedly using the sheet, comparing answers and refining the document. The construction of the sheet prevented us using reliability statistics for each section, however Trivette’s (Trivette 1993) scoring system for family-centred care had yielded a median Cohen’s kappa score of 0.85 (range 0.65 to 1.0) for each element.

In the original review, we used an 80% cut-off point for inclusion, and called that “a high degree of family-centredness”. A score of 42 from a possible total of 52 (80%) had been chosen, based on the Pareto distribution, which says that for many events, roughly 80% of the effects come from 20% of the causes (Narula 2008).

No studies were included.

In Shields 2007, we found no studies which could be included, mainly because so few met the 80% cut-off. While our justification of implementation of the Pareto principle is sound, we decided that greater flexibility may have afforded us the opportunity to capture RCTs which tested family-centred models but which still provided a way of testing effectiveness. Hence, in this update, we lowered the cut-off point for inclusion to 50% (26 points from a total of 52). We rated a score of 50 to 80% as a ‘moderate degree of family-centredness’; and below 50% as a ‘low degree of family-centredness’. In the update, we excluded all those studies for which the intervention rated less than 50% for family-centredness, and planned to analyse separately those studies which fell into the high and moderate categories respectively.

Data extraction and management

Data were extracted from included studies by three review authors working independently (EP, LS, HZ). Any discrepancies were resolved by discussion to reach consensus. We collected descriptive data on the author, year of publication, setting, country, time span of the study, basis for calculated sample size, number of study participants, description of study participants, number of participants analysed, timing of data collection, and description of the intervention (particularly in terms of the nine elements of family-centred care as discussed earlier). We created a structured narrative presentation of the study, based on the categorisation of the interventions listed under ‘Types of interventions’, i.e. family-centred models and standard models of care. Extracted data were entered into RevMan by one review author (LS) and checked for accuracy by a second review author (HZ).

Assessment of risk of bias in included studies

We assessed the methodological risk of bias in included studies using the Cochrane Collaboration’s Risk of Bias tool (Cochrane 2008). We rated each of the following domains as ‘yes (low risk) / unclear (unclear risk) / no (high risk)’:

- random sequence generation
- allocation concealment
- blinding of participants, personnel and outcome assessors
- incomplete outcome data assessment
- selective outcome reporting
- other potential threats to validity

Two authors (LS, HZ) assessed risk of bias, and discrepancies were resolved at first by discussion and consensus, or by recourse to two other authors (JP, JH).

The Risk of Bias tool is presented in Appendix 8 and the results of the assessment are presented in the Characteristics of included studies table and Figure 1.
Data synthesis

Meta-analysis was not possible, as we identified only one study (Bolton 2004) for inclusion. Had other studies been included, the following methods would have applied: Meta-analysis would have been conducted using the fixed-effects model. Heterogeneity would have been assessed using the Chi² test of heterogeneity along with visual inspection of the graph. A significance level less than 0.10 would have been interpreted as evidence of heterogeneity. Where heterogeneity was found, the authors would have looked for an explanation. If studies with heterogeneous results were found to be comparable, the statistical synthesis of the results would have been done using a random-effects model. Sensitivity analysis would have been conducted to determine the impact of risk of bias on outcomes, if studies of different risk of bias were identified. The risk of bias criteria used in this analysis would have been in accord with the method of allocation to treatment.

Consumer participation

There are several organisations worldwide which are advocates for children and families who use health services. A representative of the Australian Association for the Wellbeing of Children in Healthcare (AWCH) provided feedback on the 2007 version of the review (Shields 2007) via the Cochrane Consumers and Communication Review Group’s standard editorial process for reviews.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

Results of the search
In the original review of family-centred care for children in hospital, of which this is an update (Shields 2007), of the 1688 records found through the searches, of which 103 were broadly relevant and thus assessed, none were found that met the inclusion criteria. For this update, from the 9271 records produced from the 2009 and 2011 searches, we identified approximately 122 papers as broadly relevant, and these were assessed in full text. Those excluded before obtaining full text papers included papers which were not research or were reports of quality improvement activities, were unrelated to family-centred care (for example, were about diseases or obesity), and were outside the age ranges of this review update. Those assessed in full text and excluded were, in the main, either ineligible study designs, mainly qualitative studies, or were about a single intervention rather than the family-centred care model as described above. After all searches were completed, we found one study (Bolton 2004) (through informal communication with a colleague), which was a chapter in a doctoral thesis, which met the inclusion criteria.

**Included studies**

We included one randomised controlled trial involving 288 participants (Bolton 2004). This trial was one part of a PhD thesis which examined the postoperative care of children post-tonsillectomy. It compared children who received standard inpatient care with children who were cared for in a care-by-parent unit (CBPU). The study was undertaken from 2002 to 2004. The CBPU met the description of family-centred care, as not only was it physically and environmentally family-centred, it was also an holistic approach which involved parents, children and family members, and met the FCC score (36/52 = 69%) (see Appendix 9).

One hundred and forty three of the participants were nursed with standard inpatient care, while 145 were admitted to the CBPU. Of these, 124 (87%) inpatients and 136 (94%) CBPU children were between 3 and 13 years of age. The study was conducted in two wards: one standard inpatient, the other a CBPU in an Australian metropolitan tertiary referral children's hospital. All public patients who were scheduled to undergo tonsillectomy with or without adenoidectomy were reviewed to assess their eligibility for inclusion. These were that the children were at least 3 years of age, had no evidence of obstructive sleep apnoea, no history of significant cardiac, respiratory or hepatic disease, and their parents did not require an interpreter or have trouble with written English.

**Interventions**

Bolton 2004 assessed the effects of admission to the care-by-parent unit (CBPU) compared with standard inpatient care post-tonsillectomy. The CBPU was a unit where parents were accommodated with their admitted children, where parents (and children as appropriate) were supported and encouraged to be part of the decision-making team, and were expected to provide as much of the care as they could appropriately undertake.

**Outcomes**

The primary outcome was a composite indicator of ‘inadequate clinical care’, which was recorded as ‘yes’ or ‘no’. This outcome was considered to be met (i.e. care was considered to be ‘inadequate’) if there was one or more instances of inadequate care from five markers:

- less than good control of nausea and vomiting (assessed by parents as fair, poor, very poor),
- less than good pain control (assessed by parents as fair, poor, very poor),
- medical attention needed but not provided within 30 minutes,
- discharge delay beyond 1200h one day post-surgery, and
- unplanned medical consultation within seven days of surgery.

This composite outcome incorporates aspects of the child’s physical health outcomes (see Types of outcome measures). Additional serious physical outcomes were assessed, such as significant haemorrhage, readmission due to complications, and pain scores. Bolton 2004 also assessed:

- child behavioural outcomes measured using the Posthospital Behaviour Questionnaire (PHBQ) (Vernon 1966) for those under 13 years and the Child Behaviour Questionnaire for parents of adolescents (the latter measure was not included in our review) (Rutter 1970);
- parental satisfaction using the standard questionnaire used by the hospital; and
- costs of post-operative care.

**Analysis**

It was planned that all data would be analysed on an intention-to-treat (ITT) basis in the first instance, although some outcomes were only able to be analysed based on return questionnaire numbers. The authors provide ITT and as-treated data for the primary outcome ‘inadequate clinical care’.

**Excluded studies**

Five studies (see Appendix 9) met all inclusion criteria except the requisite degree of family-centredness (Akinici 2008; Bauchner 1996; Landry 2007; Li 2007; Melnyk 2004). Most fell short on the family-centredness cluster ‘Cluster 2: cultural’, however, many studies were also deficient in ‘Cluster 3: supporting families’. ‘Cluster 1: family as a constant in the child’s life’ was the most consistently well scored.

In this update, we revisited the studies (Bauchner 1996; Curley 1988; Gray 2000; K-Hallstrom 1997b) which we had excluded from Shields 2007 due to lack of, or lack of clarity of, blinding of outcome assessment. They remained excluded as they did not meet the minimum family-centredness score (50%) for this update. We have identified 26 qualitative studies, which again are scored as family-centred, but, because they are qualitative studies, are not included in this update (Aein 2007; Bsiri-Moghadam 2011, etc.)
Risk of bias in included studies

We report the risk of bias assessment for Bolton 2004 below, in a risk of bias table and at Figure 1. Overall, the risk of bias for this study is rated as unclear to low risk.

Allocation

Allocation to standard inpatient care or the CBPU was done by a computer generated block randomization method. The randomisation in Bolton 2004 was conducted by an independent epidemiology and statistics unit, and the group allocations were placed in sealed opaque envelopes. Following consent, participants were allocated to the next available study number and the corresponding envelope opened.

Blinding

Given that placing a child in either the inpatient ward or CBPU could not be hidden from either researchers, staff or parents, blinding was not possible.

Incomplete outcome data

Overall, response rates across all measures were high, for example only 1% of data were missing for the primary outcome, and the authors provided reasons. Missing data were equally distributed between groups.

Selective reporting

The protocol for this study was not available; however authors reported all outcomes stated in the study's methods section.

Other potential sources of bias

While use of validated questionnaires (Posthospital Behaviour Questionnaire (Vernon 1966) and Child Behaviour Questionnaire (Rutter 1970) helped minimize possible bias in reported answers, it is possible that respondents gave results which were subjective, for example, parents assessing the behaviour of their children. Recall bias may have occurred, but this was minimized by contacting the families several times post-discharge, and was thought not to have influenced the result. The possible impact of interviewer bias was minimised by use of the same research assistant and a script.

Effects of interventions

Child

Physical outcomes

The primary outcome of 'inadequate clinical care' was analysed using intention-to-treat (ITT) and as-treated (AT) approaches. According to the ITT analysis, the CBPU patients had significantly less inadequate care than children receiving standard inpatient care. The absolute risk difference in favour of CBPU was -12.4% (95% CI -23.8% to CI -0.03%; Analysis 1.1). This difference was not influenced by age, weight, sex or concurrent adenoidectomy. When applying an ‘as treated’ analysis to account for the failure of ten allocated patients to reach the CBPU, the absolute risk difference in favour of CBPU was slightly larger: -17.6% (95% CI - 28.8% to -6.3%). Of the five components of the ‘inadequate clinical care’ composite outcome measure, the component with the largest effect was that of delayed discharges in the inpatient group (25.2%) compared with the CBPU group (6.2%). We present the individual results for each component of this outcome measure at Table 2. Other physical outcomes such as significant haemorrhage, readmission due to complications, and pain scores are also reported in Table 2. There were no significant differences between groups on any of these measures.

Behavioural outcomes

Behavioural changes in the children under 13 years measured by the Posthospital Behaviour Questionnaire (PHBQ) (Vernon 1966) showed no significant difference in behaviour change for inpatients compared to CBPU patients (mean difference (MD) -0.35 (95% CI -2.71 to 2.01; Analysis 1.2)).

Other child outcomes

None of the following child outcomes we sought were addressed in the included study:

- Psychosocial outcomes including psychological health (such as anxiety, confidence, sense of control, coping, adjustment, stress, upset, crying, insomnia, fears, behavioural regression),
attitudes towards caregivers and attitudes towards rehospitalization.
- Developmental outcomes including weight gain, developmental milestones.
- Knowledge and understanding including knowledge of condition, treatment, knowledge about personnel or procedure.
- Satisfaction: for example, with involvement in decision making, with level of communication.
- Attitudes: for example, views of cultural appropriateness, flexibility.

Parent satisfaction

Total parental satisfaction, measured before discharge on a 29-item scale, was significantly higher for parents of CBPU patients (MD 25 (95% CI 21.34 to 28.66; Analysis 1.3). Parental satisfaction measured via telephone one week after discharge (3 of 29 items reassessed) was also higher for parents whose children were in the CBPU (MD 1.3 (95% CI 0.64 to 1.96; Analysis 1.3). This result is derived from a sample that included some children over 12 years of age.

Other parent outcomes

The included study did not measure parents’ stress, perceptions of coping, sense of control, or attitudes (such as complaints, evaluations of cultural appropriateness, flexibility and responsiveness of the intervention).

Staff

We looked for psychological and satisfaction outcomes for staff but these were not measured in the included study.

Health services

Costs

Total costs (to parents and hospital combined and for the entire stay) were calculated with a range of measures, including nursing care, accommodation for parents of inpatient children who had to stay outside the hospital, surgery, recovery room and hospital costs, post-discharge medical assistance, and others. Overall, the total cost of care per admission to CBPU was estimated to be AUD$959 which was less than the total cost of care per inpatient admission, estimated to be AUD$1185.

Other health service outcomes

No other health service outcomes were measured.

Discussion

Summary of main results

The one included study was part of a composite project incorporating several sub-studies which examined the care of children following tonsillectomy, with or without adenoidectomy. Only one sub-study was an RCT that was eligible for inclusion in this review. The results show that children receiving care in a ‘care by parent unit’ (CBPU) were significantly less likely to receive inadequate care compared with standard inpatient admission, and there were no significant differences for their behavioural outcomes or other physical outcomes. Parents were significantly more satisfied with CBPU care than standard care, assessed both before discharge and at 7 days after discharge. Costs were lower for CPBU care compared with standard inpatient care. No other outcomes were reported.

Overall completeness and applicability of evidence

As some studies came close to meeting the inclusion criteria, we examined them in detail. Some studies met the criteria for study design and participants but did not fulfil the required degree of family-centredness, despite the fact that the threshold for inclusion using this scale was considerably relaxed (from 80% to 50% cut off) in this review update (see Appendix 9).

We could only include one study which provided limited evidence for some outcomes. The study did not measure the intervention’s effects on: children’s psychosocial or developmental outcomes, knowledge and understanding, satisfaction or attitudes; parents’ stress, perceptions of coping, sense of control, or attitudes, staff outcomes, and health services outcomes other than costs. The study was conducted at a single tertiary-care hospital in Australia, involving patients undergoing a relatively minor procedure (tonsillectomy). Its applicability to other settings and patient groups may be limited.

Quality of the evidence

We included one study involving 288 participants. The included study was at low risk of bias for sequence generation, allocation concealment and attrition bias and at unclear risk of bias for other items.
The fact that some data pertained to children older than 12 years, and we were unable to contact the author to obtain results for children under 12 only, means that some of the data presented here relates to children slightly outside the age range specified for this review. Overall the evidence suggests some benefit for the family-centred care intervention but this is based on a small dataset and needs confirmation in larger RCTs.

Potential biases in the review process

The tool used for scoring family-centredness (Trivette 1993; Appendix 8) has been used for scoring existing literature (as well as our previous review, Shields 2007) and so was thought to be particularly relevant for this update. The fact that the scored studies consistently fell short in Cluster 2: cultural, may indicate a need for revision of the tool before further work is conducted in this area. However, it has not been possible to find other tools. Some studies investigating family-centred service delivery have developed tools, for example the MPOC (King 1995), but this instrument, which has been widely validated in many clinical areas, examines processes of care delivery rather than assessment of existing research. We have not included the studies using MPOC because while they suggest they are about family-centred care delivery, they examine relationships between parents and health professionals only, without the holistic approach that we see as an inherent part of a family-centred care model.

It is possible that the combination of the scoring system for family-centred care and the limitation to RCTs may have created a stringency that precluded inclusion of most studies in this field. The team discussed revising the scoring criteria, but decided to retain these as a way of establishing a baseline for further investigations of the effectiveness of family-centred care. Much of the very large literature on family-centred care is anecdotal, containing descriptions, stories and reports rather than research. We therefore wanted to ensure that this review was as rigorous as possible. Future reviews may consider it reasonable to revisit these inclusion criteria and scoring systems and to consider broadening the selection criteria to include other study designs. We will address this, in part, by undertaking two reviews for the Joanna Briggs Institute. The first will be of the qualitative research found, while a second review examines the quasi-RCTs which were excluded from this updated Cochrane review (Shields 2012).

Agreements and disagreements with other studies or reviews

Because of the difficulty of measuring the family-centredness of care, much of the published research in this area has used qualitative approaches. While useful in their own right, these studies do not answer questions of effectiveness. While we do not want to pre-empt the review of qualitative studies for the Joanna Briggs Institute, early reading of the possible included studies reveal consistent themes about the delivery of family-centred care. For example, several papers (Darbyshire 1994; Coyne 1996; Coyne 2007a; O’Haire 2005) have described the resentment felt by parents when staff expect them to undertake some of the care of their hospitalised child, staff acting as gatekeepers for parents to access their own children (Coyne 2008), and parents having to negotiate with staff to have their needs met (K-Hallstrom 1999). These provide ideas for further qualitative research, which could subsequently form a basis for generating hypotheses for quantitative studies about both the acceptability and effectiveness of family-centred care.

As lifestyles continue to change over time, with the evolution of non-nuclear families, for example, parents have increasing expectations of their abilities to combine work and family life. As family structures and expectations of the healthcare experience change (often related to the development of innovative technologies in health care, and new models of care delivery) so such perspectives will affect the way care is given in hospitals. It is important that ways of measuring the effects of models such as family-centred care are developed, so that ultimately we can determine the best way to provide care for children and families in health services. Recent research has developed and validated tools to examine the family-centredness of care (Aggarwal 2009a; Aggarwal 2009b; Mitchell 2009; Shields 2004; Gill 2011; Shields 2011). These could be the basis for measurement within future quantitative studies.

Authors’ Conclusions

Implications for practice

This update has found limited evidence, in the form of a single moderate-quality RCT, to guide practice. The study suggests there may be some positive effects of family-centre care on outcomes such as adequacy of clinical care, parental satisfaction and costs. There is no evidence of harm; nor is there evidence for a range of other relevant outcomes. While awaiting further definitive evidence of the effects of family-centred care models, health services can continue to explore the application of these models as an option for children’s care in hospital.

Current arrangements in some hospital settings, whereby children and their families receive care using a model that incorporates some aspects of family-centred care, but which militate against truly regarding the family as the central unit of care, and in which ineffective negotiation about roles of both family members and staff are common, can cause resentment and inappropriate communication between families and hospital staff (Coyne 2008; Coyne 1996; Coyne 2007a; Darbyshire 1994). Future research will hopefully identify effective models of care which may ameliorate such communication breakdown between staff and families.
Implications for research

This updated review has shown that more high-quality research is needed. We found only one randomised trial providing limited evidence for the benefits of family-centred care for particular outcomes.

The included study (Bolton 2004) considered a narrow, discrete category of children having a single type of surgery (tonsillectomy), in one hospital, where contamination across groups would have been possible, and blinding difficult. Also, family-centred care is influenced by a range of factors, including the diagnosis for which the child is admitted, and the length or frequency of their hospital stay. The included study did not consider the influence of culture and ethnicity (and notably, the cultural component of the family-centredness score was given a 0 result for this study). Future research should examine the effects of family-centred care for children with a range of diagnoses, and length and frequency of hospital stays, as well as for children from different ethnic and cultural groups. This updated review has also highlighted the need for a review to examine the effects of family-centred care on adolescents and their families/careers.

We have identified clearly the elements of family-centredness that should be addressed by future intervention research. Any family-centred care intervention (model) should include the family as the centre point of the child’s life, and therefore the family should be integral to care delivery. The intervention should also include structural and environmental factors, such as accommodation for parents (which would be more than a chair beside the child’s bed) and should include bathrooms, laundries, eating places, parking and other facilities for parents and family members. A family-centred care model should take cultural differences of families into consideration, perhaps including separate spaces for prayer and reflection, culture-specific foods, and awareness of the needs of family members. Education and effective communication are important parts of a family-centred care model, and these need to be in place for both health professionals, and children and family members. Support of all kinds, for example parent to parent, or consumer groups and information services are available in a true family-centred care model. Specific interventions (venipuncture, dressings, injections, for example) in a family-centred context require the presence of parents and family members.

To minimise the risk of contamination between intervention and control groups, and to ensure a sufficiently large sample size, cluster RCTs may be the preferred model for future research. These would require the cooperation of several hospitals which were run on similar lines. Future single site studies may be at risk of contamination between groups and find blinding difficult to implement. In some situations, for example, in a town where there is only one children’s hospital/ward/unit, allocation to an experimental or control hospital/ward/unit would not be possible. Random allocation may also not be feasible when a child is admitted to a particular hospital/ward/unit for specific specialist care available only at that hospital. Further, parents’ choices may dictate where a child is admitted. If the difficulties in conducting RCTs of family-centred care prove insurmountable, before and after studies in one or two sites may be a feasible way of ascertaining the effects of family-centred care, though this would not provide the same level of evidence as a randomised trial.

Models of care are changing with differing methods of running hospitals. A family-centred care model could contain, for example, a learning package for staff and families about family-centred care, and a period of implementation of the principles learned. This becomes problematic in an era of short stays in hospital, with models of day admission and treatment the norm for many conditions. Such models could suggest that family-centred care is irrelevant, as the child stays in hospital for less than a day. However, family-centred care may be important whatever the health setting may be, and for any length of stay and involvement, including the pre-hospitalisation and follow-up phases, and so should be investigated in all healthcare settings: acute hospital, community services, and long-term facilities.

Future research should measure a range of important outcomes that have not been addressed to date, including children’s knowledge and understanding, satisfaction, parental stress, coping and sense of control, and outcomes for staff including satisfaction. Comprehensive cost measures as well as staffing and time outcomes are also needed (Shields 2006).

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Ryder 1991 [published data only]

Sacchetti 1996 [published data only]

Saenz 2009 [published data only]

Sarisoy 2011 [published data only]

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Wolfer 1975  [published data only]

Wolfer 1979  [published data only]

Wolfram 1996  [published data only]

Yager 2010  [published data only]

Ygge 2007  [published data only]

Zelkowitz 2008  [published data only]

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Aggarwal 2009b

Ahmann 1998

Ahmann 2001

Allen 1998

Bowlby 1971

Bowlby 1973

Brophy 2006

Cochrane 2008

Costello 1998

Coyne 1996

Coyne 2008

DOH 2003

Gill 2011

Higgins 2009

Hill 1996

Hurst 1993

Hutchfield 1999
IPFCC 2010

Irlam 2002

Johnson 1990

Jolley 2009

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**Shields 2012**

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Webster PD, Johnson BH. Developing family-centered vision, mission, and philosophy of care statements. Bethesda, Maryland: Institute of Family-Centered Care, 1999:55.

**References to other published versions of this review**

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**Shields 2007**

* Indicates the major publication for the study
**CHARACTERISTICS OF STUDIES**

**Characteristics of included studies  [ordered by study ID]**

**Bolton 2004**

| Methods | RCT (this was sub-study of a larger project which examined the postoperative care of children having tonsillectomy)  
The RCT compared routine inpatient care with care in a Care-by-Parent Unit (CBPU) in a tertiary referral paediatric hospital in Australia. Other investigations included various types of pain control, control of postoperative nausea and vomiting, and costs of admission |
|---|---|
| Participants | All public patients who were scheduled to undergo tonsillectomy with or without adenoidectomy were reviewed to assess their eligibility for inclusion (at least 3 years of age, no evidence of obstructive sleep apnoea, no history of significant cardiac, respiratory or hepatic disease, and parents did not require an interpreter or have trouble with written English)  
A total of 153 (inpatient) and 148 (CBPU) participants were enrolled. Of these 3 inpatients refused written consent and 7 cancelled surgery or had it performed elsewhere prior to informed consent being obtained. A further 3 CBPU participants withdrew prior to consent being obtained.  
A total of 288 participants consented to the trial and were randomly allocated to routine inpatient care (n=143) or CBPU (n=145). Some of these were over 13 years, but it was found that 260 of these children were aged between 3 and 13 years, and were analysed separately, hence were able to be included in this review (124 inpatient, 136 CBPU)  
The sample size was adjusted incrementally throughout the study as the original sample size calculation was not able to be met through the recruitment strategies employed. The author stated that initial calculations indicated that a two-group, large sample normal approximation test of proportions with a one sided 0.05 significance level of 207 participants in each group would provide an 80% power to reject the non-equivalence null hypothesis that the CBPU intervention (though it must be remembered that this part of the study constituted only a small component of the overall study) offered a lesser quality of treatment than routine inpatient care. The prespecified zone of equivalence was stated to be 0.12 (an absolute difference in the proportion of each study group reaching the primary outcome of 0.12 or more). The assumptions underpinning these sample size and zone of equivalence calculations were that the expected differences in proportions between CBPU and routine inpatient care groups was zero, and that the proportion of participants registering at least one marker of inadequate care in each study group was equal to 0.4  
Revision of the sample size was accepted by the Human Research Ethics Committee at the end of 2002 when it was apparent that the sample size would not be reached. A larger pre-specified zone of equivalence of 0.14 (the absolute difference in the proportion of each study group reaching the primary outcome was 0.14 or more) was therefore accepted. The assumptions were that the incidence of the primary outcome was unchanged at 0.4 (routine care group), that the study’s power also remained stable at 80% and so that a total of 300 subjects would be needed. In addition, the age range was enlarged to allow children over 13 years to be included |
### Interventions

Admission to care-by-parent unit (CBPU) versus standard inpatient care post-tonsillectomy. The CBPU was a unit where parents were accommodated with their admitted children, where parents (and children as appropriate) were supported and encouraged to be part of the decision-making team, and to give as much of the care as they could appropriately undertake.

### Outcomes

**Primary outcome:**

"Inadequate clinical care", which was recorded as yes or no based on a single instance of inadequate care from 5 markers:

- less than good control of nausea and vomiting (assessed by parents),
- less than good pain control (assessed by parents),
- medical attention needed but not provided within 30 minutes,
- discharge delay beyond 1200h one day post-surgery, and
- unplanned medical consultation within seven days of surgery

**Secondary outcomes:**

- Physical outcomes including primary haemorrhage, readmission, pain.
- Behavioural outcomes measured using the Posthospital Behaviour Questionnaire *(Vernon 1966)* and the Child Behaviour Questionnaire for parents *(Rutter 1970)*.
- Parental satisfaction (using the standard questionnaire used by the hospital).
- Costs of post-operative care.
- Financial impact on the family, measured as need for additional (paid and unpaid) childcare (during the admission), and number of days taken off work by the main adults involved in the child's care.

### Notes

The study was undertaken from 2002 to 2004.

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Computer generated block randomization. Random blocks of 2, 4, 6 and 8 were used</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Low risk</td>
<td>Procedure prepared by an independent epidemiology and statistics unit, and the group allocations were placed in sealed opaque envelopes. Following consent, participants were allocated to the next available study number and the corresponding envelope opened</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias) All outcomes</td>
<td>Unclear risk</td>
<td>Once the participants were in the ward or CBPU, it would have been impossible to blind them, researchers, staff or parents as to the type of care they were receiving</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>Low risk</td>
<td>Overall, response rates across all measures were high, for example only 1% of data</td>
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</tbody>
</table>
were missing for the primary outcome, and the authors provided reasons. Missing data were equally distributed between groups.

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<thead>
<tr>
<th>Bias</th>
<th>Risk</th>
<th>Details</th>
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<tbody>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Unclear risk</td>
<td>The protocol for this study was not available; however authors reported all outcomes stated in the methods section.</td>
</tr>
<tr>
<td>Other bias</td>
<td>Unclear risk</td>
<td>While use of validated questionnaires (Posthospital Behaviour Questionnaire (Vernon 1966) and Child Behaviour Questionnaire (Rutter 1970) helped minimize possible bias in reported answers, it is possible that respondents gave results which were somewhat subjective, for example, parents assessing the behaviour of their children. Recall bias may have occurred, but this was minimized by contacting the families several times post-discharge, and was thought not to have influenced the result. The possible impact of interviewer bias was minimised by use of the same research assistant and a script.</td>
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**Characteristics of excluded studies [ordered by study ID]**

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
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<tr>
<td>Abu-Hasheesh 2011</td>
<td>Intervention did not meet FCC criteria</td>
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<tr>
<td>Aein 2007</td>
<td>Ineligible study design</td>
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<td>Aggarwal 2007</td>
<td>Intervention did not meet FCC criteria</td>
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<tr>
<td>Ainhinder 1998</td>
<td>Ineligible study design</td>
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<tr>
<td>Akinci 2008</td>
<td>Less than 50% of family-centredness score</td>
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<td>Aksornsri 2011</td>
<td>Intervention did not meet FCC criteria</td>
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<tr>
<td>Almquist 1986</td>
<td>Ineligible study design</td>
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<tr>
<td>Baker 1995</td>
<td>Ineligible study design</td>
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<tr>
<td>Bauchner 1991</td>
<td>Ineligible study design</td>
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</table>
Bauchner 1996 | Excluded from Shields 2007 due to inadequate or unclear blinding of outcome assessment. Revisited for the update: less than 50% of family-centredness score
---|---
Bernaix 2008 | Intervention did not meet FCC criteria
Bevan 1990 | Intervention did not meet FCC criteria
Blank 2011 | Intervention did not meet FCC criteria
Blesch 1996 | Ineligible study design
Bloch 2008 | Intervention did not meet FCC criteria
Borghini 2006 | Intervention did not meet FCC criteria
Bouve 1999 | Intervention did not meet FCC criteria
Braude 1990 | Intervention did not meet FCC criteria
Brewer 2006 | Intervention did not meet FCC criteria
Brown 1999 | Intervention did not meet FCC criteria
Bruce 1997 | Ineligible study design
Bruce 2002 | Ineligible study design
Bsiri-Moghaddam 2011 | Ineligible study design
Burke 1997 | Intervention did not meet FCC criteria
Burke 2001 | Ineligible population
Byers 2006 | Ineligible study design
Callery 1991 | Ineligible study design
Callery 1996 | Ineligible study design
Callery 1997 | Ineligible study design
Cameron 1996 | Intervention did not meet FCC criteria
Cassady 1999 | Intervention did not meet FCC criteria
Cevasco 2008 | Intervention did not meet FCC criteria
Cheung 2004 | Ineligible study design
(Continued)

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<td>Coyne 2010</td>
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<td>Dave 2011</td>
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<td>Melnyk 2004</td>
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</tr>
<tr>
<td>Reference</td>
<td>Reason for Exclusion</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------------------</td>
</tr>
<tr>
<td>Melnyk 2007</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Meltzer 2009</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Meng 1982</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Neill 1996a</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Neill 1996b</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Newnham 2009</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Nowicka 2010</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>O’Haire 2005</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Oliveira 2011</td>
<td>ineligible study design</td>
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<tr>
<td>Ozcan 2011</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Page 1990</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Paliadelis 2005</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Parker 1992</td>
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</tr>
<tr>
<td>Parsons 2011</td>
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</tr>
<tr>
<td>Patel 2010</td>
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</tr>
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<td>Penticuff 2005</td>
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</tr>
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<td>Phipps 2007</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Pinto 1989</td>
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</tr>
<tr>
<td>Pinto 2005</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Polkki 2008</td>
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</tr>
<tr>
<td>Powers 1999</td>
<td>Ineligible population</td>
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<tr>
<td>Proctor 1987</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Reid 1995</td>
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</tr>
<tr>
<td>Rennick 2011</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Reference</td>
<td>Result</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Robinson 1991</td>
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</tr>
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<td>Roden 2005</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Roman 1995</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Rosen 2009</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Roskies 1978</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Ryder 1991</td>
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</tr>
<tr>
<td>Sacchetti 1996</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Saenz 2009</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Sarisoy 2011</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Scholten 2011</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Schroeder 2006</td>
<td>Intervention did not meet FCC criteria</td>
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</tr>
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<td>Shaw 1982</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Shields 2001a</td>
<td>Ineligible study design</td>
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<tr>
<td>Shields 2001b</td>
<td>Ineligible study design</td>
</tr>
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<td>Shin 2005</td>
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</tr>
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<tr>
<td>Silveira 2006</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Simons 2001</td>
<td>Intervention did not meet FCC criteria</td>
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<tr>
<td>Skipper 1968</td>
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<tr>
<td>Skuladottir 2003</td>
<td>Intervention did not meet FCC criteria</td>
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<tr>
<td>Smith 2011</td>
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<td>So 2011</td>
<td>ineligible study design</td>
</tr>
<tr>
<td>Spence 2006</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Author</td>
<td>Reason</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>Stratton 2004</td>
<td>Ineligible study design</td>
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<tr>
<td>Stratton 2010</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Teare 2004</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Tsuruta 2005</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Vagnoli 2010</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>van der Pal 2007</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Vavarouta 2011</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Verwey 2008</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Vessey 1994</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Voos 2010</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Vulcan 1988</td>
<td>Intervention not directed at children in hospital</td>
</tr>
<tr>
<td>Wakefield 2011</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Wang 2008</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Weinstein 1991</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Westrup 2000</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Widrick 1991</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Wolfer 1975</td>
<td>Age group outside defined parameters</td>
</tr>
<tr>
<td>Wolfer 1979</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Wolfram 1996</td>
<td>Ineligible population</td>
</tr>
<tr>
<td>Yager 2010</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
<tr>
<td>Ygge 2007</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>Zelkowitz 2008</td>
<td>Intervention did not meet FCC criteria</td>
</tr>
</tbody>
</table>
### DATA AND ANALYSES

#### Comparison 1. CBPU v usual care

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Physical outcomes</td>
<td>1</td>
<td></td>
<td>Risk Difference (M-H, Fixed, 95% CI)</td>
<td>Subtotals only</td>
</tr>
<tr>
<td>2 Behavioural outcomes (mean change in PHBQ)</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Subtotals only</td>
</tr>
<tr>
<td>3 Parental satisfaction</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Subtotals only</td>
</tr>
</tbody>
</table>

#### Analysis 1.1. Comparison 1 CBPU v usual care, Outcome 1 Physical outcomes.

**Review:** Family-centred care for hospitalised children aged 0-12 years

**Comparison:** 1 CBPU v usual care

**Outcome:** 1 Physical outcomes

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Care By Parent Unit</th>
<th>Usual care</th>
<th>Risk Difference</th>
<th>Weight</th>
<th>Risk Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolton 2004 (1)</td>
<td>54/145</td>
<td>71/143</td>
<td>-0.12 [-0.24, -0.01]</td>
<td></td>
<td>-0.12 [-0.24, -0.01]</td>
</tr>
</tbody>
</table>

**Subtotal (95% CI)**

Total events: 54 (Care By Parent Unit), 71 (Usual care)
Heterogeneity: not applicable
Test for overall effect: Z = 0.0 (P < 0.00001)
Test for subgroup differences: Not applicable

---

1. 'Inadequate clinical care' (composite outcome)
### Analysis 1.2. Comparison 1 CBPU v usual care, Outcome 2 Behavioural outcomes (mean change in PHBQ).

**Review:** Family-centred care for hospitalised children aged 0-12 years

**Comparison:** 1 CBPU v usual care

**Outcome:** 2 Behavioural outcomes (mean change in PHBQ)

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Care By Parent Unit</th>
<th>Usual care</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolton 2004</td>
<td>95</td>
<td>93</td>
<td>-0.35 [-2.71, 2.01]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: not applicable

Test for overall effect: Z = 0.0 (P < 0.00001)

![Favours CBPU](#)

### Analysis 1.3. Comparison 1 CBPU v usual care, Outcome 3 Parental satisfaction.

**Review:** Family-centred care for hospitalised children aged 0-12 years

**Comparison:** 1 CBPU v usual care

**Outcome:** 3 Parental satisfaction

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Mean Difference</th>
<th>Weight</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolton 2004 (1)</td>
<td>135</td>
<td>142</td>
<td>25.00 [21.34, 28.66]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bolton 2004 (2)</td>
<td>135</td>
<td>139</td>
<td>1.30 [0.64, 1.96]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Subtotal (95% CI) 0.0 [0.0, 0.0]

Heterogeneity: Chi² = 0.0, df = 0 (P<0.00001); I² =0.0%

Test for overall effect: Z = 0.0 (P < 0.00001)

Test for subgroup differences: Not applicable

(1) Before discharge (29 item measure)

(2) One week after discharge (3 of 29 items reassessed)
### Table 1. Association for the Care of Children’s Health: Elements of Family-Centered Care

<table>
<thead>
<tr>
<th>Elements of Family-centred Care</th>
<th>Evaluative Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recognising the family as a constant in the child’s life</td>
<td>1. Family as the principle context for the provision of a child’s health care</td>
</tr>
<tr>
<td>Facilitating parent-professional collaboration at all levels of health care</td>
<td>2. Promoting and utilizing parent-professional collaboration and partnerships</td>
</tr>
<tr>
<td>Honouring the racial, ethnic, cultural, and socioeconomic diversity of families</td>
<td>3. Respect for family diversity</td>
</tr>
<tr>
<td>Recognizing family strengths and individuality and respecting different methods of coping</td>
<td>4. Recognising the strengths and capabilities of families</td>
</tr>
<tr>
<td>5. Recognising different methods of family coping</td>
<td></td>
</tr>
<tr>
<td>Sharing complete and unbiased information with families on a continuous basis</td>
<td>6. Complete sharing of all relevant information with families</td>
</tr>
<tr>
<td>Encouraging and facilitating family-to-family support and networking</td>
<td>7. Promoting parent-to-parent and family-to-family support</td>
</tr>
<tr>
<td>Responding to child and family developmental needs as part of health care practices</td>
<td>8. Attention to the developmental needs of children and families as part of health care delivery</td>
</tr>
<tr>
<td>Adopting policies and practices that provide families with emotional and financial support</td>
<td>9. Recognising and responding to family emotional needs</td>
</tr>
<tr>
<td>10. Recognising and responding to family financial needs</td>
<td></td>
</tr>
<tr>
<td>Designing health care that is flexible, culturally competent, and responsive to family needs</td>
<td>11. Flexible delivery of health care to children and their families</td>
</tr>
<tr>
<td>12. Culturally-competent delivery of health care</td>
<td></td>
</tr>
<tr>
<td>13. Recognising and responding to family-identified needs</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2. Additional results from included study

<table>
<thead>
<tr>
<th>Outcome category</th>
<th>Data</th>
</tr>
</thead>
</table>
| Components of primary outcome ‘inadequate clinical care’ (Table 45 of Bolton 2004) | **Inadequate control of nausea and vomiting**  
Inpatient 13 (9.4%); CBPU 6 (4.4%); OR 0.5 (95% CI 0.3 to 1.4)  
**Inadequate pain control**  
Inpatient 21 (14.8%); CBPU 13 (9.6%); OR 0.61 (95% CI 0.3 to 1.4)  
**Medical attention not received within 30 mins**  
Inpatient 1 (0.7%); CBPU 0; absolute difference 0.7% |

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Table 2. Additional results from included study  (Continued)

<table>
<thead>
<tr>
<th>Delayed discharge</th>
<th>Unplanned consultation within 7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient 36 (25.2%); CBPU 9 (6.2%); OR 0.2 (95% CI 0.1 to 0.4)</td>
<td>Inpatient 52 (36.4%); CBPU 49 (33.8%); OR 0.9 (95% CI 0.5 to 1.5)</td>
</tr>
</tbody>
</table>

Secondary clinical outcomes results (no significant differences) (Table 46 of Bolton 2004)

Inpatient n = 143, CBPU n = 145

<table>
<thead>
<tr>
<th>Incidence of significant haemorrhage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient 1 (0.7%), CBPU 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incidence of respiratory events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient 1 (0.7%), CBPU 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incidence of readmission within 7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient 5 (3.5%), CBPU 7 (4.8%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Admission to ICU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient 1 (0.7%), CBPU 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deaths due to complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient 0, CBPU 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Severe vomiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient 10 (7%), CBPU 8 (5.5%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pain score greater than that acceptable by parents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient 45 (31.5%), CBPU 51 (32.5%)</td>
</tr>
</tbody>
</table>

**Appendices**

**Appendix 1. Inclusion Criteria**

Form version: 1.4 11 NOV 2009

Review title: Family Centred Care for Hospitalised Children Aged 0-12 Years

Study ID (Author Surname Year):

Name of review author completing this form:

Date form completed:

Notes (Unpublished for own use) Eg. Reference to be followed up, source of information (especially if multiple reports of same trial, or unpublished data/personal communication included).

**IN - OUT- QUERY**

Q1 Is the study an RCT? (YES/NO)

Q2 Are the children aged 0-12 years? (YES/NO)

Q3 Does this study implement a family-centred care intervention? (YES/NO)

Q4 Does the model of family-centred care in this study score >26 based on criteria below? (YES/NO)

Instructions for Applying Inclusion Criteria

Q1: Include studies that are cluster randomised trials; Include studies where the sequence generation is 'adequate' according to the Cochrane Handbook;
Simple/unrestricted randomisation, including repeated coin-tossing, throwing dice, dealing previously shuffled cards, a published list of random numbers, a list of random assignments generated by a computer; Restricted randomisation, including blocked randomisation, stratified randomisation, minimisation, biased coin or urn randomisation, replacement randomisation, mixed randomisation and maximal randomisation.

Include studies which state they are an RCT but don’t state the randomisation method (the trial authors will be contacted for information about the sequence generation method).

Exclude studies where the sequence generation is ‘inadequate’ according to the Handbook; exclude studies which state they are RCTs but turn out to be a quasi-randomized trial.

Systematic methods such as alternation, assignment based on date of birth, case record number and data of presentation are sometimes referred to as ‘quasi-random’.

Q2: Include studies if the data for children 0-12 years can be extracted and analysed. If a study mostly contains children 0-12 years of age, with a few outliers, it will be included, but no subset analysis will be undertaken.

EXCLUDE studies examined premature neonates as infants born prematurely and who are patients in a neonatal intensive or special care nursery, as their requirements for family-centred care, and the ethics and philosophies of care around this particular group, are different to those in a ward/unit where full term infants and children are nursed.

Q3: Include any healthcare intervention that aims to promote the family-centred model of care during a child’s hospitalisation. Only studies which provide clear evidence that the family and/or child were actively involved in the planning and/or delivery of healthcare during the child’s hospitalisation will be considered for inclusion in this review.

For the purposes of the review, the minimum criteria for active involvement will include evidence of collaboration between health carers and the family and/or child in the planning and/or delivery of care as soon as possible after admission, or during the preadmission period. Included studies must also compare family-centred models with standard model of care.

Types of interventions could include:
- Environmental interventions as evidenced by collaboration with the family and/or child in the design or redevelopment of facilities to provide an environment that maximises parental involvement and enhances child recovery and/or convalescence, care-by-parent units, privacy areas;
- Family-centred policies which may include open visiting hours for siblings or extended family, parent participation in their child’s care to the extent they choose (for example, feeding, bathing);
- Communication interventions could include parental presence and participation at daily interdisciplinary ward rounds and family conferences to plan future care, developing collaborative care pathways where both parent and/or child and health carer document issues and progress, reorganisation of health care to provide continuity of care-giver (such as, primary nursing), shared medical records, local hospital based interpreters;
- Educational interventions could include structured educational sessions for parents of technologically dependant children, continuing education programs to equip staff to provide care within a family-centred framework, preadmission programs;
- Family support interventions such as flexible charging schemes for poor families, referrals to other hospital or community services (such as, social workers, chaplains, patient representatives, mental health professionals, home health care, rehabilitation services), facilitating parent-to-parent support.

EXCLUDE Studies where there is no clear evidence of collaboration between the family and/or child and health care provider in the planning and/or delivery of care. Such studies could include parental presence during health care procedures such as routine examinations, anaesthetic induction, venipuncture and post-anaesthetic recovery, bereavement team/protocols, because singular interventions such as parental presence without any collaboration, communication etc does not meet the holism of FCC.

Studies which examine parental presence for a singular procedure, for the same reason. As an example, parental presence for anaesthesia induction might occur in the OR, but there's nothing to say that the same hospital will let parents be involved in any other aspect of the child’s care. Similarly, a study that examines parental presence for venepuncture is not studying FCC, rather it is only parental presence for a specific reason.

Q4: Scoring Criteria for Family Centredness
<table>
<thead>
<tr>
<th>13 Elements of FCC</th>
<th>RATING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

**Cluster 1: Family as a constant**

- Family as a constant in child’s life
- Recognising family strengths
- Parent/professional collaboration
- Needs-based family support
- Flexible provision of health care
- Sharing information with families

**Cluster 2: Culturally responsive**

- Culturally competent health care
- Respecting family diversity
- Providing financial support

**Cluster 3: Supporting family individuality & need for different types of family support**

- Respecting family coping methods
- Providing emotional support
- Family-to-family support
- Attending to the developmental needs of children and fami-
(Continued)

<table>
<thead>
<tr>
<th>ilies</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL SCORE</td>
<td>52 (___%)</td>
</tr>
</tbody>
</table>

(EXCLUDE Studies with FCC score less than 26)

<table>
<thead>
<tr>
<th>0</th>
<th>Article includes <strong>no evidence</strong> that the author(s) either implicitly or explicitly addressed, endorsed, or advocated adoption of adherence to the elements of FCC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Article includes <strong>minimal amount of implicit evidence</strong> that the author(s) advanced adoption or support of the elements of FCC</td>
</tr>
<tr>
<td>2</td>
<td>Article includes <strong>numerous instances of implicit evidence</strong> that the author(s) advanced adoption or support of the elements of FCC</td>
</tr>
<tr>
<td>3</td>
<td>Article includes <strong>minimal amount of explicit evidence</strong> that the author(s) advanced adoption or support of the elements of FCC</td>
</tr>
<tr>
<td>4</td>
<td>Article includes <strong>numerous instances of explicit evidence</strong> that the author(s) advanced adoption or support of the elements of FCC</td>
</tr>
</tbody>
</table>

Explicit evidence = an element was clearly stated and distinctly expressed
Implicit evidence = If it could be inferred that the author(s) descriptions, arguments etc. were consistent with the intent of the elements of FCC

**Appendix 2. MEDLINE (OvidSP) search strategy**

2004 to 10 December 2011 (3134)
1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. random*.tw.
4. placebo*.tw.
5. drug therapy.fs.
6. trial.tw.
7. groups.ab.
8. clinical trial.pt.
9. evaluation studies.pt.
10. research design/
11. follow up studies/
12. prospective studies/
13. cross over studies/
15. (experiment* or intervention*).tw.
16. (pre test or pretest or post test or posttest).tw.
17. (preintervention or postintervention).tw.
18. (cross over or crossover or factorial* or latin square).tw.
19. (assign* or allocat* or prospectiv*).tw.
20. (control* or compar* or prospectiv*).tw.
21. (impact* or effect? or chang* or evaluat*).tw.
Appendix 3. Cochrane Central Register of Controlled Trials (CENTRAL) search strategy

2004 - 2011

#1 MeSH descriptor Child explode all trees
#2 MeSH descriptor Infant explode all trees
#3 MeSH descriptor Pediatrics explode all trees
#4 MeSH descriptor Pediatric Nursing explode all trees
#5 (child* or Infant* or pediatric* or paediatric* or perinat* or neonat* or newborn* or baby or babies or toddler* or preterm or prematur*):ti,ab,kw
#6 ("school age" or schoolage):ti,ab,kw
#7 (#1 OR #2 OR #3 OR #4 OR #5 OR #6)
#8 MeSH descriptor Hospitalization, this term only
Appendix 4. EMBASE (OvidSP) search strategy

2004 - December Week 50 2011 (3582)
1. randomized controlled trial/
2. single blind procedure/ or double blind procedure/
3. crossover procedure/
4. random*.tw.
5. trial.tw.
6. placebo*.tw.
7. ((singl* or doubl*) adj (blind* or mask*)).tw.
8. (experiment* or intervention*).tw.
9. (pre test or pretest or post test or posttest).tw.
10. (preintervention or postintervention).tw.
11. (cross over or crossover or factorial* or latin square).tw.
12. (assign* or allocat* or volunteer*).tw.
13. (control* or compar* or prospectiv*).tw.
14. (impact* or effect* or chang* or evaluat*).tw.
15. or/1-14
16. nonhuman/
17. 15 not 16
18. exp child/
19. child*.tw.
20. exp pediatrics/
21. pediatric*.tw.
22. (perinat* or neonat* or newborn* or infant* or baby or babies or toddler*).tw.
23. (preterm or prematur*).tw.
24. (school age or school age).tw.
25. or/18-24
26. exp hospital/ or hospitalization/
27. hospital*.tw.
28. child hospitalization/ or hospitalized child/ or hospitalized infant/
29. 26 or 27
30. (29 and 25) or 28
31. family centred care/
32. family cent?red.tw.
33. caregiver/ or caregiver*.tw.
34. (famil* adj5 support*).tw.
35. exp parent/ or exp child parent relation/ or parental behavior/
36. family health/ or family/
37. family nursing/ or maternal care/
38. family coping/ or family interaction/
39. ((child or famil*) adj focus*).tw.
40. (share* adj3 care).tw.
41. ((care or cared or caring) adj3 (parent* or mother* or father* or famil*)).tw.
42. or/31-42
43. (famil* or parent* or mother* or father* or care* or mutual) adj4 (partner* or participat* or presence or involv* or decision* or 
        communicat* or collaborat* or visit*)).tw.
44. 43 or 44
45. 30 and 44
46. 30 and 45
47. 17 and 46
48. limit 47 to yr="2004-2011"

Appendix 5. PsycINFO (OvidSP) search strategy

2004 December 21 2011 (1042)
1. random*.ti,ab,hw, id.
2. (experiment* or intervention*).ti,ab,hw, id.
3. trial*.ti,ab,hw, id.
4. placebo*.ti,ab,hw, id.
5. groups.ab.
6. ((singl* or doubl* or tripl*) and (blind* or mask*)).ti,ab,hw, id.
7. (pre test or pretest or post test or posttest).ti,ab,hw, id.
8. (preintervention or postintervention).ti,ab,hw, id.
9. (cross over or crossover or factorial* or latin square).ti,ab,hw, id.
10. (assign* or allocat* or volunteer*).ti,ab,hw, id.
11. (control* or compar* or prospectiv*).ti,ab,hw, id.
12. (impact* or effect? or change* or evaluat*).ti,ab,hw, id.
13. exp experimental design/
14. ("0430" or "0450" or "0451" or "1800" or "2000").md.
15. or/1-14
16. limit 15 to human
17. (child* or infant*).ti,ab,hw, id.
18. p*ediatric*.ti,ab,hw, id.
19. (perinat* or neonat* or newborn* or infant* or baby or babies or toddler*).ti,ab,hw, id.
20. (preterm or prematur*).ti,ab,hw, id.
21. (school age or schoolage).ti,ab,hw,id.
22. or/17-21
23. (hospitals or hospitalization or hospitalized patients or hospital admission).sh.
24. hospital*.ti,ab,id.
25. 22 and (23 or 24)
26. patient cent?ered.ti,ab,id.
27. family cent?ered.ti,ab,id.
28. ((child* or famil*) adj focus*).ti,ab,id.
29. (famil* adj5 support*).ti,ab,id.
30. caregivers/
31. (mother child relations or father child relations or parent child relations).sh.
32. parental involvement/
33. exp parents/ or exp family/ or family members/
34. (shar* adj3 care).ti,ab,id.
35. ((care or cared or caring) adj3 (parent* or mother* or father* or famil*)).ti,ab,id.
36. ((famil* or parent* or mother* or father* or care* or mutual) adj4 (partner* or participat* or presence or involv* or decision* or communicat* or negotiat* or collaborat* or visit*).ti,ab,id.
37. or/26-36
38. 25 and 37
39. 38 and 16
40. limit 39 to yr="2004-2011"

Appendix 6. CINAHL (EbscoHOST) search strategy

2004 December 22, 2011 (1113)
S1. randomi?ed controlled trial*
S2. (MH "Experimental Studies+")
S3. MH Random assignment
S4. MH comparative studies
S5. MH crossover design
S6. MH placebos
S7. MH quantitative studies
S8. MH quasi-experimental studies+
S9. PT clinical trial
S10. AB (random* or trial or groups or placebo* or assign* or volunteer* or factorial* or crossover or cross over or experiment* or control* or compar* or intervention* or chang* or evaluat* or impact* or effect?) or TI (random* or trial or groups or placebo* or assign* or volunteer* or factorial* or crossover or cross over or experiment* or control* or compar* or intervention* or chang* or evaluat* or impact* or effect?)
S11. AB (singl* or doubl* or tripl* or trebl*) and AB(blind* or mask*)
S12. TI (singl* or doubl* or tripl* or trebl*) and TI (blind* or mask*)
S13. AB (pre test or pretest or post test or posttest or preintervention or postintervention) or TI (pre test or pretest or post test or posttest or preintervention or postintervention)
S14. s1 or s2 or s3 or s4 or s5 or s6 or s7 or s8 or s9 or s10 or s11 or s12 or s13
S15. MH child+
S16. AB child* or TI child*
S17. MH pediatrics+ or MH pediatric nursing+ or MH perinatal nursing
S18. ti (pediatric* or paediatric*) or ab (pediatric* or paediatric*)
S19. ti (perinat* or neonat* or newborn* or infant* or baby or babies or toddler*) or ab (perinat* or neonat* or newborn* or infant* or baby or babies or toddler*)
S20. ti (preterm or prematur*) or ab (preterm or prematur*)
S21. ti (school age or schoolage) or ab (school age or schoolage)
S22. s15 or s16 or s17 or s18 or s19 or s20 or s21
Appendix 7. Sociological Abstracts (CSA) search strategy

2004 - 5 January 2011 (53)

(KW=(random* or trial* or placebo* or assign* or allocat* or volunteer* or crossover or cross over or factorial* or singl* blind* or doubl* blind* or clinical study* or control* or compar* or intervention* or preintervention or postintervention or pre test or pretest or post test or posttest or experiment* or prospectiv* or chang* or evaluat* or impact* or effect*)) and (((DE=(children or preschool children or infants+ or pediatrics)) or (KW=(child* or pediatric or perinat* or neonat* or newborn* or infant* or baby or babies or toddler* or preterm or prematur*)) or (KW=(child* or p*diatric or perinat* or neonat* or newborn* or infant* or baby or babies or toddler* or preterm or prematur*)) or (KW=(child* or p*diatric or perinat* or neonat* or newborn* or infant* or baby or babies or toddler* or preterm or prematur*)) or (KW=(child* or p*diatric or perinat* or neonat* or newborn* or infant* or baby or babies or toddler* or preterm or prematur*)) or (KW=(schoolage or school age))) and ((DE=(hospitalization or hospitals)) or (KW=(hospital*))) and ((DE=(patient cent* or KW=(family cent*))) or (DE=(family or parents+ or caregivers))) or (KW=(child or famil*)) within 2 focus) or (KW=(child or famil*) within 2 focus) or (KW=(child or famil*) within 2 focus) or (KW=shar* within 3 care) or (KW=famil* within 5 support*) or (KW=(care or cared or caring) within 3 (parent* or mother* or father* or famil*)) or (KW=((parent* or mother* or father* or famil* or care*) within 4 (partner* or participat* or presence or involve* or decision or communicat* or negotiat* or collaborat* or visit*)))

Limited to 2004+
Appendix 8. Data Extraction Form


Form version: 1.4 11 NOV 2009

Review title: Family Centred Care for Hospitalised Children Aged 0-12 Years

Study ID (Author Surname Year):

Name of review author completing this form:

Date form completed:

Notes for Review Author

Please record the source of each piece of information, including the precise location within a document (e.g. Page, Paragraph, line); Please highlight any missing information as unclear or not described; It may be reasonable to make assumptions about how the study was conducted, but these assumptions must be reported by the review author for transparency

Methods

Aim of intervention (As stated in the trial report/s. What was the problem that this intervention was designed to address?)

Aim of study (As stated in the trial report/s. What was the trial designed to assess?)

Study design (Include number of arms involved)

Methods of recruitment of participants (How were potential participants approached and invited to participate?)

Inclusion/exclusion criteria for participation in study

Informed consent obtained? (Yes/No/Unclear)

Ethical approval (Yes/No/Unclear)

Funding (including source, amount, if stated).

Statistical methods and their appropriateness (if relevant)

Consumer involvement (e.g. In design of study and/or intervention; in delivery of intervention; in evaluation of intervention; in interpretation of study findings)

Risk of bias assessment:

<table>
<thead>
<tr>
<th>Domain</th>
<th>Review Author's Judgment</th>
<th>Description (Quote or Comment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate sequence generation?</td>
<td>Yes/No/ Unclear*</td>
<td></td>
</tr>
<tr>
<td>Allocation concealment?</td>
<td>Yes/No/ Unclear</td>
<td></td>
</tr>
<tr>
<td>Blinding for each outcome?</td>
<td>Yes/No/ Unclear</td>
<td></td>
</tr>
<tr>
<td>Incomplete outcome data addressed?</td>
<td>Yes/No/ Unclear</td>
<td></td>
</tr>
<tr>
<td>Free of selective reporting?</td>
<td>Yes/No/ Unclear</td>
<td></td>
</tr>
<tr>
<td>Free of other bias?</td>
<td>Yes/No/ Unclear</td>
<td></td>
</tr>
</tbody>
</table>

*Note: 'Yes' indicates a 'low risk of bias'; 'No' indicates a 'high risk of bias'; 'Unclear' indicates an 'uncertain risk of bias'.

Review author please refer to Table 8.5.d: Criteria for judging risk of bias in the ‘Risk of bias’ assessment tool in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2009).
Participants

Description (e.g. children/patients; carers/parents of patients; health professionals)

Geographic location (e.g. City/State/Country)

Setting (e.g. acute care hospital)

Number

- Eligible, excluded, refused to take part, randomised to intervention, randomised to control, excluded post randomisation, withdrawn, lost to follow up, died, included in analysis, included for each outcome
- Note reasons for attrition, and if attrition is different in control or intervention group, as this may be an indication of the acceptability of the intervention to the participants (e.g. people voting with their feet)

Age range, mean (standard deviation)

Gender

Ethnicity

Principal health problem or diagnosis

Treatment received/receiving

Other social/demographic details

Interventions

Details of intervention, including theoretical basis (with key references) and content (Capture this information for each arm of the study, e.g., Intervention A, Intervention B)

Details of control/usual or routine care

Details of co-interventions in all groups (co-interventions may be separate to the intervention of interest for this review, or they may be other similar elements in a suite of interventions having a common purpose. Record all relevant information).

Delivery of intervention (e.g., stages, timing, frequency, duration) (for each intervention included in the study, e.g., Intervention A; Intervention B)

Details of providers (Who delivers the intervention? number of providers; training of providers in delivery of intervention).

Intervention quality (Record any information on the quality of the intervention - assessed by study authors, others, or by you - such as the evidence base of the intervention, or the quality of staff training for intervention delivery)

Family Centeredness Score /52 ( %) (See Appendix 1)

Fidelity/integrity (Was the intervention delivered as intended? Record any assessment of this)

Outcomes

Principal and secondary outcome measures (as identified by the study authors)

Methods of assessing outcome measures (e.g., phone survey, questionnaire, physical measurements (for each outcome)

Potential sources of imprecision

- Where outcome measurement tools validated
- Are outcome measures reliable

Methods of follow-up for non-respondents

Timing of outcome assessment (Including frequency, length of follow up (for each outcome)

Adverse events (e.g. complaints, levels of dissatisfaction, adverse incidents, side effects)

Notes

- Contact with author (No /Yes (information obtained))
- Power calculation? (No / Yes)
- Record if the study was translated from a language other than English (No /Yes)
- Record if the study was a duplicate publication (No /Yes)
- Any changes in trial protocol? (No/Yes, record details)
- Record any limitations explicitly noted by the study authors
Results

Dichotomous Outcomes

<table>
<thead>
<tr>
<th>OUTCOME (Specify timing of measurement e.g. Days/Months)</th>
<th>Intervention Group Total Randomised N=</th>
<th>Control Group Total Randomised N=</th>
<th>Other reported dichotomous statistical results</th>
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<tbody>
<tr>
<td></td>
<td>Outcome N</td>
<td>Assessed N</td>
<td>Outcome N</td>
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<tr>
<td>Time</td>
<td>Family</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stress</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anxiety</td>
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<td>Stress</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Anxiety</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Length of hospital stay</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
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</tr>
<tr>
<td></td>
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</tr>
<tr>
<td></td>
<td>Stress</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Anxiety</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Work satisfaction</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
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<td>Health Services</td>
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### Rehospitalization

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<th>Control Group</th>
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<td>Mean</td>
<td>SD</td>
<td>N</td>
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</table>

### Continuous Outcomes

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<th>OUTCOMES</th>
<th>Intervention Group</th>
<th>Control Group</th>
<th>Other reported statistical results</th>
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</thead>
<tbody>
<tr>
<td>Mean</td>
<td>SD</td>
<td>N</td>
<td>Mean</td>
</tr>
</tbody>
</table>

#### Time (eg days/months)

- **Family**
  - Stress
  - Anxiety
  - Depression
  - Other

#### Child

- Stress
- Anxiety
- Length of hospital stay
- Other

#### Healthcare providers

- Stress
- Anxiety
- Work Satisfaction
- Other
<table>
<thead>
<tr>
<th>Study ID</th>
<th>Review Author</th>
<th>Family Centredness Score</th>
<th>Mean Score</th>
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<td>Cluster 1</td>
<td>Cluster 2</td>
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<td>12</td>
<td>1</td>
</tr>
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<td></td>
<td>#2</td>
<td>4</td>
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<tr>
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WHAT'S NEW

Last assessed as up-to-date: 10 December 2011.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
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HISTORY

Protocol first published: Issue 2, 2004
Review first published: Issue 1, 2007

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
</table>
| 6 July 2012        | New citation required and conclusions have changed | The newly-included study provides limited evidence for the effects of a family-centred care model on some outcomes for children and parents, and on costs. We changed the following criteria for the update of this review:  
  • included RCTs only (previously RCTs, quasi-RCTs and CBAs);  
  • lowered the threshold for inclusion in the FCC score from 80% in the original review to 50%;  
  • excluded single interventions that did not reflect a FCC model of care;  
  • excluded premature neonates from the eligible participants;  
  • removed the selection criterion whereby studies with inadequate or unclear blinding of outcome assessment were excluded from the review; and  
  • adopted the Cochrane Collaboration’s Risk of Bias tool to assess included studies.  
We have also changed terminology to describe the control comparison group: in the previous version of the review we described ‘professionally-centred models of care’ but as these are the same as standard models of care we have now adopted ‘standard models’ to describe the control group. |
| 10 December 2011   | New search has been performed              | Updated searches run, 9271 new studies assessed for inclusion, one study included                                                                                                                           |
| 9 December 2011    | Amended                                    | The title for this review has been changed to ensure that the age range of birth to 12 years is clearly identified                                                                                         |
CONTRIBUTIONS OF AUTHORS

Linda Shields, Jan Pratt and Judith Hunter: conceived the review and were content experts, providing input into the development of the background and objectives of the review.

Huaqiong Zhou: undertook review and assessment of studies, and helped with writing of completed review.

Marjory Taylor: devised search strategy, undertook searches and helped with writing completed review.

Linda Shields: helped with searches and review and assessment of studies and writing of completed review.

Elaine Pascoe: helped with the assessment of studies and data extraction and writing of completed review, and would have undertaken statistical analysis.

Jan Pratt: undertook review and assessment of studies, and assisted with writing.

Judith Hunter: undertook review and assessment of studies.

Linda Shields will be responsible for future updates.

DECLARATIONS OF INTEREST

LS, JP, HZ, and MT work for paediatric health facilities which have stated policies of family-centred care. LS is an author of potentially relevant studies and was not involved in the assessment of these studies for inclusion in the review.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In the original protocol and review (Shields 2007), we included a range of study designs (RCTs, quasi-RCTs and CBAs). For this update, we included only RCTs in an attempt to improve the methodological rigour of studies eligible for inclusion in the review. However, as a way of potentially including studies on family-centred care, we decreased the threshold for inclusion in the family-centred care intervention score from the 80% of the original review to 50%.

We have also excluded single interventions that did not reflect a FCC model of care from the review, and excluded premature neonates from the eligible participant group. Finally, we have removed the selection criterion whereby studies with inadequate or unclear blinding of outcome assessment were excluded from the review. We have also adopted the Cochrane Collaboration's Risk of Bias tool to assess included studies.

Another important difference between the original protocol and review and this update relates to screening of studies and interventions. Initial assessment in the original protocol and review was, at times, confusing, as we had to have many deliberations over whether or not to move studies of varying interventions forward for scoring of the family-centredness of interventions and quality assessment. In this update, we corrected this to ensure that only studies of a family-centred model of care, as opposed to studies of a single intervention, for example, venipuncture or parental present anaesthesia induction, became potential inclusions. This ensured a greater degree of precision within the methods of the update.

We have also changed terminology to describe the control comparison group: in the previous version of the review we described 'professionally-centred models of care' but as these are the same as standard models of care we have now adopted 'standard models' to describe the control group.

In the original review, our population of interest included premature neonates. This update has removed these from the eligible participant group because premature neonates’ requirements for family-centred care, and the ethics and philosophies of care around this particular group, are different to those in a ward/unit where full term infants and children are nursed.

In the original review we excluded studies based on blinding of outcome assessment. This update has removed this exclusion criterion.
INDEX TERMS
Medical Subject Headings (MeSH)
*Child, Hospitalized; *Family; Comprehensive Health Care [*methods]; Family Health; Infant, Newborn; Patient-Centered Care [methods]; Randomized Controlled Trials as Topic

MeSH check words
Child; Child, Preschool; Humans; Infant