Family-centred interventions for Indigenous early childhood well-being by primary healthcare services

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[Intervention Protocol]

Family-centred interventions for Indigenous early childhood well-being by primary healthcare services

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects of family-centred interventions for Indigenous early childhood well-being, delivered by primary healthcare services in Canada, Australia, New Zealand, and the USA, on a range of physical, psychosocial and behavioural outcomes of Indigenous children, parents and families.

BACKGROUND

Description of the condition

The clear need for improved approaches to the health of Indigenous families is evidenced by the striking disparities in health between Indigenous and non-Indigenous children in Canada, Australia, New Zealand, and the USA. Disparities are evident in infant mortality rates which are 1.7 to 4 times higher than those of non-Indigenous infants (Smylie 2009). In addition, higher rates of sudden infant death syndrome, child injury, accidental death, suicide, ear infections, respiratory tract illness and mortality, dental caries and exposure to environmental contaminants have been reported (Smylie 2009). Health inequities are consistently reported across the four countries examined in this review, although there is diversity in indicators across and within their Indigenous populations: the Aboriginal people and Torres Strait Islanders of Australia; First Nations, Metis and Inuit peoples of Canada; the Maori of New Zealand; and American Indian, Alaskan Native and Native Hawaiian peoples of the USA (Cunningham 2003; Welch 2015). To inform health equity, it is important to examine and use diverse data from these different populations; yet consistent with Cochrane

Library Special Collections on the health of Indigenous peoples (Welch 2015), restricting the review to Indigenous populations of the four included countries allows identification of important differences.

Indigenous populations across the included four colonial settler countries have experienced colonisation by Britain as a shared and underlying determinant of Indigenous health; health systems and services are similar; and exclusionary social policies have to varying degrees disrupted family relations, continuity and functioning (Smylie 2009). Unlike many Western families that are typified by a nuclear family unit, Indigenous families across each of these countries commonly include members of their extended families, with child rearing practices that differ from those of the dominant settler cultures. However, strong bonding capital commonly characterises Indigenous families and constitutes a strength upon which engagement in health promoting approaches with services can be built.

A functioning family is defined as one in which members communicate, relate, maintain relationships in healthy ways, and make decisions and solve problems (Silburn 2006; Zubrick 2000). However, the enduring impact of colonial legacies means that many Indigenous families live in environments that are not conducive to good health. Some families have to deal with ongoing stressors, which can impact on their contributions to work, family life, community, culture and broader society, and their ability to nurture children. Family dysfunction can manifest in issues which affect the health and well-being of children. These include psychological distress, grief, smoking, alcohol and drug misuse, mental illnesses, and/or violence. In turn, families can experience issues such as lack of food security and neglect. Indigenous children are currently many times more likely to be removed from their families than other children (e.g. AIHW 2015).

Health promoting approaches (including the practices and key issues of family-centred practice) that are effective in non-Indigenous settings cannot necessarily be translated effectively to Indigenous applications (Health Council of Canada 2011; McCalman 2014). However, the family context is critical to primary health care for Indigenous children.

Description of the intervention

Historically, maternal and child health delivered through primary healthcare services has focused on the management of women's pregnancies and infants' health and development, rather than support and care for the whole family, their lives and well-being concerns. The concept of family-centred health care for children originated more than 35 years ago through the ecological theory of child development of Bronfenbrenner 1979, which stressed the importance of considering both the immediate and extended family, and home environment (Hammer 1998). The concept also draws on the theory of patient-centred care, which advocates that healthcare delivery should be focused on the patient's needs, values and preferences (Dwamena 2012). Primary health services have attempted to implement family-centred interventions into practice as "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). Indigenous primary healthcare services have implemented family-centred interventions to reflect the decision-making processes of Indigenous families, and potentially improve maternal and early childhood outcomes. A scoping review of Indigenous family-centred approaches targeting pregnant women and their children aged 0 to 5 years in Australia, Canada, New Zealand and the USA found 18 evaluation studies of such interventions (McCalman unpublished). The studies generally reported care provided to extended family members by or with Indigenous health professionals or paraprofessionals, and focused on health promotion as well as clinical care (McCalman unpublished).

However, differing definitions of family-centred health care have prompted various approaches to the implementation of Indigenous family-centred care. Homer 2012, for example, described an urban intervention akin to a standard maternal and child healthcare approach but based on a group practice caseload model, providing individualised care by a midwife and Aboriginal health educator, and with continuity of care provided during pregnancy, labour, birth, and postnatally, with referral to child health services after discharge. Griew 2007, on the other hand, proposed an intersectoral approach, linking health and childcare services, encompassing both: 1) provision of care to patients by seeing them as embedded in a family and providing services on that basis; and 2) a life course approach, which, without neglecting adult health, focuses specific attention on establishing early life resilience and advantages through a focus on child development.

How the intervention might work

A literature review by MacKean 2005 found that family-centred care entailed six core principles. These are: 1) recognising the family as central to and/or the constant in the child's life, and the child's primary source of strength and support; 2) acknowledging the uniqueness and diversity of children and families; 3) acknowledging that parents bring expertise at both the individual care-giving level and the systems level; 4) recognising that family-centred care is competency enhancing rather than weakness focused; 5) encouraging the development of true collaborative relations between families, healthcare providers and partner organisations; and 6) facilitating family-to-family support and networking, and providing services that offer emotional and financial support to meet the needs of families (p. 75). The implementation of these principles in practice, however, has been more problematic. Based on these principles, a checklist of the elements of family-centred care was developed (Trivette 1993). This checklist was used to score studies that were included in a Cochrane review of family-centred care for

hospitalised children (Shields 2012), and in a scoping review of Indigenous family-centred approaches (McCalman unpublished). As described below, the principles of family-centred interventions can be found in a broad range of intervention types. These include:

1. environmental interventions that provide an environment to maximise parental involvement and enhance child health or well-being;
2. communication interventions that include parents in collaborative care pathways, and/or reorganisation of health care to provide continuity of caregiver;
3. educational interventions that include structured educational sessions for parents or staff;
4. counselling interventions that include brief interventions, home visiting and other approaches; and
5. family support interventions such as flexible charging schemes for poor families, referrals to other community services, and facilitating parent-to-parent support (Shields 2012).

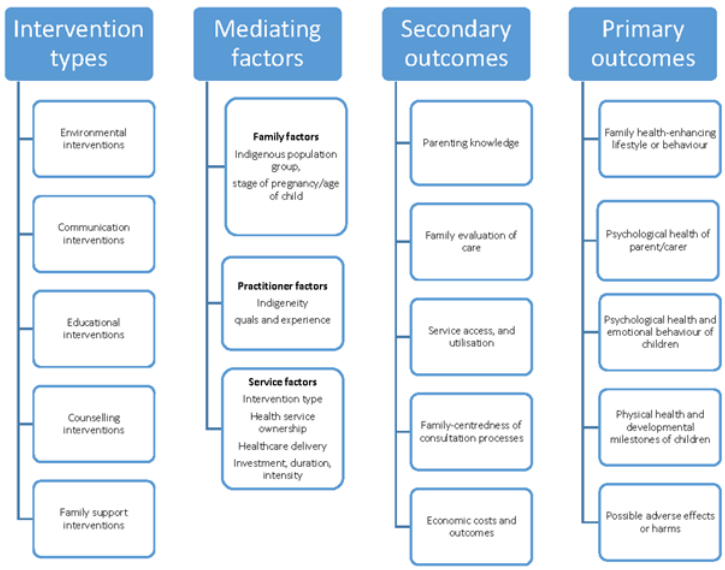
Considerable debate continues among health professionals and researchers about the strategies needed for the implementation of family-centred health care. The debates have centred on five key issues. First, there is debate about the necessary types of relationships between healthcare providers and families (DHS Disability Services Division 2012; Dodd 2009). Bamm 2008 described health professionals' consideration of their primary responsibility as providing education, counselling, and information. In contrast, principles most valued by families were availability, accessibility, and communication. Patients and families considered partnerships as important, yet this was not mentioned by healthcare providers (Bamm 2008). Such diversity of perspective has created tensions relating to the focus of and strategies for family healthcare implementation. Second is the emphasis on family choice and participation (Dodd 2009). MacKean 2005 iterated the key tension thus: "Family-centred care is beginning to sound like something that is being defined by experts and then carried out to families, which is ironic given that the concept of family-centred care emerged from a strong family advocacy movement" (p. 81). Third, there is a debate about the knowledge and expertise required to apply information and deliver quality family-centred supports and services (DHS Disability Services Division 2012; Dodd 2009). Barlow 2015 suggests that well-trained Indigenous paraprofessionals can effectively enhance parenting knowledge, parental locus of control and psychosocial outcomes; whereas D'Espaignet 2003 focused on the role of midwives supported by Aboriginal female Elders (Barlow 2015; D'Espaignet 2003). Fourth, debates have centred on the optimal context/s for family-centred health care, including home visiting or clinic-based service provision or both (Dodd 2009). Fifth, methodological issues have centred on the selection of comparison interventions, defining the treatment regimen or intervention components, and identification of adverse effects (Dodd 2009).

Family-centred health care has the potential to generate a range of outcomes. These have included a decrease in depression rates and burden in carers, clinically-important improvements in treatment outcomes (both functionally and with respect to time), and satisfaction with care and quality of life of the entire family (Bamm 2008). Bamm 2008 indicated that although family-centred care required an initial investment for the education of staff and the development of new strategies, in the long term it improved the effectiveness and efficiency of the health services and reduced the financial burden on the system. However, the authors concluded that further research was needed to explore the direct financial benefits of a family-centred approach.

Our scoping review of family-centred interventions found the following outcomes for Indigenous children: increased birthweight (D'Espaignet 2003); promise for obesity prevention (Harvey-Berino 2003); and reduced behavioural problems (Barlow 2013; Barlow 2015; Turner 2007; Walkup 2009). Outcomes for primary carers included reduced maternal depression and illegal drug use (Barlow 2013; Barlow 2015); significantly better parenting knowledge, skills, attitudes and locus of control (Barlow 2013; Barlow 2015; Harvey-Berino 2003; Turner 2007; Walkup 2009); as well as improved service access and consumer satisfaction (Turner 2007).

Our logic model delineates the outcomes of family-centred care (Figure 1). These outcomes might be expected to vary with different types of family-centred healthcare intervention, Indigenous populations, and stages of pregnancy or child development.

Figure 1. Logic model



Why it is important to do this review

There has been no systematic review of studies about the effects of family-centred health care delivered through primary healthcare services on the health and well-being of Indigenous children and their parents or carers. Neither has there been a review of the effects of family-centred health care on the healthcare encounters experienced by Indigenous families, their satisfaction or healthcare behaviour, or the delivery of these services. The authors of a 2012 Cochrane review found one randomised controlled trial (RCT) providing moderate-quality evidence of the effects of family-centred care for children in hospitals (Shields 2012). Based on a small sample size, the included study suggested some benefit for children's clinical care, parental satisfaction, and costs; with no evidence of harms. The focus of the review however, was on tertiary rather than primary healthcare settings, and all population groups rather than Indigenous populations.

With regard to Indigenous maternal and child health, one review of the health of Indigenous children (from birth to age 12) evaluated the quality of Indigenous child health data collection in Canada, Australia, New Zealand, and the USA (Smylie 2009). This review did not focus on family-centred health care and is now seven years old. An Australian review of family-centred primary health care for Indigenous families (Griew 2007); and another of Indigenous family functioning (Walker 2008) were completed, but these were not systematic reviews and are now seven to eight years old. Other reviews were restricted to Indigenous Australian populations (Eades 2004; Herceg 2005; Jongen 2014), did not focus on family-centred care, and were completed over 10 years ago (Eades 2004; Herceg 2005).

Our scoping review found 24 papers that described, theorised or evaluated Indigenous family-centred interventions. Only three of these studies (seven papers) used RCT or controlled before and after study designs that enable evaluation of the effectiveness of family-centred interventions (McCalman unpublished). This Cochrane review will enable primary healthcare service providers to make evidence-informed decisions about how family-centred approaches are likely to affect the well-being of Indigenous children aged from conception to five years, the lifestyle and behavioural outcomes of their families, and the psychological health of their parents/carers. It will also assist services to determine whether there are likely to be any adverse events or harms of these interventions. The review will also inform decisions about the

likely effects of family-centred interventions on parenting knowledge and satisfaction with care, healthcare service access or utilisation, consultation processes and economic costs and outcomes.

OBJECTIVES

To assess the effects of family-centred interventions for Indigenous early childhood well-being, delivered by primary healthcare services in Canada, Australia, New Zealand, and the USA, on a range of physical, psychosocial and behavioural outcomes of Indigenous children, parents and families.

METHODS

Criteria for considering studies for this review

Types of studies

Due to the complex nature of many family-centred interventions, it is likely that limiting the review to randomised controlled trials (RCTs) would exclude important evidence. Additionally, there are inherent ethical considerations for researchers proposing RCTs with Indigenous populations due to historically poor relationships between predominantly non-Indigenous researchers and Indigenous participants (Bainbridge 2015; Glover 2015). The inclusion of alternative study designs is likely to provide relevant and meaningful data. Review results will be presented according to study design to facilitate meaningful comparisons and enable robust estimates of confidence.

To evaluate the effectiveness of the family-centred interventions, we will include RCTs, cluster RCTs and quasi-RCTs (a trial in which randomisation is attempted but subject to potential manipulation, such as allocating participants by day of the week, date of birth, or sequence of entry into trial) (CCCRG 2016). We will also include controlled before-after (CBA) studies meeting the following criteria:

- there are at least two intervention sites and two control sites;
- the timing of the periods of study for the control and intervention groups is comparable (that is, the pre- and post-intervention periods of measurement for the control and intervention groups should be the same); and
- the intervention and control groups are comparable on key characteristics.

Interrupted time series (ITS) designs will also be included if:

- the intervention occurred at a clearly-defined point in time specified by the researchers; and
- there were at least three data points before and three data points after the intervention was introduced (CCCRG 2016).

Types of participants

We will include studies in which the population includes either the families who receive family-centred care and/or health service providers of family-centred care.

For the purposes of this review, we define 'Indigenous' as peoples who self-identify at the individual level and are accepted by the community as a member (UN Permanent Forum on Indigenous Issues). A family is considered to be Indigenous if the child is identified by the family as Indigenous (one parent may be non-Indigenous).

We define a 'child' as a foetus, newborn infant, baby and child up to the age of five years. Five years is a common age at which final early child health checks are carried out by primary healthcare services prior to school entry. Studies including school-aged children will only be included if the main focus of the family-centred intervention is health care for children under five years, or if the majority of participants were aged from conception to five years. Studies relating to family-centred antenatal care delivered by primary healthcare services will be included.

We define a 'family' as a basic social unit having two or more persons, irrespective of age, in which each of the following conditions is 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 (Nixon 1988).

We define 'healthcare providers' as those involved in providing primary health care for Indigenous children.

Types of interventions

Studies will be included if they target Australian, Canadian, New Zealander or USA Indigenous children aged from conception up to five years, and evaluate a family-centred intervention implemented by a primary healthcare service. The family-centredness of interventions will be delineated using a modified rating scale used for the aforementioned scoping study (McCalman unpublished). The scale is based on a validated instrument which includes 13 evaluation items that describe the features of family-centred care, clustered under three groups: 1) family as a constant, 2) culturally responsive, and 3) supporting family individuality (Appendix 2) (Shields 2012; Trivette 1993). Pregnancy care models that do not continue beyond the standard postpartum period of 6 weeks to at least 3 months are considered to not meet criteria for recognition of constancy or meeting children's developmental needs. Each of the 13 elements is equally weighted and scored from 0 to 4, with 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. An element of family-centred

care will be considered to be implicitly addressed if it can be inferred that the author(s)' descriptions or arguments are consistent with the intent of the elements of family-centred care, whereas it will be considered to explicitly address the element if the author/s clearly state and distinctly express that this element is present in health practice (Trivette 1993).The scores are added together to give an overall rating of family-centredness for each study. Following Shields 2012, the family-centredness score for inclusion is 26/52 or greater than 50%; studies which do not meet criteria for family-centredness will be excluded.

Interventions may comprise a broad range of types, including the following:

- environmental interventions as evidenced by collaboration with the family and/or child in the design or redevelopment of the home or primary healthcare centre to provide an environment that maximises parental involvement and enhances child health or well-being;
- communication interventions which promote parental participation in health education to plan antenatal or postnatal care, develop collaborative care pathways where both parent and/or child and health carer document issues and progress, or reorganise health care to provide continuity of caregiver;
- educational interventions which deliver structured educational sessions for parents, or continuing education programs to equip staff to provide care within a family-centred framework;
- counselling interventions such as brief interventions about family violence or other well-being issues, home visiting and other approaches; and
- family support interventions such as flexible charging schemes for low-income families, referrals to other community services (such as social workers, chaplains, patient representatives, mental health professionals, home health care, rehabilitation services), or facilitation of parent-to-parent support.

We will include studies which compare family-centred healthcare intervention versus usual maternal and child health care or one form of intervention versus another. We will disentangle complex or multifaceted interventions by noting where the intervention components are also included in the comparison arm, and hence effectively 'cancel those components' from the assessment. Where a component is not included in the comparison arm, we will compare each separately to no intervention/control; and with one another. We will then report the effects as being attributable to the 'active' or 'unique' components of the intervention arm only.

Interventions must be implemented by a primary healthcare service/s. A primary healthcare service is defined as a service providing the first level of contact of individuals, families and the community with the healthcare system (APHCRI 2009). All components of primary healthcare services that provide a service to children will be included. Where studies describe interventions at the interface between services (e.g. hospital discharge to primary health care; integrated approaches with child care or child protection services) they will be included only if the intervention is led by the primary healthcare service.

Types of outcome measures

The focus of this review on family-centred interventions means that study outcomes may focus on either the whole family, parents/carers, children, the health practitioner and/or health service factors. The outcome measures are selected to account for this potential diversity.

The primary outcome categories of family-centred care are:

1. family health enhancing lifestyle or behaviour outcomes;
2. the psychological health of parent/carer; and
3. the psychological health and emotional behaviour of Indigenous children aged from conception to five years.

Adverse outcomes are also included as primary outcomes.

Secondary outcomes are the immediate effects of the healthcare encounter on:

1. family factors: parenting knowledge and evaluation of care; and
2. health practitioner and service factors: service access and utilisation; the family-centredness of consultation processes and economic costs and outcomes (Figure 1).

Primary outcomes

1. Psychological health and emotional behaviour of children including:

- level of stress, upset, crying, infant separation distress, child anxiety, insomnia, mood, fears and behavioural regression, well-being;
- self-esteem, levels of confidence, self-expression; and
- coping, adjustment, compliance.

2. Physical health and developmental health outcomes of children including:

- clinical assessments (e.g. injury resolution);
- physiological measures (e.g. anaemia levels); and
- developmental milestones.

3. Family health enhancing lifestyle or behaviour outcomes including:

- weight control, control over child's food intake, birth weight;
- breastfeeding;
- reduced substance misuse, reduced smoking, reduced alcohol consumption, reduced addictions and other risk taking;
- home safety, safe sleeping.

4. Psychological health of parent/carer including:

- level of stress, anxiety, depression, mood, well-being;
- self-esteem, levels of confidence in parenting; and
- perceptions of coping, sense of control.

5. Possible adverse events or harms, including:

- health behaviours (e.g. violence);
- clinical adverse effects;
- poor utilisation or access;
- low quality of care; and
- increased inequities.

Secondary outcomes

1. Parenting knowledge and awareness including:
   - knowledge about nutrition, smoking, alcohol in pregnancy, children's early years' conditions and treatment; and
   - awareness of home safety issues.

2. Family evaluation of care including:
   - family-professional interactions' experience, relationship with healthcare practitioner, involvement in decision making, level of communication, flexibility and responsiveness of the intervention, cultural competency;
   - perceptions and ratings of care or interventions, complaints; and
   - family satisfaction with the information and/or resources provided, satisfaction with the decision/s made, satisfaction with care, sense of control.

3. Service access and utilisation including:
   - proportion of women who received antenatal care, proportion of other family members who received health education, extent to which healthcare providers gave specific advice or delivered specific interventions;
   - adherence to antenatal or postnatal care plans;
   - proportion of children who received child health checks;
   - linkages to other services; and
   - family healthcare utilisation.

4. Family-centredness of consultation processes including:
   - practice style, level of family-centred care, service flexibility and responsiveness, practitioner knowledge;
   - provision of interventions, choices offered, visiting services, home visiting, tailored literacy and language initiatives; and
   - service quality, adherence to recommended practice or guidelines, cultural competence.

5. Economic costs and outcomes associated with the interventions including:
   - costs of specific interventions (e.g. educational, clinical, immunisation);
   - costs of care (e.g. costs of home-visiting care, costs of staffing requirements, time needed for the intervention); and
   - cost savings.

Selection of outcomes

Family-centred interventions are complex and may have many outcomes, measured in many different ways. Outcomes will not be used as criteria for including studies. Instead, outcomes will be categorised at review stage. Two authors will independently assign the outcomes reported in each included study to the review's outcome categories and resolve any differences in categorisation, if they occur, by consensus with a third author. This may mean that more than one outcome is assigned to each outcome category at review stage. For such cases, objective measures (e.g. anaemia levels, antenatal visit records) will be used in preference to subjective or self-reported measures (e.g. self-reported levels of parental/caregiver confidence or coping). Again, two authors will independently make these decisions before mutual discussion and final consensus with a third author. In cases where one trial has measured the same outcome with more than one measure, we will select the most 'clinically' important measure so as not to over-represent this data. Given that family-centred interventions are complex interventions and may have been carried out across many health conditions, the type of outcomes within an outcome category may be quite varied. However, each outcome will be considered and analysed separately.

Timing of outcome assessment

Time points will be grouped into short-, medium- and long-term time points with no more than one time interval for each outcome from each study selected. Short-term outcomes are defined as those which occur within 3 months, medium-term outcomes from 3 to 12 months, and long-term outcomes greater than 12 months.

Main outcomes for 'Summary of findings' table

The review's primary outcomes intended for inclusion in the 'Summary of findings' table are:

1. family health enhancing lifestyle or behaviour outcomes;
2. the psychological health of the parent/carer;
3. the psychological health and emotional behaviour of Indigenous children; and
4. adverse outcomes.

For each of these outcomes, we will report in the 'Summary of findings' table a measure of the typical burden of these outcomes, absolute and relative magnitude of effect (where relevant), numbers of participants and studies addressing these outcomes, a grade of the overall quality of the body of evidence for each outcome (which will vary by outcome) and comments.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library;

- MEDLINE OvidSP;
- Embase OvidSP;
- PsycINFO OvidSP;
- CINAHL EBSCOhost;
- Informit Indigenous Collection (Informit); and
- Current Contents (Ovid).

We will search the following clinical trial registries:

- ClinicalTrials.gov;
- Current Controlled Trials; and
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (who.int/ictrp/en/).

We present the strategy for MEDLINE (OvidSP) in Appendix 1. We will tailor strategies to other databases and report them in the review.

No language or date restriction will be applied to the searches. We will seek translation when necessary.

We will search grey literature sources, such as reports and conference proceedings, through clearinghouses: the Australian Indigenous Health InfoNet, Australian Institute of Family Studies, Indigenous Knowledge Network for Infants (Canada), Child and Family Health (Canada), Li Ka Shing database (Canada), Child Welfare Information Gateway: Working with American Indian Children and Families (USA), and New Zealand Social Policy Evaluation and Research Unit.

We will handsearch the reference lists of Indigenous maternal and child health reviews, reviews of family-centred care in general populations and any study chosen for potential inclusion in this review to identify further relevant studies. We will contact authors of included studies and experts in the field to determine whether there are any additional studies that may be relevant.

Data collection and analysis

Selection of studies

Two authors will independently screen all titles and abstracts identified from searches to determine which of them meet the inclusion criteria for full text review. We will retrieve in full text any papers identified as potentially relevant by at least one author. Two review authors will independently screen full text articles for inclusion or exclusion, with discrepancies resolved by discussion and by consulting a third author if necessary to reach consensus. All potentially-relevant papers excluded after full text review will be listed as excluded studies, with reasons provided in the 'Characteristics of excluded studies' table. We will also provide citation details and any available information about ongoing studies, and collate and report details of duplicate publications, so that each study (rather than each report) is the unit of interest in the review. We will report the screening and selection process in an adapted PRISMA flow chart (Liberati 2009).

Data extraction and management

Two review authors will extract data independently from included studies. Any discrepancies will be resolved by discussion until consensus is reached, or through consultation with a third author where necessary. We will develop and pilot a data extraction form using the Cochrane Consumers and Communication Review Group Data Extraction Template (available at: cccrg.cochrane.org/author-resources). Data to be extracted will include the following: study aim, study design, number and description of comparison group/s, consumer involvement, funding source, declaration of interests by authors, informed consent, ethical approval, risk of bias (including random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias), overall quality rating, description of participants, geographical location, setting, methods of recruitment, participation rate, attrition, inclusion criteria, gender, Indigenous population, stage of pregnancy/age of child, exclusion of any group from study, principal health focus, study numbers (as per Data Extraction Template), intervention name, intervention aims and rationale, type of intervention (environmental, education, communication, counselling, family support), what was done, who delivered the intervention, where was it provided, when and how often was it provided, tailoring of intervention, modification or adaptation of intervention, assessment of implementation fidelity, score on family-centredness scale, primary and secondary outcomes (including adverse events), method of assessing outcome measures, method of follow up for non-respondents, timing of outcome assessment, other information and notes (author contact details, correspondence with authors and response, translation, duplicate publication), dichotomous and continuous and/or other data and results (as per Data Extraction Template). A summary report for individual studies will be outlined in the 'Characteristics of included studies' tables and outcome data will be entered into RevMan (RevMan 2014) by one review author, and will be checked for accuracy against the data extraction sheets by a second review author working independently.

Assessment of risk of bias in included studies

We will assess and report on the methodological risk of bias of included studies in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) and the guidelines of the Cochrane Consumers and Communication Review Group (Ryan 2013). The *Handbook* and guidelines recommend the explicit reporting of the following individual elements for RCTs: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data; selective outcome reporting; and other potential sources of bias, for example, baseline imbalance, contamination, differential diagnostic activity. We will consider blinding separately for different outcomes where ap-

propriate (for example, blinding may have the potential to differently affect subjective versus objective outcome measures). We will judge each item as being at high, low or unclear risk of bias as set out in the criteria provided by Higgins 2011, and provide a quote from the study report and a justification for our judgement for each item in the 'Risk of bias' table.

Studies will be deemed to be at the highest risk of bias if they are scored as being at high or unclear risk of bias for either the sequence generation or allocation concealment domains, or objectivity of outcome data or completeness of outcome data (intention-to-treat), based on growing empirical evidence that these factors are particularly important potential sources of bias (Higgins 2011).

In all cases, two authors will independently assess the risk of bias of included studies, with any disagreements resolved by discussion to reach consensus. We will contact study authors for additional information about the included studies, or for clarification of the study methods as required. We will incorporate the results of the 'Risk of bias' assessment into the review through standard tables, and systematic narrative description and commentary about each of the elements, leading to an overall assessment the risk of bias of included studies and a judgment about the internal validity of the review's results.

We will assess and report quasi-RCTs as being at a high risk of bias on the random sequence generation item of the 'Risk of bias' tool. For cluster RCTs we will also assess and report the risk of bias associated with an additional domain: selective recruitment of cluster participants.

We will assess CBA studies against the same criteria as RCTs but report them as being at high risk of bias on both the random sequence generation and allocation sequence concealment items. We will exclude CBA studies that are not reasonably comparable at baseline.

We will assess and report on the following items for ITS studies: intervention independence of other changes; pre-specification of the shape of the intervention effect; likelihood of intervention affecting data collection; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data; selective outcome reporting; and other sources of bias including baseline imbalance (due to lack of randomisation).

Measures of treatment effect

For dichotomous outcomes, we will analyse data based on the number of events and the number of people assessed in the intervention and comparison groups. We will use these to calculate the risk ratio (RR) and 95% confidence interval (CI).

For continuous measures, we will analyse data based on the mean, standard deviation (SD) and number of people assessed for both the intervention and comparison groups to calculate mean difference (MD) and 95% CI. If the MD is reported without individual group data, we will use this to report the study results. If more than one study measures the same outcome using different tools, we will calculate the standardised mean difference (SMD) and 95% CI using the inverse variance method in RevMan 2014.

For CBAs we will use appropriate effect measures for dichotomous outcomes (RR, adjusted RR) and for continuous outcomes (relative % change post intervention, SMD).

For ITS, effect measures used will include: i) change in level of the outcome at the first point after the introduction of the intervention, and ii) the post-intervention slope minus the pre-intervention slope. These estimates are calculated from regression models adjusting for autocorrelation. It is not appropriate to present means and SDs of pre-intervention versus post-intervention time points.

Unit of analysis issues

If cluster RCTs are included we will check for unit-of-analysis errors. If errors are found, and sufficient information is available, we will reanalyse the data using the appropriate unit of analysis, by taking account of the intracluster correlation (ICC). We will obtain estimates of the ICC by contacting authors of included studies, or impute them using estimates from external sources. If it not possible to obtain sufficient information to reanalyse the data we will report effect estimates and annotate "unit-of-analysis error".

Dealing with missing data

We will attempt to contact study authors to obtain missing data (participant, outcome, or summary data). For participant data, we will, where possible, conduct analysis on an intention-to-treat basis; otherwise data will be analysed as reported. We will report on the levels of loss to follow-up and assess this as a source of potential bias.

For missing outcome or summary data we will impute missing data where possible and report any assumptions in the review. We will investigate, through sensitivity analyses, the effects of any imputed data on pooled effect estimates.

Assessment of heterogeneity

Where studies are considered similar enough (based on types of family-centred healthcare intervention, Indigenous populations and child's age) to allow pooling of data using meta-analysis, we will assess the degree of heterogeneity by visual inspection of forest plots and by examining the Chi^2 test for heterogeneity. We will report our reasons for deciding that studies were similar enough to pool statistically. Heterogeneity will be quantified using the I^2 statistic. An I^2 value of 50% or more will be considered to represent substantial levels of heterogeneity, but this value will be interpreted in light of the size and direction of effects and the strength of the evidence for heterogeneity, based on the P value from the Chi^2 test (Higgins 2011). Where heterogeneity is present in pooled

effect estimates we will explore possible reasons for variability by conducting subgroup analysis.

Where we detect substantial clinical, methodological or statistical heterogeneity across included studies (> 75%) we will not report pooled results from meta-analysis but will instead use a narrative approach to data synthesis. In this event we will attempt to explore possible clinical or methodological reasons for this variation by grouping studies that are similar in terms of country, Indigenous populations and types of family-centred healthcare intervention to explore differences in intervention effects.

Assessment of reporting biases

We will assess reporting bias qualitatively, based on the characteristics of the included studies (e.g. if only small studies that indicate positive findings are identified for inclusion), and if information that we obtain from contacting experts and authors or studies suggests that there are relevant unpublished studies.

If we identify sufficient studies (at least 10) for inclusion in the review we will construct a funnel plot to investigate small study effects, which may indicate the presence of publication bias. We will formally test for funnel plot asymmetry, with the choice of test made based on advice in Higgins 2011, and bearing in mind that there may be several reasons for funnel plot asymmetry when interpreting the results.

Data synthesis

We will decide whether to meta-analyse data based on whether the interventions in the included trials are similar enough in terms of participants, settings, intervention, comparison and outcome measures to ensure meaningful conclusions from a statistically pooled result. Due to the anticipated variability in the intervention types and populations of included studies, we will use a random-effects model for meta-analysis.

Given the expected heterogeneity, it is unlikely that we will report pooled results from meta-analysis, but will instead apply a narrative approach to data synthesis. In this event we will clearly report our reasons for deciding that studies were too dissimilar to meta-analyse. We will also attempt to explore possible clinical or methodological reasons for this variation by grouping studies that are similar in terms of the major types of intervention (i.e. environmental, communication, educational, counselling, family support) to explore differences in intervention effects. Depending on the assembled research, we may also explore the possibility of organising the data by Indigenous population and child's age. Within the data categories we will explore the main comparisons of the review:

- intervention versus usual care; and
- one form of intervention versus another.

Where studies compare more than one intervention, we will compare each separately to no intervention/ control; and with one another.

If we are unable to pool the data statistically using meta-analysis, we will group the data based on the category that best explores the heterogeneity of studies and makes most sense to the reader (i.e. by interventions, populations or outcomes). Within each category we will present the data in tables and summarise the results narratively.

Subgroup analysis and investigation of heterogeneity

Three potential effect modifiers will be investigated through subgroup analyses to determine whether these might impact the intervention effect. These are intervention type (i.e. environmental, communication, educational, counselling, family support); Indigenous population (Aboriginal, Torres Strait Islander, First Nations, Metis, Inuit, American Indian, Native Alaskan, Native Hawaiian, Maori/Tangata Whenua); and age of child.

The effect of the intervention might be expected to be different for different intervention types because these have different aims and foci, may be delivered through diverse healthcare service ownership (government, non-government, Indigenous-controlled), healthcare modes (e.g. outreach, in clinic, home-based), by different healthcare providers (e.g. doctor, allied health, nurse, health-worker-led, support groups or peers, traditional birth attendants) and have various levels of investment, duration or intensities of delivery (Smylie 2009). The type of healthcare service, provider and setting (clinic, home or other) will affect the nature of their relationship with families (Hammer 1998).

The effect of the intervention might be different for diverse Indigenous populations within and between countries (Bamm 2008; Hammer 1998; Smylie 2009). Although Indigenous peoples across Australia, Canada, New Zealand and the USA have all experienced family disruption and health effects from processes of colonisation, they each have differing cultural family rearing practices and have experienced differing policies that have affected family continuity in diverse ways and to differing extents.

The effects of family-centred interventions might be expected to be different depending on the age of the child because health care needs vary at different ages. There is evidence from the literature of differing effects of family-centred interventions according to the age group targeted (Bamm 2008). These factors also have practical relevance for how family-centred interventions are delivered. Age of children will be categorised according to 3 groups: antenatal, i.e. conception to birth; postnatal to 12 months; more than 12 months up to 5 years.

If there are too few included studies to warrant statistical subgroup analyses, we will explore relationships in the data through narrative, i.e. presenting a narrative form of subgroup analyses.

Sensitivity analysis

If appropriate, we will complete a sensitivity analysis to assess the impact on the primary outcomes of excluding studies assessed as being at high risk of bias. We will manage the situation whereby 'true' RCTs are unclear or at high risk of bias for sequence generation (some of which may not be RCTs but quasi-RCTs) by including them in meta-analysis irrespective of their rating for sequence generation. We will then conduct sensitivity analyses, excluding those at unclear or high risk of bias, to examine the robustness of the meta-analysis results to methodological limitations of the included studies. It is likely that we will conduct the sensitivity analysis by comparing the results from fixed-effect versus random-effects meta-analysis. However, the decision regarding sensitivity analysis will be made based on the assembled data and included studies.

'Summary of findings' table

We will prepare a 'Summary of findings' table to present the results of meta-analysis, based on the methods described in chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011). We will include the major comparisons of the review, for each of the major primary outcomes, including potential harms, as outlined in the Types of outcome measures section. We will provide a source and rationale for each assumed risk cited in the table/s, and will use the GRADE system to rank the quality of the evidence using the GRADEprofiler (GRADEpro) software (Schünemann 2011). If meta-analysis is not possible, we will present results in a narrative 'Summary of findings' table format, such as that used by Chan 2011.

Ensuring relevance to decisions in health care

The protocol received feedback from health providers and family members who receive a family-centred intervention through Apunipima Cape York Health Service (Australia) about the meaning and relevance for them of family-centred interventions. We will conduct further pre-planned meetings using formal group methods to reach consensus decisions on key issues relating to the structure and methods of the review. As per the method of Pollock 2015, primary healthcare providers and family members will be asked to reach consensus over the key components of family-centred approaches and the key messages emerging from the completed review. We have ethics approval (H6260) to engage the health workers and midwives who deliver the Baby One Program and (as resources allow) Cape York family members who care for young children.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

1. (aborigin* or indigen*).ti,ab,kw.
2. (first nation* or native people*).ti,ab,kw.
3. oceanic ancestry group/
4. (first australian* or torres strait* islander*).ti,ab,kw.
5. maori*.ti,ab,kw.
6. american native continental ancestry group/
7. indians north american/
8. ((american* or canadian) adj1 indian*).ti,ab,kw.
9. (exp united states/ or exp canada/ or exp new zealand/ or (america* or canad* or alaska* or new zealand*).ti,ab,kw.) and native*.ti,ab,kw.
10. (metis or cherokee* or chippewa* or choctaw* or navajo* or sioux).ti,ab,kw.
11. inuits/
12. (inuit* or eskimo* or inupiat* or yupik*).ti,ab,kw.
13. hawai*.ti,ab,kw.
14. or/1-13
15. (family or families).mp.
16. (father* or mother* or husband* or wife* or paternal or maternal or grandparent* or guardian*).mp.
17. parenting/
18. (parent or parents or parental or parenting).ti,ab,kw.
19. exp maternal health services/
20. (prenatal or perinatal or postnatal or postpartum).ti,ab,kw.
21. or/15-20
22. 14 and 21
23. exp pregnancy/
24. pregnan*.mp.
25. exp "embryonic and fetal development"/
26. exp fetus/
27. exp infant/
28. child preschool/
29. (fetus* or foetus* or unborn child* or baby or babies or newborn or neonat* or infant? or toddler* or preschool* or pre-school* or kindergarten or early child*).ti,ab,kw.
30. exp pregnancy complications/
31. exp infant newborn diseases/
32. exp neurodevelopmental disorders/
33. "early intervention (education)"/
34. or/23-33
35. 22 and 34
36. randomized controlled trial.pt.
37. controlled clinical trial.pt.
38. random*.tw.
39. placebo*.tw.
40. trial.tw.
41. groups.ab.
42. clinical trial.pt.
43. evaluation studies.pt.
44. research design/
45. follow up studies/
46. prospective studies/
47. cross over studies/

48. comparative study.pt.
49. (experiment* or intervention*).tw.
50. (pre test or pretest or post test or posttest).tw.
51. (preintervention or postintervention).tw.
52. time series.tw.
53. (cross over or crossover or factorial* or latin square).tw.
54. (assign* or allocat* or volunteer*).tw.
55. (control* or compar* or prospectiv*).tw.
56. (impact* or effect? or chang* or evaluat*).tw.
57. or/36-56
58. 35 and 57

Appendix 2. Criteria for family-centredness

Family-centredness rating score (13 elements)
RATING 0 1 2 3 4

	Paper 1	Paper 2	Paper 3	Paper 4
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				

(*Continued*)

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 families				
TOTAL SCORE / 52 (%)				

(EXCLUDE Studies with Family centredness score less than 26 or 50%)
0 Article includes no evidence that the author(s) either implicitly or explicitly addressed, endorsed, or advocated adoption of adherence to the elements of family-centred care
1 Article includes a minimal amount of implicit evidence that the author(s) advanced adoption or support of the elements of family centred care
2 Article includes numerous instances of implicit evidence that the author(s) advanced adoption or support of the elements of family centred care
3 Article includes a minimal amount of explicit evidence that the author(s) advanced adoption or support of the elements of family centred care
4 Article includes numerous instances of explicit evidence that the author(s) advanced adoption or support of the elements of family centred care
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 family centred care

CONTRIBUTIONS OF AUTHORS

- Janya McCalman: drafted the protocol, will contribute to selecting included studies, contribute to extracting data, draft the final manuscript, guarantee the review, revise the final manuscript, and take responsibility for updating the review.

- Sandra Campbell: assisted with drafting the protocol, will contribute to selecting included studies, extracting data, assessing levels of family-centredness, advising on processes for consumer feedback, carrying out the analysis, interpreting the analysis, contributing to drafting of the final review, and revising the final manuscript.

- Catherine Chamberlain: assisted with drafting the protocol, will contribute to selecting included studies, extracting data, assessing levels of family-centredness, advise on the analysis, advise on interpretation of the analysis, and revise the final manuscript.

- Natalie Strobel: assisted with drafting the protocol, will contribute to extracting data, contribute to assessing levels of family-centredness, carry out the analysis, interpret the analysis, contribute to drafting of the final review and revise the final manuscript.

- Roxanne Bainbridge: will contribute to selecting studies for inclusion, assess level of family-centredness and revise the final manuscript.

- Mark Wenitong: will contribute to selecting studies for inclusion, advise on processes for consumer feedback, provide advice about the clinical relevance of outcomes and revise the final manuscript.

- Alan Ruben: will contribute to selecting studies for inclusion, advise on processes for consumer feedback, provide advice about the clinical relevance of outcomes and revise the final manuscript.

- Karen Edmond: will contribute to selecting studies for inclusion, provide advice about the clinical relevance of outcomes, and revise the final manuscript.

- Rhonda Marriott: will contribute to selecting studies for inclusion, provide advice about the clinical relevance of outcomes, and revise the final manuscript.

- Komla Tsey: will contribute to drafting the final review and revise the final manuscript.

- Katrina Keith: will assist in developing the search strategy, run the search strategy, obtain copies of studies, enter data into RevMan 2014 and revise the final manuscript.

- Linda Shields: will advise on assessment of family-centredness and revise the final manuscript.

DECLARATIONS OF INTEREST

Study authors, including McCalman, Bainbridge, Campbell and Tsey, have published papers which might be included in the review. In such cases, the author/s in question will not be involved in assessing the study for inclusion, nor extracting or analysing data from that study.

- Janya McCalman: Funding was provided by the Centre for Research Excellence for Improving Health Services for Aboriginal and Torres Strait Islander Children (ISAC) via Apunipima Cape York Health Service to James Cook University for leadership and co-ordination of the review. This funding supported employment through a short-term, part-time contract.

- Sandra K Campbell: Funding was received by James Cook University (my employer) to support employment of the lead author of the review.

- Catherine Chamberlain: I am a recipient of an Australian National Health and Medical Research Council Early Career Fellowship, which has a focus on Indigenous maternal public health.

- Natalie A Strobel: None known.

- Roxanne G Bainbridge: None known.

- Mark Wenitong: None known.

- Alan Ruben: None known.

- Karen M Edmond: None known.
- Rhonda Marriott: No other competing interest.
- Komla Tsey: None known.
- Katrina Keith: None known.
- Linda Shields: None known.

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NOTES

This protocol is based on standard text and guidance provided by Cochrane Consumers and Communication.