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

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TABLE OF CONTENTS

[Intervention Review]

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

Natalie A Strobel[1,2], Catherine Chamberlain[3], Sandra K Campbell[4], Linda Shields[5,6], Roxanne G Bainbridge[7], Claire Adams[1], Karen M Edmond[8], Rhonda Marriott[9], Janya McCalman[7]

[1]Kurongkurl Katitjin, Edith Cowan University, Mount Lawley, Australia. [2]Medical School, The University of Western Australia, Perth, Australia. [3]Melbourne School of Population and Global Health, University of Melbourne, Carlton, Australia. [4]College of Nursing & Midwifery, Charles Darwin University, Darwin, Australia. [5]Faculty of Medicine, The University of Queensland, Brisbane, Australia. [6]School of Nursing, Midwifery and Paramedicine, University of the Sunshine Coast, Sunshine Coast, Australia. [7]School of Human Health and Social Sciences, Central Queensland University, Cairns, Australia. [8]Department of Women and Children's Health, King's College London, London, UK. [9]Ngangk Yira Research Centre for Aboriginal Health and Social Equity, Murdoch University, Murdoch, Australia

Contact: Natalie A Strobel, n.strobel@ecu.edu.au.

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ABSTRACT

Background

Primary healthcare, particularly Indigenous-led services, are well placed to deliver services that reflect the needs of Indigenous children and their families. Important characteristics identified by families for primary health care include services that support families, accommodate sociocultural needs, recognise extended family child-rearing practices, and Indigenous ways of knowing and doing business. Indigenous family-centred care interventions have been developed and implemented within primary healthcare services to plan, implement, and support the care of children, immediate and extended family and the home environment. The delivery of family-centred interventions can be through environmental, communication, educational, counselling, and family support approaches.

Objectives

To evaluate the benefits and harms of family-centred interventions 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 (aged from conception to less than five years), parents, and families.

Search methods

We used standard, extensive Cochrane search methods. The latest search date was 22 September 2021.

Selection criteria

We included randomised controlled trials (RCTs), cluster RCTs, quasi-RCTs, controlled before-after studies, and interrupted time series of family-centred care interventions that included Indigenous children aged less than five years from Canada, Australia, New Zealand, and the USA. Interventions were included if they met the assessment criteria for family-centred interventions and were delivered in primary health care. Comparison interventions could include usual maternal and child health care or one form of family-centred intervention versus another.

Data collection and analysis

We used standard Cochrane methods. Our primary outcomes were 1. overall health and well-being, 2. psychological health and emotional behaviour of children, 3. physical health and developmental health outcomes of children, 4. family health-enhancing lifestyle or behaviour outcomes, 5. psychological health of parent/carer. 6. adverse events or harms. Our secondary outcomes were 7. parenting knowledge and awareness, 8. family evaluation of care, 9. service access and utilisation, 10. family-centredness of consultation processes, and 11. economic costs and outcomes associated with the interventions. We used GRADE to assess the certainty of the evidence for our primary outcomes.

Main results

We included nine RCTs and two cluster-RCTs that investigated the effect of family-centred care interventions delivered by primary healthcare services for Indigenous early child well-being. There were 1270 mother–child dyads and 1924 children aged less than five years recruited. Seven studies were from the USA, two from New Zealand, one from Canada, and one delivered in both Australia and New Zealand. The focus of interventions varied and included three studies focused on early childhood caries; three on childhood obesity; two on child behavioural problems; and one each on negative parenting patterns, child acute respiratory illness, and sudden unexpected death in infancy. Family-centred education was the most common type of intervention delivered. Three studies compared family-centred care to usual care and seven studies provided some 'minimal' intervention to families such as education in the form of pamphlets or newsletters. One study provided a minimal intervention during the child's first 24 months and then the family-centred care intervention for one year. No studies had low or unclear risk of bias across all domains. All studies had a high risk of bias for the blinding of participants and personnel domain.

Family-centred care may improve overall health and well-being of Indigenous children and their families, but the evidence was very uncertain. The pooled effect estimate from 11 studies suggests that family-centred care improved the overall health and well-being of Indigenous children and their families compared no family-centred care (standardised mean difference (SMD) 0.14, 95% confidence interval (CI) 0.03 to 0.24; 2386 participants).

We are very uncertain whether family-centred care compared to no family-centred care improves the psychological health and emotional behaviour of children as measured by the Infant Toddler Social Emotional Assessment (ITSEA) (Competence domain) (mean difference (MD) 0.04, 95% CI −0.03 to 0.11; 2 studies, 384 participants). We assessed the evidence as being very uncertain about the effect of family-centred care on physical health and developmental health outcomes of children. Pooled data from eight trials on physical health and developmental outcomes found there was little to no difference between the intervention and the control groups (SMD 0.13, 95% CI −0.00 to 0.26; 1961 participants). The evidence is also very unclear whether family-centred care improved family-enhancing lifestyle and behaviours outcomes. Nine studies measured family health-enhancing lifestyle and behaviours and pooled analysis found there was little to no difference between groups (SMD 0.16, 95% CI −0.06 to 0.39; 1969 participants; very low-certainty evidence). There was very low-certainty evidence of little to no difference for the psychological health of parents and carers when they participated in family-centred care compared to any control group (SMD 0.10, 95% CI −0.03 to 0.22; 5 studies, 975 parents/carers).

Two studies stated that there were no adverse events as a result of the intervention. No additional data were provided. No studies reported from the health service providers perspective or on outcomes for family's evaluation of care or family-centredness of consultation processes.

Authors' conclusions

There is some evidence to suggest that family-centred care delivered by primary healthcare services improves the overall health and well-being of Indigenous children, parents, and families. However, due to lack of data, there was not enough evidence to determine whether specific outcomes such as child health and development improved as a result of family-centred interventions. Seven of the 11 studies delivered family-centred education interventions. Seven studies were from the USA and centred on two particular trials, the 'Healthy Children, Strong Families' and 'Family Spirit' trials. As the evidence is very low certainty for all outcomes, further high-quality trials are needed to provide robust evidence for the use of family-centred care interventions for Indigenous children aged less than five years.

PLAIN LANGUAGE SUMMARY

Care involving families for Indigenous early childhood well-being

Key messages

There was a small improvement on the overall health and well-being of Indigenous children and their families when they participated in family-centred care programmes at a primary healthcare service, but we have very low confidence in the overall evidence.

All studies used community engagement strategies, which is an important aspect of working with Indigenous communities.

Further adequately powered studies are likely to provide better estimates of the effects of family-centred care.

What is family-centred care?

Family-centred care is a way of providing care that focuses on the needs of children and provides planned care around the whole family unit. It recognises that all family members are care recipients and aims to involve families in partnership with primary healthcare services.

Why is a specific focus needed on family-centred care in Indigenous health?

Family-centred care is important for all children, but interventions must consider sociocultural needs. Caring for children within Indigenous families often involves extended family member' roles and responsibilities, cultural child-rearing practices, and holistic (treatment of the whole person, taking into account mental and social factors rather than just the symptoms of a disease) understandings of well-being centred on connectedness. Engaging in family-centred health promoting approaches through primary healthcare services could be an effective means of delivering care to children that considers the needs and functioning of the wider family.

What did we want to find out?

There has been no well-conducted review of studies examining the effects of family-centred health care delivered through primary healthcare services on the health and well-being of Indigenous children and their families. One scoping review (a brief assessment of the research and evidence) completed in 2017 found 18 evaluations on family-centred care for Indigenous children and families with three randomised controlled trials (well-designed studies that provide the best evidence) identified. As a result, we wanted to find out if family-centred care improved:

– the overall health and well-being of Indigenous children and their families;

– specific aspects of care such as physical health and development of children or the psychological health of families.

We also wanted to know how delivering family-centred care affected health service providers and the care they delivered.

What did we do?

We searched for studies that looked at family-centred care interventions that were delivered in Canada, Australia, New Zealand, and the USA led by primary healthcare services to Indigenous children aged less than five years. We compared and summarised the results of the studies and rated our confidence in the evidence.

What did we find?

We found 11 studies that enrolled 1270 mother–child pairs and 1924 children aged less than five years. Most of the family-centred interventions delivered to children had different foci such as childhood obesity, behavioural problems, negative parenting patterns, and acute respiratory illness. Seven studies used education as a way of delivering family-centred care. All studies compared family-centred care interventions to usual care or a minimal control comparison. Seven studies were from the USA, two from New Zealand, one from Canada, and one from both Australia and New Zealand.

Family-centred care may improve overall health and well-being of Indigenous children and their families, but the evidence was very uncertain. There was little to no difference in psychological health and emotional behaviour of children, physical health and developmental outcomes of children, family health-enhancing lifestyle and behaviours, and psychological health of parents and carers, but the evidence was very uncertain.

What were the limitations of the evidence?

We are not confident in the evidence because people in the studies were aware of what intervention they were getting, and many people did not come back to report their results. Not all the studies reported the information we were interested in. Studies that did report on the data we were interested in were very specific to that particular study, so we had to make some assumptions about whether the data were applied to all families.

How up to date is this evidence?

The evidence is up to date to 22 September 2021.

SUMMARY OF FINDINGS

Summary of findings 1. Family-centred care compared to any control for Indigenous children aged less than five years

Family-centred care compared to any control for Indigenous children aged < 5 years

Patient or population: Indigenous children aged < 5 years

Setting: primary health care

Intervention: family-centred care

Comparison: usual care or minimal intervention

Outcomes	Illustrative comparative risks* (95% CI)		№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with any control	Risk with family-centred care			
Overall health and well-being Timing: the longest time point available for each study Direction of effect: higher beneficial	—	The mean SMD score in the intervention group was 0.14 SD higher (0.03 higher to 0.24 higher)	2386 (11 RCTs)	⊕⊖⊖⊖ **Very low**[a,b]	Family-centred care may improve the overall health and well-being of Indigenous children and their families, but the evidence is very uncertain.
Psychological health and emotional behaviour of children Timing: the longest time point available for each study Direction of effect: higher beneficial	The mean psychological health and emotional behaviour of children ranged from 0.95 to 1.02 points	The mean MD score in the intervention group was 0.04 points higher (0.03 lower to 0.11 higher)	384 (2 RCTs)	⊕⊖⊖⊖ **Very low**[a,c]	The evidence is very uncertain about the effect of family-centred care on psychological health and emotional behaviour of children.
Physical health and developmental health outcomes of children Timing: the longest time point available for each study Direction of effect: higher beneficial	—	The mean SMD score in the intervention group was 0.13 SD higher (0.00 lower to 0.26 higher)	1961 (8 RCTs)	⊕⊖⊖⊖ **Very low**[a,b]	The evidence is very uncertain about the effect of family-centred care on physical health and developmental health outcomes of children.
Family health-enhancing lifestyle or behavioural outcomes Timing: the longest time point available for each study	—	The mean SMD score in the intervention group was 0.16 SD higher (0.06 lower to 0.39 higher)	1969 (9 RCTs)	⊕⊖⊖⊖ **Very low**[a,b]	The evidence is very uncertain about the effect of family-centred care on family health-enhancing lifestyle or behavioural outcomes.

Direction of effect: higher beneficial					
Psychological health of parent/carer Timing: the longest time point available for each study Direction of effect: higher beneficial	The mean psychological health of a parent carer was 48.71.	The mean SMD mental health scores were 0.10 SD higher (0.03 lower to 0.22 higher).[e]	975 (5 RCTs)	⊕⊖⊖⊖ **Very low**[a,d]	The evidence is very uncertain about the effect of family-centred care on psychological health of parent/carer.
Adverse events or harms Direction of effect: lower beneficial	2 studies reported narrative information on adverse events. 1 study measured adverse events and side effects and reported that no aspect of the intervention including the application of fluoride varnish resulted in any reported adverse events. 1 study reported on emergency department presentations and hospital admissions as adverse events. No adverse events reported were deemed to be the result of the intervention.		Unclear participants (2 RCTs)	⊕⊖⊖⊖ **Very low**[a,c]	The evidence is very uncertain about the effect of family-centred care on adverse events of harm.

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: confidence interval; **RCT:** randomised controlled trial; **SD: s**tandard deviation; **SMD:** standardised mean difference.

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a]Crucial biases on multiple criteria and likely to seriously alter results. This included no blinding of participants and interventionist, people delivering the intervention collected the data, high attrition, and selective outcome reporting. Downgraded two levels.
[b]Individual outcome measure had different constructs but we combined them to provide a broad result for the outcome. Downgraded one level.
[c]Small sample size. Downgraded one level.
[d]Outcome measure had similar constructs but did not completely overlap (e.g. general mental health compared to depression). Downgraded one level.
[e]We converted the standardised mean difference value 0.10 to a mean difference. The mean of the control group, as measured by the Short Form Health Survey – Mental Health component (SF-12), was used for comparison as it was the most recent study (HCSF 2 2017).

BACKGROUND

Description of the condition

There are striking disparities in health between Indigenous and non-Indigenous children in Canada, Australia, New Zealand, and the USA. Infant mortality rate ratios are 1.6 to 4 times higher among Indigenous infants than non-Indigenous infants, and higher rates of morbidities are consistently reported (Smylie 2010). These include injuries, respiratory infections, ear infections, and increased potentially preventable hospitalisations (Barnes 2019; Falster 2016; Jervis-Bardy 2014). Health inequalities are consistently reported across the four countries that are the focus of this review. However, there is diversity in health 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).

Indigenous populations across the included four countries have experienced colonisation by European countries as a shared and underlying determinant of Indigenous health; and harmful social policies, to varying degrees, have disrupted family relations, continuity, and functioning (Smylie 2009). Unlike many non-Indigenous families that are typified by a nuclear family unit, Indigenous families across each of these countries commonly include childcare responsibilities for extended family members and communities, with cultural child-rearing practices fostering physical, social, and emotional well-being (McMahon 2017). Connectedness is central to Indigenous social and emotional well-being (Gee 2014; Waterson 2004).

A 'functioning family' is defined as one in which members communicate, relate, maintain relationships in healthy ways, make decisions, and solve problems (Silburn 2006; Zubrick 2000). The enduring impact of colonial legacies means that some Indigenous families experience historical and transgenerational trauma and live in environments that are not conducive to good health (Atkinson 2003; Ka'apu 2019). 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. Intergenerational trauma can manifest in issues that affect the health and well-being of families (Chamberlain 2019). These include psychological distress, grief, smoking, alcohol and drug misuse, mental illnesses, and violence. In turn, families can experience issues such as lack of food security and neglect. Health-promoting approaches (including the practices and key issues of family-centred practice) that are effective for non-Indigenous children might not necessarily translate effectively for Indigenous children (Health Council of Canada 2011; McCalman 2014). However, families are central to the well-being of children, and there is a clear need to ensure that family-centred primary healthcare interventions consider the sociocultural needs, context, and experiences Indigenous families.

Description of the intervention

Historically, child health delivered through primary healthcare services focused on the management of infants' health and development, rather than support and care for the whole family, their lives, and well-being concerns. The concept of family-centred care for children originated in the 1970s through the ecological theory of child development (Bronfenbrenner 1979), which stressed the importance of considering both the immediate and extended family, and home environment (Hammer 1998; Jolley 2009). The concept also draws on the theory of patient-centred care, which advocates that healthcare delivery should focus on the patient's needs, values, and preferences (Dwamena 2012). Primary healthcare services have attempted to implement family-centred interventions 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).

Important characteristics identified by families for primary healthcare include services that support families, accommodate sociocultural needs, recognise extended family child-rearing practices, Indigenous ways of knowing and doing business, accessibility, and delivering care responsive to holistic health (Gomersall 2017). As a result, Indigenous primary healthcare services are well-placed to deliver family-centred care interventions and have implemented family-centred interventions to reflect the decision-making processes of Indigenous families, and potentially improve early childhood outcomes. A scoping review of Indigenous family-centred approaches targeting pregnant women and their children from birth to aged five years in Canada, Australia, New Zealand, and the USA found 18 evaluation studies of family-centred interventions (McCalman 2017). The studies generally reported care provided to extended family members by or with Indigenous health professionals or paraprofessionals, and focused on health promotion and clinical care (McCalman 2017).

However, differing definitions of family-centred care have prompted various approaches to the implementation of family-centred care. For example, Homer 2012 described an urban intervention akin to a standard maternal and child healthcare approach but based on a group midwifery practice caseload model. The intervention model provided individualised care by a known midwife and Aboriginal health educator during pregnancy, labour, birth, and postnatally, with referral to child health services after discharge. In contrast, Griew 2007 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, focused specific attention on establishing early life resilience and advantages through a focus on child development.

How the intervention might work

One literature review found that family-centred care entailed six core principles (MacKean 2005). These were: 1. recognising the family as central to or the constant (or both) 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 caring 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 offered emotional and financial support to meet the needs of families (p. 75). 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 one Cochrane Review of family-centred care for hospitalised children (Shields 2012), and in a scoping review of family-centred approaches for Indigenous children (McCalman 2017).

Considerable debate continues among health professionals, family representatives, communities, and researchers about the strategies needed for the implementation of family-centred care. The debates centre 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 suggested 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, some debates centre on the optimal context/s for family-centred care, including home visiting or clinic-based service provision, or both (Dodd 2009). Finally, methodological issues centre on the selection of comparison interventions, defining the treatment regimen or intervention components, and identification of adverse effects (Dodd 2009).

Family-centred care aims to improve a range of outcomes including a decrease in parental depression rates and burden in carers, and satisfaction with care and increased quality of life of the entire family (Bamm 2008). Bamm 2008 indicated that while family-centred care required an initial investment in the education of staff and the development of new strategies, in the long term it improved the effectiveness and efficiency of health services and reduced the financial burden on the system; particularly because families are empowered to be active partners in providing care. 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 using a range of study designs 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); and improved service access and consumer satisfaction (Turner 2007). These outcomes might be expected to vary with different types of family-centred healthcare intervention, Indigenous populations, and stages of pregnancy or child development.

Why it is important to do this review

There are no meta-analyses of studies specifically examining 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 one 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. However, the focus of the review was on tertiary rather than primary healthcare settings, and all population groups rather than a specific focus on Indigenous populations.

With regard to Indigenous child health, one review of the health of Indigenous children (from birth to age 12 years) 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 over 10 years old. One 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 over 10 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 15 to 20 years ago (Eades 2004; Herceg 2005).

Our previous narrative 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-after (CBA) study designs that enabled evaluation of the effectiveness of family-centred interventions (McCalman 2017). This Cochrane systematic review and meta-analysis will generate data on the combined intervention effect to enable primary healthcare service providers and families to make more 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 from these interventions. This review may inform decisions about the likely effects of family-centred interventions on parenting knowledge and evaluation of care, healthcare service access or utilisation, consultation processes, and economic costs and outcomes.

OBJECTIVES

To evaluate the benefits and harms of family-centred interventions 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 (aged from conception to less than five years), parents, and families.

METHODS

Criteria for considering studies for this review

Types of studies

Many family-centred interventions are complex in nature. Therefore, this review did not limit study designs to RCTs because doing so could exclude important evidence. Additionally, there are inherent ethical considerations for researchers proposing RCTs with Indigenous populations. Some of these considerations include the distrust between predominantly non-Indigenous researchers and Indigenous participants, and culturally inappropriate material or procedures (Bainbridge 2015; Glover 2015). People who do participate in RCTs often face barriers such as trials not addressing likely participant barriers such as telephone availability and travel costs as well as a lack of recognition in adapting and incorporating of Indigenous knowledge systems (Glover 2015). The inclusion of alternative study designs was likely to provide relevant and meaningful data. Review results are 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 included 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 also included CBA studies meeting the following criteria:

- there were at least two intervention sites and two control sites;
- the timing of the periods of study for the control and intervention groups was comparable (i.e. the pre- and postintervention periods of measurement for the control and intervention groups were the same); and
- the intervention and control groups were comparable on key characteristics.

Interrupted time series (ITS) designs were also 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 included studies in which the population included either the families who received family-centred care or health service providers of family-centred care, or both.

For this review, we defined 'Indigenous' as peoples who self-identified at the individual level and were accepted by the community as a member (UN Permanent Forum on Indigenous Issues). A family was considered Indigenous if the child was identified by the family as Indigenous (one parent could be non-Indigenous).

We defined 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 were included only if the main focus of the family-centred intervention was care for children aged under five years, or if the majority (greater than 50%) of participants were aged from conception to five years. Studies relating to family-centred antenatal care delivered by primary healthcare services were included if they continued beyond the standard postpartum period of six weeks to at least three months.

We defined a 'family' as a basic social unit having two or more people, irrespective of age, in which each of the following conditions was present: 1. the members were related by blood, marriage, adoption, or by a contract that was either explicit or implied; 2. the members communicated 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 adopted or created and maintained common customs and traditions (Nixon 1988). We defined 'primary healthcare providers' as those involved in providing primary health care for Indigenous children.

Types of interventions

Studies were included if they targeted Canadian, Australian, New Zealand, or USA Indigenous children aged from conception up to five years and evaluated a family-centred intervention implemented by a primary healthcare service. The family centredness of interventions were delineated using a modified rating scale used by our scoping review (McCalman 2017). The scale was based on a validated instrument that included 13 evaluation elements that described the features of family-centred care, clustered under three groups: 1. family as a constant, 2. culturally responsiveness, and 3. support of family individuality (Appendix 1) (Shields 2012; Trivette 1993). Pregnancy care models that did not continue beyond the standard postpartum period of six weeks to at least three months were considered as not meeting the criteria for recognition of constancy or meeting children's developmental needs. Each of the 13 elements were equally weighted and scored from 0 to 4, with 0 indicating the study included no evidence that the intervention was either implicitly or explicitly 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 was considered to be implicitly addressed if it could be inferred that the author/s' descriptions or arguments were consistent with the intent of the elements of family-centred care, whereas it was considered to explicitly address the element if the author/s clearly state and distinctly express that the element was present in health practice (Trivette 1993). The scores were added to give an overall rating of family centredness for each study. Following Shields 2012, the family-centredness score for inclusion was 26/52 or greater than 50%; we excluded studies that did not meet criteria for family-centredness.

Included interventions comprised a broad range of types, including the following.

- Environmental interventions as evidenced by collaboration with the family or child (or both) in the design or redevelopment of the home or primary healthcare centre to provide an environment that maximised parental involvement and enhanced child health or well-being (or both).
- Communication interventions that promote parental participation in health education to plan antenatal or postnatal

care, develop collaborative care pathways where both parent or child (or both) and health carer could document issues and progress, or reorganise healthcare to provide continuity of care.
- Educational interventions that delivered structured educational sessions for parents, or continuing education programmes 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.
- Family support interventions such as flexible fee 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 included studies that compared a family-centred healthcare intervention versus usual maternal and child healthcare or one form of family-centred intervention versus another. We disentangled complex or multifaceted interventions by noting where the intervention components were also included in the comparison arm, and hence effectively cancelled those components from the assessment. Where a component was not included in the comparison arm, we compared each component separately to no intervention/control; and with one another within the intervention arm. We then reported the effects as being attributable to the 'active' or 'unique' components of the intervention arm only.

Interventions were included only if they were implemented by a primary healthcare service. A primary healthcare service was 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 provided a service to children were included. Where studies described interventions at the interface between services (e.g. hospital discharge to primary healthcare; integrated approaches with childcare or child protection services), we included them only if the intervention was led by the primary healthcare service. We included programmes delivered within rural reservations by Indian health services or tribal health services, and early childhood centres (see Differences between protocol and review for further information).

Types of outcome measures

The focus of this review on family-centred interventions means that study outcomes can apply to the whole family, parents/carers, children, the health practitioner, health service factors, or a combination of these. The selected outcome measures account for this potential diversity. We included an additional primary outcome called 'overall health and well-being' with a justification and the selection of each outcome for inclusion provided in the Differences between protocol and review section.

Primary outcomes

- Overall health and well-being
  - If available, the inclusion of one primary outcome (listed below) from each included study.
- 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.
- Physical health and developmental health outcomes of children including:
  - Clinical assessments (e.g. injury resolution);
  - Physiological measures (e.g. anaemia levels); and
  - Developmental milestones.
- 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.
- 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.
- 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

- 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.
- 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 or resources (or both) provided, satisfaction with the decision/s made, satisfaction with care, sense of control.
- 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.
- 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.
- 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 reported

Family-centred interventions are complex and trials can report many outcomes that are measured in many ways at multiple time points. Outcomes were not used as the criteria for including studies, but selected outcomes under each of the categories listed above were identified a priori for meta-analysis for this review. To select outcomes of inclusion of the meta-analysis, blinded to outcomes results, two review authors (NA; CA) independently assigned the outcomes (category and timing) reported in each included study to the review's outcome categories. We resolved any differences in categorisation through consensus with a third review author (CC). This meant that more than one outcome might have been assigned to each outcome category at the review stage. Initially our plan to determine multiplicity of outcomes was to consider objective measures (e.g. anaemia levels, antenatal visit records) over subjective or self-reported measures (e.g. self-reported levels of parental/carer confidence or coping). In cases where one study measured the same outcome with more than one measure, we selected the most clinically important measure to avoid over-representing these data. However, when it came to determining outcomes, the above process was deemed insufficient as some outcomes did not include any objective measures, only subjective measures. As such, we modified the process by which we chose outcomes due to multiplicity and have outlined them in the Differences between protocol and review section. Briefly, review authors (with experience working in this field) received a spreadsheet of all outcome measures with each assigned to its respective outcome category. No results were provided. Led by one review author (NS), each outcome from each study was determined by the group for inclusion in the review. Outcome measures were prioritised for inclusion based on objective versus subjective measures, author team judgement of overall relevance to family centred-care interventions, and strengths-based rather than deficit measures. The final outcomes included from each study in each category were based on the decision rules by the authorship team or the most frequently reported outcome, or both.

Timing of outcome assessment

Time points were determined from time since the start of the intervention 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 were those which occur within three months, medium-term outcomes from three to 12 months, and long-term outcomes greater than 12 months. If multiple time points were given in each time point period, we chose the time point that was closest to the end of the time interval (Differences between protocol and review).

Main outcomes for the summary of findings table

The review's primary outcomes included in the summary of findings table were:

- overall health and well-being;
- psychological health and emotional behaviour of children;
- physical health and developmental health outcomes of children;
- family health-enhancing lifestyle or behaviour outcomes;
- psychological health of the parent/carer;
- adverse events or harms.

For each of these outcomes, we reported the typical burden of the outcome, absolute and relative magnitude of effect (where relevant), numbers of participants and studies, and the overall certainty of the body of evidence (which varied by outcome).

Search methods for identification of studies

We applied no language or date restrictions. We sought translation when necessary.

Electronic searches

We completed searches from inception to 22 September 2021 on the following electronic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL; Issue 8, 2021) in the Cochrane Library;
- MEDLINE OvidSP;
- Embase OvidSP;
- PsycINFO OvidSP;
- CINAHL EBSCOhost;
- Informit Indigenous Collection (Informit);
- Current Contents (Ovid) (only up to 11 April 2017).

We completed searches from inception to 22 September 2021 on the following clinical trial registries:

- ClinicalTrials.gov (clinicaltrials.gov);
- ISRCTN registry (www.isrctn.com/); and
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (who.int/ictrp/en/).

The search strategy for all databases are in Appendix 2; Appendix 3; Appendix 4; Appendix 5; Appendix 6; Appendix 7; Appendix 8.

We tailored strategies to other databases and reported them in the review.

We handsearched 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 contacted authors and inspected forward citations of included studies to determine whether there were any additional relevant studies.

Searching other resources

We searched grey literature sources for reports and conference proceedings through clearinghouses in February 2022: the Australian Indigenous Health InfoNet, Australian Institute of Family Studies, Indigenous Knowledge Network for Infants (Canada), Child

and Family Health (Canada), Child Welfare Information Gateway: Working with American Indian Children and Families (USA), and New Zealand Social Policy Evaluation and Research Unit. We were unable to gain access to the Li Ka Shing database (Canada).

Data collection and analysis

Data collection and analysis followed the published protocol (McCalman 2016). Differences from the protocol are summarised in the Differences between protocol and review section.

Where review authors had published papers that might be included in the review, the review author/s in question were not involved in assessing the study for inclusion, or extracting or analysing data from that study.

Selection of studies

We downloaded results of the search into Covidence to select studies for inclusion in this review and removed duplicates within Covidence prior to screening (Covidence). Two review authors (from NS; CA; BA (non-author acknowledged)) independently screened all titles and abstracts identified from searches to determine which met the inclusion criteria for full-text review. We retrieved full-text papers identified as potentially relevant by at least one review author. Two review authors (from NS; CC; SC; LS; RB; CA; JM) independently screened full-text articles for inclusion or exclusion, with discrepancies resolved by discussion and by consulting a third review author (from NS; CC) where necessary to reach consensus. All potentially relevant papers excluded after full-text review are listed as excluded studies, with reasons provided in the Characteristics of excluded studies table. We provided citation details and any available information about ongoing studies, and collated and reported details of duplicate publications, so that each study (rather than each report) is the unit of interest in the review. We reported the screening and selection process in an adapted PRISMA flow chart (Liberati 2009).

Data extraction and management

Two review authors (from NS; CA; CC) extracted data from the included studies. We resolved any discrepancies by discussion until reaching consensus, or through consultation with a third review author (from NS; CC) where necessary. We developed and piloted a data extraction form using the Cochrane Consumers and Communication Review Group Data Extraction Template (available at: cccrg.cochrane.org/author-resources). Data extracted included 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, intervention name, intervention aims and rationale, type of intervention (environmental, education, communication, counselling, family support), what was done, who delivered the intervention, where it was provided, when and how often it was 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 other data and results. We prepared a summary report for individual studies in the Characteristics of included studies table. One review author (NS) entered data for analysis into Review Manager Web (Review Manager Web 2020), and a second review author (CA) checked them for accuracy against the data extraction sheets.

Assessment of risk of bias in included studies

We assessed and reported on the methodological risk of bias of included studies in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021a) and the guidelines of the Cochrane Consumers and Communication Review Group (Ryan 2013). The *Cochrane Handbook for Systematic Reviews of Interventions* 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 (e.g. baseline imbalance, contamination, differential diagnostic activity). We considered blinding separately for different outcomes where appropriate (e.g. blinding may have the potential to differently affect subjective versus objective outcome measures). We judged each item at high, low, or unclear risk of bias as set out in the criteria provided in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021a), and provided a quote from the study report and a justification for our judgement for the risk of bias in within the Characteristics of included studies table.

Studies were deemed at high risk of bias if they scored at high or unclear risk of bias for either 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 2021a).

Two review authors (from NS; SC; LS; JM) independently assessed the risk of bias of included studies, with any disagreements resolved by discussion to reach consensus or consultation with a third review author (NS; CC) if needed. We contacted study authors for additional information about the included studies, or for clarification of the study methods as required. We incorporated 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 of the risk of bias of included studies and a judgement about the internal validity of the review's results.

For cluster-RCTs, we assessed and reported the risk of bias associated with an additional domain: selective recruitment of cluster participants. For non-randomised studies, we assessed and reported quasi-RCTs as being at a high risk of bias on the random sequence generation item of the risk of bias tool.

We intended to assess CBA studies against the same criteria as RCTs and report them as being at high risk of bias on

both the random sequence generation and allocation sequence concealment items. We would have excluded CBA studies that were not reasonably comparable at baseline. We also intended to assess and report ITS studies as being a high risk of bias on sequence generation. In addition, we would have assessed the following items for ITS studies: intervention independence of other changes; prespecification 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). However, no CBA or ITS studies were eligible for inclusion.

Where review authors had published papers that might be included in the review, the review author/s in question were not involved in assessing risk of bias for that study.

Measures of treatment effect

For dichotomous outcomes, we analysed data based on the number of events and the number of people assessed in the intervention and comparison groups. We then used these to calculate the risk ratio (RR) and 95% confidence interval (CI). For continuous measures, we analysed 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 was reported without individual group data, we used this to report the study results. If more than one study measured the same outcome using different tools, we calculated the standardised mean difference (SMD) and 95% CI using the inverse variance method in Review Manager Web 2020.

For CBAs, we intended to use appropriate effect measures for dichotomous outcomes (RR, adjusted RR) and for continuous outcomes (relative % change postintervention, SMD). For ITS, we would have included the following effect measures: 1. change in level of the outcome at the first point after the introduction of the intervention, and 2. the postintervention slope minus the preintervention slope. These estimates would have been calculated from regression models adjusting for autocorrelation. It would not have been appropriate to present means and SDs of preintervention versus postintervention time points. However, no CBA or ITS studies were eligible for inclusion.

Unit of analysis issues

For cluster-RCTs, we checked for unit-of-analysis errors. If errors had been found, and sufficient information was available, we would have re-analysed the data using the appropriate unit of analysis, by taking account of the intracluster correlation (ICC). To determine estimates of ICC we would have contacted authors of included studies or, if this was not possible, imputed them using estimates from external sources. If it had not been possible to obtain sufficient information to re-analyse the data, we would have reported effect estimates and annotated 'unit-of-analysis error'. However, it was not deemed necessary to re-analyse data for the included cluster-RCTs.

Dealing with missing data

We contacted study authors to obtain missing data (participant, outcome, or summary data). For participant data, where possible, we conducted analysis on an intention-to-treat basis; otherwise we analysed data as reported. We reported the levels of loss to follow-up and assessed this as a source of potential bias. For missing outcome or summary data, we imputed missing data where possible and reported any assumptions in the Differences between protocol and review section.

Assessment of heterogeneity

Where studies were considered similar enough to allow pooling of data using meta-analysis, we assessed the degree of heterogeneity by visual inspection of forest plots and by examining the Chi^2 test for heterogeneity. We reported our reasons for deciding that studies were sufficiently similar to pool statistically. We quantified heterogeneity using the I^2 statistic. An I^2 value of 50% or more represented substantial levels of heterogeneity, but this value was 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 2021a). Where heterogeneity was present in pooled effect estimates, we explored possible reasons for variability by conducting subgroup analysis.

Where we detected substantial clinical, methodological, or statistical heterogeneity across included studies (greater than 75%) we did not report pooled results from meta-analysis but instead used a narrative approach to data synthesis. In this event, we attempted to explore possible clinical or methodological reasons for this variation by grouping studies that were 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 assessed reporting bias qualitatively, based on the characteristics of the included studies (e.g. if only small studies that indicated positive findings were identified for inclusion). We did not have sufficient studies (at least 10) for inclusion in the review to construct funnel plots to investigate small-study effects, which may indicate publication bias (Higgins 2021a).

Data synthesis

We decided to meta-analyse outcome data based on whether the interventions were sufficiently similar in terms of participants, settings, comparisons, and outcome measures to ensure meaningful conclusions from a statistically pooled result. Because of the anticipated variability in the intervention types and populations of included studies, we used a random-effects model for meta-analysis.

Where we were unable to pool data for a meta-analysis, we summarised the results narratively. We explored possible clinical or methodological reasons for this variation by grouping studies that were similar in terms of the major types of intervention (i.e. environmental, communication, educational, counselling, family support) and explored differences in intervention effects. We explored the possibility of organising the data by Indigenous population and child's age; however, this was not feasible given the small number of studies. Within the data categories, we explored the main comparisons of the review:

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

Subgroup analysis and investigation of heterogeneity

We had planned to investigate three potential effect modifiers through subgroup analyses to determine whether they might impact the intervention effect. We were only able to report on the intervention type (i.e. environmental, communication, educational, counselling, family support), with too few studies available to report on Indigenous population (Aboriginal, Torres Strait Islander, First Nations, Metis, Inuit, American Indian, Native Alaskan, Native Hawaiian, Maori/Tangata Whenua); and age of child.

Sensitivity analysis

We intended to perform a sensitivity analysis to assess the impact on the primary outcomes of excluding studies assessed at high risk of bias and by comparing the results from fixed-effect versus random-effects meta-analyses. We did not complete a sensitivity analysis for risk of bias as all studies in a meta-analysis had a low risk for sequence generation, and it was appropriate to assess studies using a random-effects analysis. Instead, we completed a sensitivity analysis on objective versus subjective outcomes. We excluded outcomes that were not from a validated questionnaire or tool, or were not administrative data. We reported this additional analysis in the Differences between protocol and review section.

Summary of findings and assessment of the certainty of the evidence

We prepared a summary of findings table to present the results of the meta-analysis, based on the methods described in Chapter 15 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2021). We included the major comparisons of the review, for each of the primary outcomes, including potential harms, as outlined in the Types of outcome measures section. Two review authors (NS; CA) independently assessed the certainty of evidence using the GRADE criteria. We provided a source and rationale for each assumed risk cited in the table/s, and used the GRADE system to rank the certainty of the evidence using the GRADEpro software (GRADEpro GDT). If meta-analysis was not possible, we presented 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 of family-centred interventions for them (McCalman 2016). We intended to 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; however, this was not possible.

RESULTS

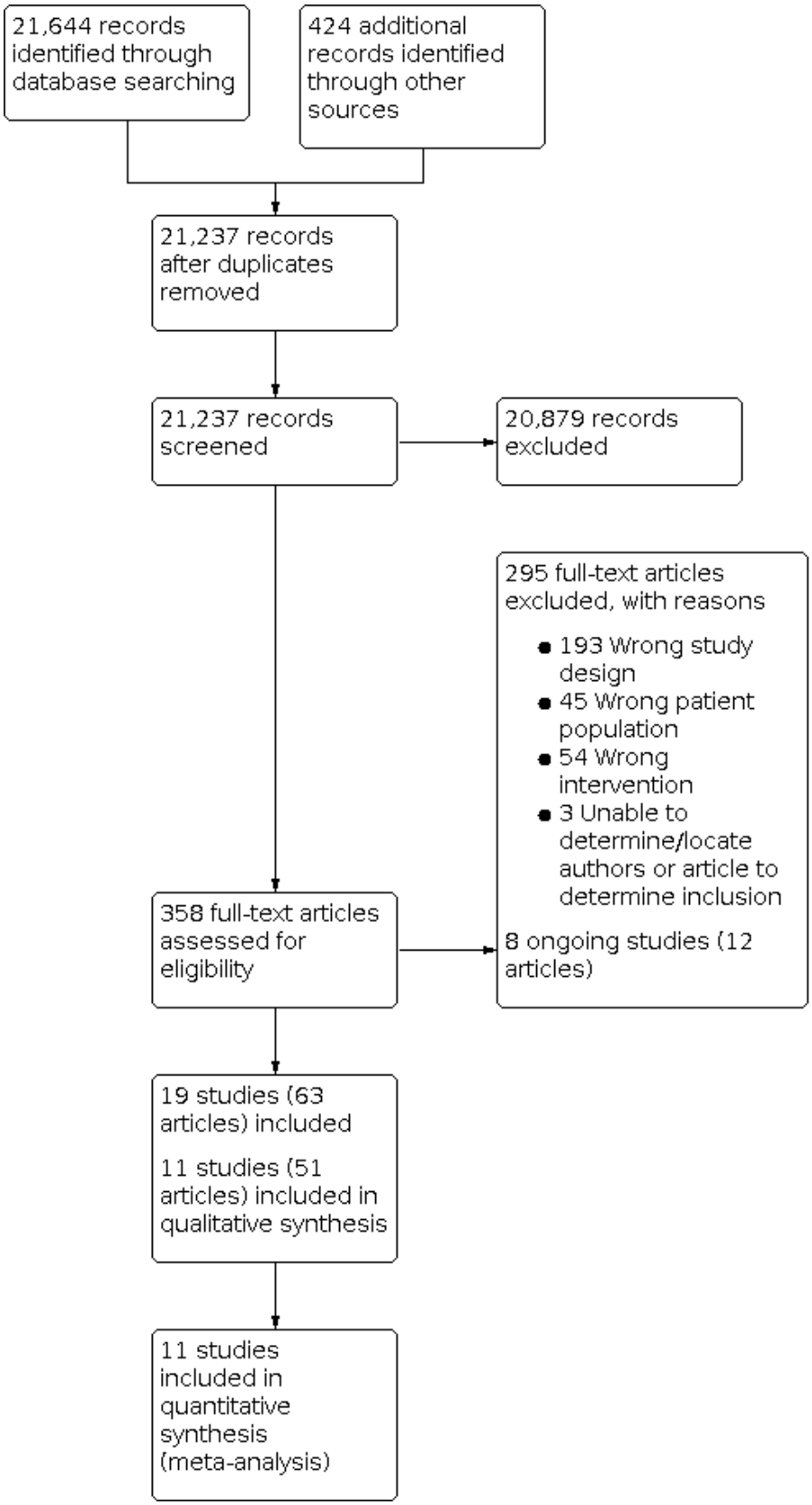
Description of studies

See Characteristics of included studies table; Characteristics of excluded studies table; Characteristics of ongoing studies table; and additional features of included studies in Table 1.

Results of the search

We identified 21,644 citations from electronic databases, 424 additional records from abstract searches and forward citations (Figure 1). After removal of 831 duplicates, there remained 21,237 records included for initial screening. We read the titles and abstracts and deleted 20,879 citations at this stage. We reviewed 358 full-text articles relevant to the review and excluded 295 articles with reasons (see Characteristics of excluded studies table). The main reasons were 193 studies with an incorrect study design, 54 had the wrong intervention, 45 had the wrong study population, and we were unable to locate three articles (Figure 1). We identified eight ongoing studies (12 articles) (see Characteristics of ongoing studies table), and there were no studies awaiting classification. We included 63 articles, trials registrations, and conference proceedings that provided data on 11 studies (see Characteristics of included studies table). We contacted authors of six studies to request information about inclusion of the study or data for the meta-analysis, or both. We received responses from three study authors (four studies; Broughton 2013; HCSF 1 2007; HCSF 2 2017; Johnston 2010).

Figure 1. Study flow diagram.



Included studies

We included 11 studies (Barlow 2006; Broughton 2013; Family Spirit Nuture Part 1 2021; Harrison 2010; HCSF 1 2007; HCSF 2 2017; Johnston 2010; Quissell 2014; Family Spirit Trial 2012; Tipene-Leach 2014; Walkup 2009).

Design

All included studies were published between 2006 and 2021 and were reported as RCTs. Eight RCTs were randomised at the individual level (Barlow 2006; Family Spirit Nuture Part 1 2021; HCSF 1 2007; HCSF 2 2017; Johnston 2010; Family Spirit Trial 2012; Tipene-Leach 2014; Walkup 2009), and two studies were cluster-RCTs (Harrison 2010; Quissell 2014). One RCT was a standard intervention comparison study design until control children were 24 months old and then received the intervention for one year. The control group then became a 'delayed intervention' (Broughton 2013). Six studies included carer–child dyads (Harrison 2010; HCSF 1 2007; HCSF 2 2017; Johnston 2010; Family Spirit Nuture Part 1 2021; Quissell 2014), and five studies randomised pregnant mothers (Barlow 2006; Broughton 2013; Family Spirit Trial 2012; Tipene-Leach 2014; Walkup 2009). Two studies provided pilot data (Barlow 2006; Walkup 2009) for the development of the Family Spirit Program intervention (Family Spirit Trial 2012). These trials were then used to inform the Family Spirit Nuture trial (Family Spirit Nuture Part 1 2021). In addition, the Healthy Child, Strong Families programme has completed two trials, the second (HCSF 2 2017) expanding on the first (HCSF 1 2007). All other studies were independent of other included studies. All studies were funded with five studies receiving funds from government funding bodies and charities (Barlow 2006; HCSF 1 2007; Johnston 2010; Tipene-Leach 2014; Walkup 2009), five government funded only (Broughton 2013; Harrison 2010; HCSF 2 2017; Quissell 2014; Family Spirit Trial 2012), and one was funded from multiple charities and an Indian Health Service (Family Spirit Nuture Part 1 2021).

Settings

There were seven studies in the USA (Barlow 2006; HCSF 1 2007; HCSF 2 2017; Quissell 2014; Family Spirit Trial 2012; Walkup 2009; Family Spirit Nuture Part 1 2021), two in New Zealand (Tipene-Leach 2014; Broughton 2013), one in Canada (Harrison 2010), and one in both Australia and New Zealand (Johnston 2010). Studies delivered in a range of clinical settings including four studies in Indian Health Services (Barlow 2006; Family Spirit Trial 2012; Family Spirit Nuture Part 1 2021; Walkup 2009), two in Indian Health Services and Head Start Centres (HCSF 1 2007; HCSF 2 2017), one in Head Start Centres (Quissell 2014), one in a hospital maternity service and Aboriginal Community Controlled Organisations (Johnston 2010), one in a health clinic (Harrison 2010), and one in primary healthcare services and dental clinics (Broughton 2013). Tipene-Leach 2014 delivered their intervention at a Maori midwifery practice, a Maori Women's Welfare League/urban marae, a Primary Health Organisation and a single weaver working with community networks in her own community. Studies provided six interventions to Indigenous families on reservation (Barlow 2006; HCSF 1 2007; Quissell 2014; Family Spirit Trial 2012; Walkup 2009; Family Spirit Nuture Part 1 2021), one in a remote area (Harrison 2010), one in a metropolitan area (Johnston 2010), one in an urban area (Tipene-Leach 2014), one on four reservations, one urban site (HCSF 2 2017), and one in a regional area (Broughton 2013).

Participants

The 11 studies recruited 1270 mother–child dyads and 1924 children aged less than five years at baseline. There were 626 mother–child dyads and 968 children aged less than five years who were part of family-centred care and 644 mother–child dyads and 956 children aged less than five years in the control group. Indigenous peoples varied substantially across all studies, particularly in the USA, where studies included more than one tribal nation (Table 1).

Control groups

Three studies provided usual care to the control group (Johnston 2010; Quissell 2014; Family Spirit Trial 2012). The remaining eight studies provided some form of 'minimal' intervention to the control group as it was often deemed inappropriate by participating communities for families to receive nothing (Barlow 2006; Harrison 2010; HCSF 1 2007; HCSF 2 2017; Tipene-Leach 2014; Walkup 2009; Broughton 2013; Family Spirit Nuture Part 1 2021). One study also provided the family-centred care intervention to the control children when they were aged 24 months for one year (Broughton 2013). Six studies providing some form of education (Barlow 2006; Harrison 2010; HCSF 1 2007; HCSF 2 2017; Walkup 2009; Family Spirit Nuture Part 1 2021), one study provided basic dental care (Broughton 2013) and one study provided an alternative sleeping device (Tipene-Leach 2014). Education included a home visiting breastfeeding programme (Barlow 2006), a home visiting breastfeeding and nutrition programme (Walkup 2009), a home visiting child safety programme (Family Spirit Nuture Part 1 2021), monthly mailed lessons and newsletters (HCSF 1 2007), mailed culturally appropriate pamphlets and standard dental care (Harrison 2010), and monthly mailed child safety newsletters (HCSF 2 2017) (Table 1).

Intervention groups

Scores for family-centredness ranged from 28 to 44 out of a potential score of 52 (Appendix 1). Overall, most studies met the family-centredness criteria for sharing information with families, culturally competent health care, and parent/professional collaboration. Studies were less likely to provide financial support (e.g. supporting families to receive government supplements for parents to care for their children) and family-to-family support.

The focus of interventions varied and included early childhood caries (Broughton 2013; Harrison 2010; Quissell 2014), childhood obesity (Family Spirit Nuture Part 1 2021; HCSF 1 2007; HCSF 2 2017), child behavioural problems (Family Spirit Trial 2012; Walkup 2009); negative parenting patterns (Barlow 2006), child acute respiratory illness (Johnston 2010), and sudden unexpected death in infancy (Tipene-Leach 2014) (Table 1). Based on the 'types of interventions', seven were categorised as predominantly educational (Barlow 2006; Family Spirit Nuture Part 1 2021; Family Spirit Trial 2012; HCSF 1 2007; HCSF 2 2017; Quissell 2014; Walkup 2009), two involved counselling (Broughton 2013; Harrison 2010), and one each of education and counselling (Johnston 2010) and environmental improvements (Tipene-Leach 2014). One study also compared a family-centred care intervention to a family-centred care intervention through a counselling intervention received from birth compared to the same intervention (delayed) received from when the child was aged 24 months (Broughton 2013).

Nine interventions were delivered face-to-face either through home or group sessions except for HCSF 2 2017, which was a mailed intervention and Tipene-Leach 2014, who provided the intervention once with written instructions. For the seven trials that had more than one face-to-face interaction, the duration of interventions ranged from three months to three years (Tipene-Leach 2014).

Nearly all studies employed or supported Indigenous community members or already existing Indigenous health workers to deliver or participate in the studies, which is consistent with Indigenous research ethical guidelines (Ewen 2019). Seven studies employed local Indigenous members or respected community members to deliver the intervention (Barlow 2006; Broughton 2013; Family Spirit Nuture Part 1 2021; Family Spirit Trial 2012; HCSF 1 2007; Quissell 2014; Walkup 2009). Two studies utilised existing paraprofessional health workers to deliver their interventions (Harrison 2010; Johnston 2010). One study employed local community members to be project co-ordinators at each site (HCSF 2 2017), and one study employed a research nurse (Tipene-Leach 2014). Nine studies provided training to their staff. The most extensive training reported was approximately 500 hours, which also required interventionists to demonstrate mastery of the training content prior to implementing the study (Barlow 2006; Walkup 2009). This was completed to ensure fidelity to the intervention. Other studies provided training ranging from more than 80 hours' extensive training on the trial protocol, policies research ethics, and the intervention (Family Spirit Trial 2012); a two-day training workshop in the first year, again in the second year, and follow-up throughout the project (Harrison 2010); and two weeks of training with a refresher prior to starting, and again during the intervention (Quissell 2014). One study did not state the duration of training but gave details on what training they provided and to whom (HCSF 1 2007). Three studies provided training but did not include specific details (Family Spirit Nuture Part 1 2021; HCSF 2 2017; Johnston 2010).

Community engagement

Consumer and community involvement is a core principle for Indigenous research to help facilitate translation and sustainability of programmes. All studies included consumer and community involvement, but levels of involvement varied. Ten studies completed consultation prior to the study commencing and received input from communities on a range of research activities such as study design (Broughton 2013; Family Spirit Trial 2012; Harrison 2010), reference groups for monitoring progress of the intervention (HCSF 1 2007; HCSF 2 2017; Johnston 2010; Quissell 2014), and providing feedback on manuscripts for publications related to the study (Johnston 2010; Walkup 2009). Ten studies applied some level of cultural adaptation to resources, activities, and materials (Barlow 2006; Broughton 2013; Family Spirit Nuture Part 1 2021; Family Spirit Trial 2012; Harrison 2010; HCSF 1 2007; HCSF 2 2017; Johnston 2010; Quissell 2014; Walkup 2009). Maori community members developed the Tipene-Leach 2014 intervention.

Outcomes

Studies reported outcomes related to overall health and well-being, psychological health and emotional behaviour of children, physical health, developmental health outcomes of children, family health-enhancing lifestyle or behaviour, psychological health of parent/carer, adverse events, parenting knowledge and awareness, service access and utilisation, and economic costs. There were no secondary outcomes for family evaluation of care and family-centredness of consultation processes reported. No studies reported on the perspective of health service provider. Table 2 provides outcomes included in the review compared against intervention, control, measure, timing of outcomes, and whether the outcome was included in a meta-analysis. We described studies with data that could not be included in a meta-analysis narratively. The Characteristics of included studies table provides a list of outcomes and time points not used for the review.

Studies included in the meta-analysis

Where appropriate, we completed meta-analyses grouping data by outcomes. As studies provided multiple time points for each outcome, we used the longest time point for each study. Data on available outcomes was guided by the information provided in Table 2. We included all 11 studies in at least one meta-analysis (Barlow 2006; Broughton 2013; Family Spirit Nuture Part 1 2021; Family Spirit Trial 2012; Harrison 2010; HCSF 1 2007; HCSF 2 2017; Johnston 2010; Quissell 2014; Tipene-Leach 2014; Walkup 2009).

Excluded studies

There were 299 studies that were considered ineligible for the review (see Characteristics of excluded studies table). Reasons for exclusion included ineligible study design, population, and intervention. Although some studies had multiple reasons for exclusion, we reported the primary reason to optimise efficiency of the screening process.

Risk of bias in included studies

Summaries of risk of bias judgements for the included studies are provided in Figure 2 and Figure 3. The authors judgements for each type of bias are presented in the Characteristics of included studies table with reasons.

Figure 2. Risk of bias summary: review authors' judgement on each risk of bias domain across all included studies.

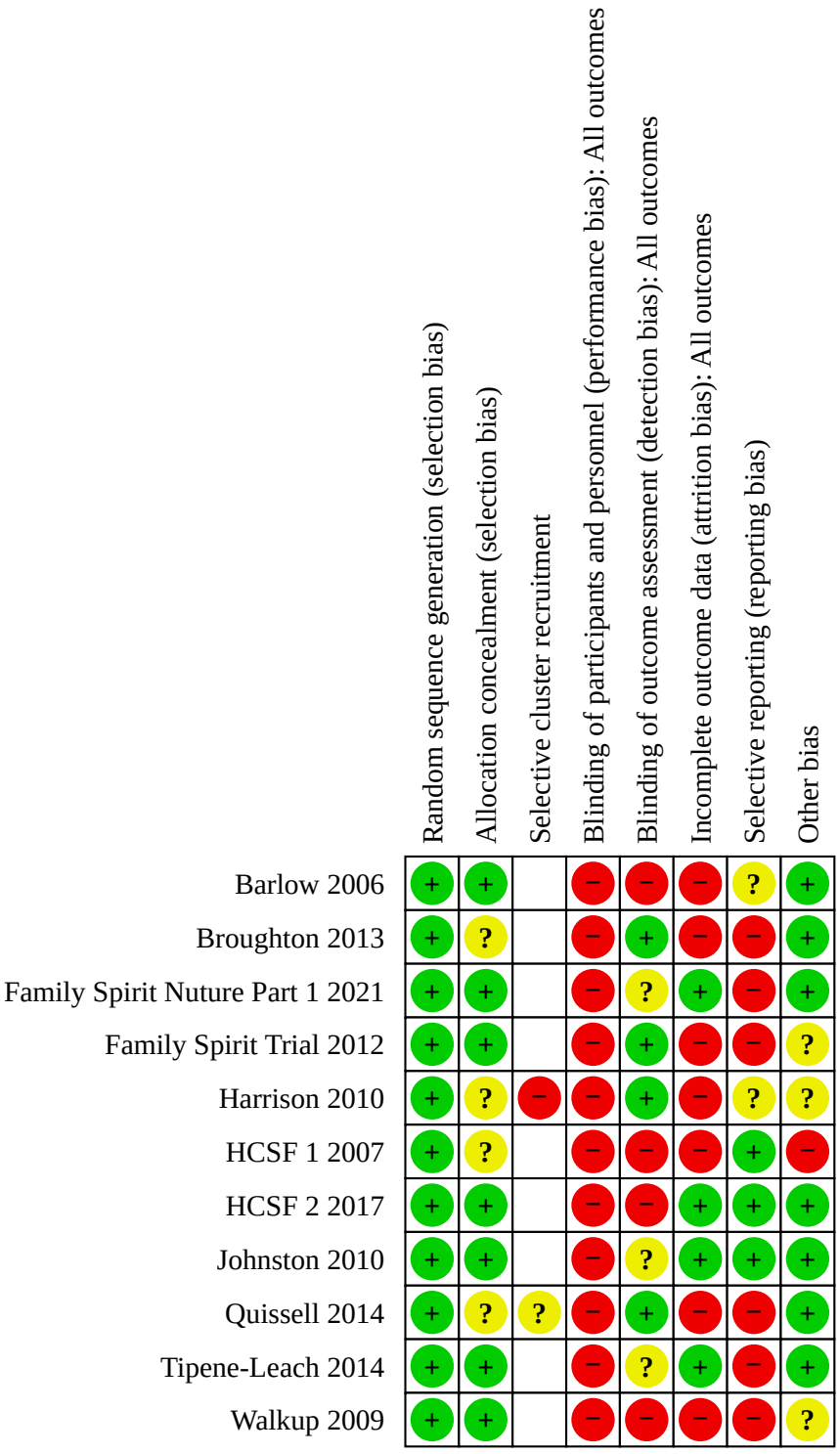
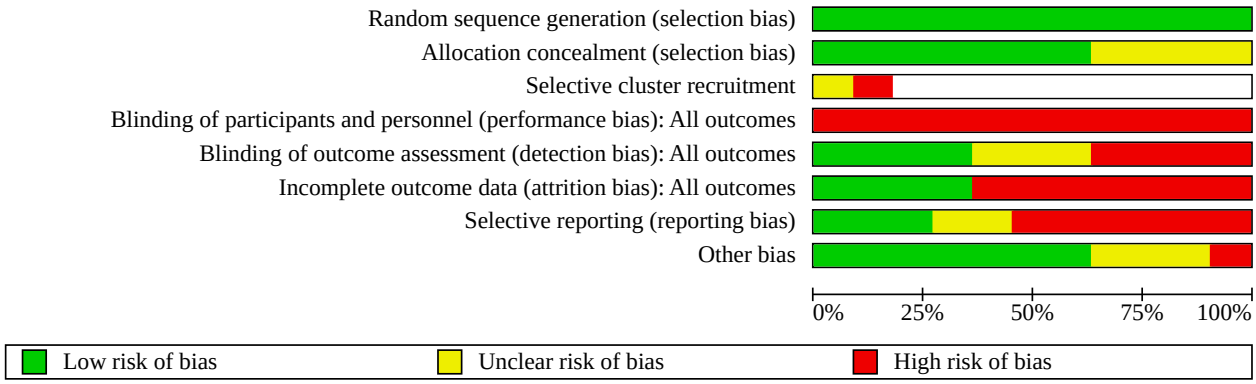


Figure 3. Risk of bias graph: review authors' judgement on each risk of bias domain as percentages across all included studies.



Allocation

All 11 studies were at low risk of bias for random sequence generation through using computer or web-based programmes, drawing lots, or providing sufficient information to deem that sequence generation had occurred at random.

Seven studies had a low risk of bias for allocation concealment with randomisation occurring after enrolment through central allocation or sealed numbered envelopes (Barlow 2006; Family Spirit Nuture Part 1 2021; Family Spirit Trial 2012; HCSF 2 2017; Johnston 2010; Tipene-Leach 2014; Walkup 2009). The remaining four studies had an unclear risk of bias for allocation concealment with little to no information provided (Broughton 2013; Harrison 2010; HCSF 1 2007; Quissell 2014).

We assessed the two cluster-RCTs for the domain selective cluster recruitment. Both studies recruited participants after randomisation. One study was at unclear risk of bias as the randomisation prior to enrolment of children in Head Start Centres did not appear to influence recruitment, with less than 1% of participants declining (Quissell 2014). There were similar numbers in each group; however, there were some baseline differences in participant characteristics. The other study was at high risk of bias as individuals who recruited the participants also delivered the intervention (Harrison 2010). There were also some baseline differences in recruitment including fewer intervention mothers who had already delivered their babies at the time of enrolment, had visited a dentist for toothache, and had other children with a previous tooth extraction.

Blinding

Given the nature of the interventions, it was not possible to blind participants or people delivering the interventions to group allocation. As a result, all studies were at high risk of performance bias.

Four studies reported adequate blinding of outcome assessments and were at low risk of bias on the detection bias domain (Broughton 2013; Family Spirit Trial 2012; Harrison 2010; Quissell 2014). Three studies were at unclear risk of bias for this domain due to one study reporting that only the primary outcome had a blinded assessment (Johnston 2010), one study reported that some outcomes were assessed blind but it was unclear about other outcomes (Tipene-Leach 2014), and for one study it was unclear whether trained staff who collected data were blind to outcome assessments (Family Spirit Nuture Part 1 2021). Four studies were at high risk of bias as the same person who delivered the intervention also completed the data collection (Barlow 2006; HCSF 1 2007; HCSF 2 2017; Walkup 2009).

Incomplete outcome data

All studies completed an intention-to-treat or modified intention-to-treat analysis. Four studies were at low risk on this domain with low attrition levels during follow-up (Family Spirit Nuture Part 1 2021; HCSF 2 2017; Johnston 2010; Tipene-Leach 2014). The remaining seven studies were at high risk of bias due to their reported high levels of attrition (Barlow 2006; Broughton 2013; Family Spirit Trial 2012; Harrison 2010; HCSF 1 2007; Quissell 2014; Walkup 2009).

Selective reporting

Three studies were at low risk of bias with study protocols that had sufficient detail to determine that the data provided were based on definitions in the protocol and analysis completed as described (HCSF 1 2007; HCSF 2 2017; Johnston 2010). One study was at unclear risk of bias because the published protocol had insufficient detail to determine whether selective outcome reporting occurred (Harrison 2010). We were unable to locate a protocol or trial registration for one study and deemed this study at unclear risk of bias (Barlow 2006). Six studies were at high risk of bias for selective outcome reporting as they had only provided adjusted analyses, reported binary and continuous data for the same outcome, combined time points in their analysis, or did not report on all the outcomes they collected (Broughton 2013; Family Spirit Nuture Part 1 2021; Family Spirit Trial 2012; Quissell 2014; Tipene-Leach 2014; Walkup 2009).

Other potential sources of bias

Seven studies were at low risk of bias with no other obvious sources of bias (Barlow 2006; Broughton 2013; Family Spirit Nuture Part 1 2021; HCSF 2 2017; Johnston 2010; Quissell 2014; Tipene-Leach 2014). Three studies were at unclear risk of bias because of deviations from intended interventions and cultural appropriateness of outcome measures (Family Spirit Trial 2012; Harrison 2010; Walkup 2009). One study was at high risk of bias

due to changing participant allocation after randomisation (HCSF 1 2007). No sensitivity analysis was completed to determine whether this influenced outcomes.

Effects of interventions

See: **Summary of findings 1** Family-centred care compared to any control for Indigenous children aged less than five years

See Summary of findings 1.

Primary outcomes

Overall health and well-being

All 11 studies contributed data to the analysis. Pooled data included outcomes from two studies reporting psychological health and emotional behaviour of children (Family Spirit Trial 2012; Walkup 2009), eight on physical health and developmental outcomes of children (Broughton 2013; Family Spirit Nuture Part 1 2021; Harrison 2010; HCSF 1 2007; HCSF 2 2017; Johnston 2010; Quissell 2014; Tipene-Leach 2014), and one on maternal mental health (Barlow 2006). The pooled effect estimate suggested that family-centred care may improve the overall health and well-being of Indigenous children and their families compared to no family-centred care (SMD 0.14, 95% CI 0.03 to 0.24; 11 studies, 2386 participants; very low-certainty evidence; Analysis 1.1; Summary of findings 1). There was low heterogeneity (I^2 = 31%). The level of confidence in the evidence is very uncertain due to high risk of bias in multiple domains for included studies and the outcomes having different underlying constructs.

Psychological health and emotional behaviour of children

Of the three studies that assessed psychological health and emotional behaviour of children, two could be combined for a meta-analysis (Family Spirit Trial 2012; Walkup 2009). There was little to no difference in the competence domain of the Infant Toddler Social Emotional Assessment (ITSEA) at 12 months' postpartum between families that received the family-centred care intervention and the control group (MD: change in ITSEA competence score 0.04, 95% CI −0.03 to 0.11; I^2 = 0%; 2 studies, 384 participants; very low-certainty evidence; Analysis 1.2; Summary of findings 1).

Family Spirit Trial 2012 also measured the competence domain of ITSEA at 36 months' postpartum and found no evidence of an improvement for families who participated in the family-centred care intervention (adjusted MD 0.04, 95% CI −0.01 to 0.09). There was no difference in dental-related child quality of life with 19.4% (21/110) American Indian families in the family-centred counselling intervention answering 'yes' to at least one question from the self-reported 'Dental-caries-related' Child Quality of Life survey compared to 28.2% (37/131) families who participated in the control group (Harrison 2010).

Physical health and developmental health outcomes of children

Eight studies assessed 11 physical health and developmental outcomes of children. There was little to no difference between the family-centred care and control groups (SMD 0.13, 95% CI 0.00 to 0.26; 8 studies, 1961 participants; I^2 = 42%; very low-certainty evidence; Analysis 1.3; Summary of findings 1).

There were three outcomes not included in the analysis. One study reported no difference in full breastfeeding in the short-term, with 37 infants in the family-centred care group fully breastfeeding compared to 35 infants in the control group (intervention (95 infants) 40%; control (88 infants) 39%; P = 0.91) (Tipene-Leach 2014). It is unclear what the definition of 'fully breastfeeding' was in this study. One study assessed body mass index (BMI) z-score when infants were aged less than two months (Family Spirit Nuture Part 1 2021). Authors reported no difference between groups (mean: intervention −0.44 (standard error (SE) 0.13); control −0.40 (SE 0.13); adjusted MD −0.04, 95% CI −0.41 to 0.33). One study compared a family-centred care education intervention delivered from birth (not delayed) to a delayed family-centred care education intervention delivered at 24 months. At 36 months, the authors reported a reduction in the mean caries in the not delayed group (mean: not delayed 1.7 (SD 3.1); delayed 2.3 (SD 5.2); MD 0.73, 95% CI 0.58 to 0.93) (Broughton 2013).

Family health-enhancing lifestyle or behaviour outcomes

Nine studies reported data on family health-enhancing lifestyle or behaviour outcomes (Barlow 2006; Family Spirit Nuture Part 1 2021; Family Spirit Trial 2012; HCSF 1 2007; HCSF 2 2017; Johnston 2010; Quissell 2014; Tipene-Leach 2014; Walkup 2009). There was little to no difference between receiving family-centred care and the control group (SMD 0.16, 95% CI −0.06 to 0.39; 9 studies, 1969 participants; I^2 = 76%; very low-certainty evidence; Analysis 1.4; Summary of findings 1).

The remainder of the outcomes were subjective and reported at various time points (Table 2). Two results were from studies that assessed the effect of the Family Spirit Program (Barlow 2006; Family Spirit Trial 2012). One study measured family cohesion at two months with no evidence of improvement for families who participated in family-centred care compared to the control group (adjusted for baseline MD 0.60, 95% CI −0.3 to 1.5; 41 participants) (Barlow 2006). The second study used the Home Observation for Measurement of the Environment tool to measure the quality of a child's home environment at 36 months' postpartum and found no evidence of improvement in those that received the family-centred care intervention (long-term outcome; adjusted MD 0.10, 95% CI −0.54 to 0.73) (Family Spirit Trial 2012).

Three outcomes were reported from the same study with one outcome related to the mother and two for the infant (Tipene-Leach 2014). At three months' postpartum, 93% (88/95) of mothers reported good maternal sleep quality in the intervention group compared to 90% (79/88) of mothers in the usual care group. There was no evidence of improvement between the family-centred care intervention and the control group. For infants, the study reported whether infants slept on their back at three and six months' postpartum. The authors reported that 85% (81/95) of infants slept on their back in the intervention group at three months compared to 83% (73/88) of infants in the control group. At six months, 87% (77/89) of infants in the intervention group slept on their back compared to 85% (71/84) in the usual care group. There was also no evidence that family-centred care improved this outcome. The third outcome was whether infants had been around tobacco smoke in the last seven days, with 18% (23/126) of infants in the intervention group being around tobacco smoke compared to 12% (15/128) in the usual care group at 12 months' postpartum (Johnston 2010).

Psychological health of parent/carer

For carer mental health, there was little to no difference between participants in family-centred care compared to the control group (SMD 0.10, 95% CI −0.03 to 0.22; 5 studies, 975 infants; I^2 = 0%; very low-certainty evidence; Analysis 1.5; Summary of findings 1).

Four outcomes were not included in the meta-analysis. Three studies measured maternal depression using the Center for Epidemiological Studies Depression scale at two months (Barlow 2006; Family Spirit Trial 2012; Walkup 2009). Each study found little to no difference between the family-centred care intervention and the control group (Barlow 2006: adjusted MD −3.10, 95% CI −8.8 to 2.5; 41 participants; Family Spirit Trial 2012: adjusted MD −0.34, 95% CI −1.19 to 0.51; 322 participants; Walkup 2009: adjusted MD: 0.05, 95% CI −4.0 to 4.1; 125 participants). In addition, Family Spirit Trial 2012 measured maternal depression at 36 months using repeated measures (2, 6, 12, 18, 24, 30, and 36 months). The authors found an improvement in maternal depression favouring family-centred care compared to no family-centred care (adjusted MD −1.17, 95% CI −2.05 to −0.28; 322 participants).

Adverse events or harms

Two studies narratively reported that there were no adverse events and side effects as a result of the intervention (Family Spirit Nuture Part 1 2021; Harrison 2010). One study reported that no aspect of the intervention including the application of fluoride varnish resulted in any adverse events (Harrison 2010). One study reported emergency department visits or hospital admissions as adverse events (Family Spirit Nuture Part 1 2021). No adverse events were deemed to be the result of the intervention. Neither study reported data to support the claim of no adverse events or side effects. As a result, we found the evidence is very uncertain about the effect of family-centred care on adverse events of harm (Summary of findings 1).

Secondary outcomes

Parenting knowledge and awareness

There was a small improvement in parenting knowledge and awareness for families who participated in family-centred care compared to the control group (SMD 0.20, 95% CI 0.01 to 0.38; 3 studies, 445 participants; I^2 = 0%; Analysis 2.1). Two studies were not included in the analysis. One study measured parenting knowledge to 36 months using repeated measures. Authors found an improvement in the family-centred care group compared to the control group (adjusted MD 1.28, 95% CI 0.70 to 1.86) (Family Spirit Trial 2012). One study measured maternal sugar-sweetened beverage knowledge through self-report and only reported that more than 90% of questions were correctly answered in both groups throughout the study (Family Spirit Nuture Part 1 2021).

Family evaluation of care

No studies reported family evaluations of care outcomes.

Service access and utilisation

Two studies reported service access and utilisation. However, when completing a meta-analysis there was substantial heterogeneity (I^2= 81%; Analysis 2.2). One study measured the number of visits to a dentist for tooth pain at 30 (SD 3) months with 17 visits recorded for 110 children in the family-centred care intervention group compared to 32 visits from 131 children in the usual care group (Harrison 2010). Data were provided as descriptive count data and dental pain was considered an adverse outcome (i.e. higher number of visits was a worse outcome). Johnston 2010 found no difference in the rate of hospitalisations for acute respiratory illness in Aboriginal and Maori infants in the first year of life by mothers who participated in a family-centred care intervention compared to usual care (incidence rate ratio 1.23, 95% CI 0.70 to 2.15). Based on the data available, it appears that family-centred care may have little to no effect on service access and utilisation for children.

Family-centredness of consultation processes

No studies reported family-centredness of consultation processes.

Economic costs and outcomes associated with the interventions

One study reported on the cost-effectiveness of delivering a family-centred counselling intervention compared to the control group to reduce dental caries (Harrison 2010). On a subsample of 173 children the authors investigated the cost/averted case of decayed, missing, or filled tooth surface (averted DMFTS) and the cost/averted for early childhood caries (averted ECC case). Cost-effectiveness ratios were estimated to be USD 81/averted DMFTS and USD 3900/averted ECC case by net benefit regression using the trial data. Overall, the authors concluded that the programme is expected to improve the dental health of children; however, this would be at an increased cost in dental service provision compared to the control group.

Subgroup analysis

We explored possible clinical reasons for differences in intervention effects by subgrouping studies with similar types of intervention delivered (i.e. environmental, communication, educational, counselling, family support). Only analyses that had different types of family-centred care interventions were included (e.g. education compared to counselling) (Table 2). We compared this to any control group (i.e. standard care, usual care, or a 'minimal' intervention group). There were no studies that compared a family-centred care intervention to another family-centred care intervention in the analysis.

There was little to no difference in subgroup differences reported for outcomes overall health and well-being of children (P = 0.10; Analysis 3.1), physical health and developmental outcomes of children (P = 0.11; Analysis 3.2), or family health-enhancing lifestyle or behaviour outcomes (P = 0.57; Analysis 3.3).

Sensitivity analysis

We performed sensitivity analysis on primary outcomes to determine whether subjective outcomes impacted whether family-centred care improved outcomes compared to the control group.

Overall health and well-being outcome

Ten studies remained in the sensitivity analysis and we removed one study (Tipene-Leach 2014). After removing the subjective outcome, there was still evidence suggesting that family-centred care may improve the overall health and well-being of Indigenous children and their families compared to no family-centred care there (SMD 0.12, 95% CI 0.01 to 0.22; 10 studies, 2208 participants; I^2 = 34%). The results were unchanged from the original analysis.

Physical health and developmental outcomes of children

Seven studies remained in the sensitivity analysis and we removed one study (Tipene-Leach 2014). There was no evidence that physical health and developmental outcomes of children improved when they participated in family-centred care (SMD 0.10, 95% CI −0.02 to 0.23; 7 studies, 1783 participants; I^2 = 35%). The results were unchanged from the original analysis.

Family health-enhancing lifestyle or behaviour outcomes

Four studies remained in the sensitivity analysis and we removed five studies (Barlow 2006; Johnston 2010; Quissell 2014; Tipene-Leach 2014; Family Spirit Nuture Part 1 2021). There was no evidence of an improvement in this outcome between family-centred care and the control group (SMD −0.00, 95% CI −0.16 to 0.15; 4 studies, 932 participants; I^2 = 26%). The results were unchanged from the original analysis.

DISCUSSION

Our initial scoping study on this topic aimed to assess the certainty of the evidence and identify published literature on family-centred care interventions for Indigenous early childhood well-being (McCalman 2017). This scoping study identified three RCTs, which resulted in the initiation and completion of this current Cochrane Review. The evidence from this review will help primary care services base their decisions on optimal interventions to improve the health and well-being of children and their families from Indigenous populations using the most current and reliable evidence.

Summary of main results

We included nine RCTs and two cluster-RCTs that investigated the effect of family-centred care delivered by primary healthcare services for Indigenous early childhood well-being. Studies were aimed at improving various health conditions with 1270 mother–child dyads and 1924 children aged less than five years recruited. Seven studies delivered family-centred education care, which was the most common type of intervention delivered.

Each study reported different types of measures and time points for each of our reported outcomes. As a result, we used a broad and flexible approach to determine whether family-centred care delivered by primary healthcare services was effective in improving physical, psychosocial, and behavioural outcomes of Indigenous children and their families. We found that family-centred care may improve the overall health and well-being of Indigenous children and their families. However, the level of confidence in the evidence was very uncertain due to high risk of biases on multiple domains including no blinding of participants and people delivering the intervention, people delivering the intervention also collected the data, high attrition, and selective outcome reporting. In addition, we downgraded the level of certainty for indirectness as the outcomes measured had different underlying constructs.

For primary outcomes, psychological health and emotional behaviour of children, physical health and developmental health of children, family enhancing lifestyle and behaviours, and psychological health of parents and carers, there was very low-certainty evidence of little to no improvement for families who participated in family-centred care compared to those in the control group. Certainty of evidence was downgraded for these outcomes due to a high risk of bias for non-blinding of participants and people delivering the intervention, people delivering the intervention also collected the data, a high attrition of participants, and selective outcome reporting. Evidence was also downgraded due to small sample size (psychological health and emotional behaviour of children outcome) and outcomes measured using different constructs (e.g. for psychological health of parent/carer we combined general mental health with specific depression scales). Two studies reported that there were no adverse events due to the intervention.

For secondary outcomes, there was a small improvement in parenting knowledge and awareness for families who participated in family-centred care compared to the control group. Two studies reported on service utilisation and access. We were unable to combine the outcomes of these studies in a meta-analysis; however, narratively these studies did not report improvements as a result of the family-centred care intervention. One study reported the economic benefits of delivering family-centred care with the authors suggesting that family-centred care was a cost-effective way to improve early childhood caries in Indigenous children. There were no data for family evaluation of care or family-centredness of consultation processes. No studies reported on the perspectives of the health service providers.

We completed subgroup analyses to explore whether types of family centred-care interventions such as environmental, communication, educational, counselling, or family support were effective in improving outcomes. We found little to no difference in subgroups for the outcomes overall health and well-being of children, physical health and developmental outcomes of children, or family health-enhancing lifestyle or behaviour outcomes.

Overall completeness and applicability of evidence

Overall, we do not consider that there was publication bias. Many trials did not report positive results and were still published. However, there was a dearth of evidence from Australia, Canada, and New Zealand with seven of the 11 trials from the USA. Data from six trials from the USA were also from two studies: the Family Spirit programme (four finished and two ongoing) and the two HCSF trials. All 11 trials were deemed to be culturally considered with some level of consumer and community engagement that included consultation prior to the study or reference groups for the study duration, or both.

Ten studies assessed family-centred care as a single broad intervention type (e.g. environmental, education, counselling) and one as a multiple intervention type (e.g. education and counselling) (Table 1). Although studies delivered several types of family-centred care interventions, there is scope for trials to consider whether combining types of family-centred care or more complex strategies would result in improved outcomes. However, to achieve this there would need to be an increased funding commitment and workforce to deliver more complex interventions, both of which can be difficult to achieve. In addition, there were no family-centred care interventions that included communication or family support as avenues of delivering care for children and their families. This may be the result of our search strategy not detecting some types of family-centred care, such as communication interventions, as they are more focussed on care co-ordination and continuity of care. We assessed studies using the family-centred care criteria previously developed by Shields 2012; however, this assessment

was based on what was provided in the publications and should be considered a minimum score for each intervention. It is likely that word limitations in peer review publishing may have prevented fuller descriptions and hence higher scores.

The control groups included in the trials were either care as usual or a minimal intervention that did not include family-centred care. Although one study included both a minimal intervention and a delayed family-centred care intervention delivered from 24 months of age for one year, there were no studies comparing one type of family-centred care intervention to another. Given that 8/11 studies provided a minimal intervention to the control group, this may explain why there were only small or no effects seen. It is possible that had only usual care been delivered, there may have been more substantive effects seen for the outcomes in this review. However, we are unlikely to see many more trials that deliver usual care only as it is largely deemed inappropriate by communities for families to receive nothing.

Studies for inclusion in the review required the child to be the main focus with the delivery of family-centred care. As such, many of our outcomes were child-related. However, we recognise that family-centred care, particularly in the context of Indigenous health, includes care not only for child health, antenatal care, family support, and early childhood care, but also for adults including mental health and chronic disease care. The latter aspects of care aim to improve adult health outcomes. Family-centred care also aims to prevent, reduce, and intervene in adverse childhood events and to reduce the long-term impacts that chronic disease, depression, and suicidal ideation have on families. Indeed, Indigenous governed health services have greater capacity to influence portfolios outside primary health care to other non-health programmes. As such, this review does not capture this wider context of family-centred care programmes that are delivered in communities.

Quality of the evidence

Using GRADE methodology, we assessed the certainty of evidence for all primary outcomes. Summary of findings 1 reports six outcomes comparing family-centred care to any control group. All outcomes were at very low certainty of evidence. This was largely due to the high risk of bias in the studies, and indirectness. For the delivery of the intervention, it was not feasible to blind participants and those delivering the intervention. The location of the trials also impacted on the capacity of trials to recruit different staff to implement the trial and collect data. This occurred in four trials where the person who delivered the intervention also collected the data (Barlow 2006; HCSF 1 2007; HCSF 2 2017; Walkup 2009). Additionally, many of the outcomes reported in the studies were self-reported, particularly in studies that were not disease specific. Lastly, long follow-up times in some studies resulted in substantial loss to follow-up. As a result, studies were scored at a high risk of bias particularly for blinding of participants and personnel and incomplete outcome data. We expect newer trials that overcome some of these issues will result in a change in the results presented.

Potential biases in the review process

We attempted to reduce bias in the review process. We requested clarification from three study authors whether interventions were delivered by primary healthcare services; all authors responded to our requests (four studies: Broughton 2013; HCSF 1 2007; HCSF 2 2017; Johnston 2010). We also requested data from one trial; this was supplied by the corresponding author (HCSF 2 2017). We contacted all authors of included and ongoing studies to determine whether there were any other studies for inclusion resulting in identification of one additional ongoing study (Family Spirit Nuture Part 2 2019).

We completed an intensive literature search, and included ITS and CBA study designs to ensure we captured relevant studies in this area. Compared to our scoping review (McCalman 2017), we found an additional eight RCTs and eight ongoing trials. At all stages, at least two review authors independently reviewed, selected, extracted, and completed the risk of bias on all data with discrepancies discussed with a third review author. Decisions on which outcomes to include in the review were completed by six review authors who selected outcomes of importance and relevance (as outlined in Differences between protocol and review). To minimise bias, review authors were unaware of the results of the outcomes during this process.

Agreements and disagreements with other studies or reviews

Only one Cochrane Review has investigated family-centred care within the hospital setting for children aged from birth to 12 years and found one RCT that met the criteria (Shields 2012). The review found moderate-quality evidence of the effects of family-centred care for children in hospitals, which suggested some benefit for children's clinical care, parental satisfaction, and costs; there was no evidence of harms. There are several systematic and scoping reviews on non-Indigenous populations and family-centred care interventions. One qualitative review to support the Cochrane effectiveness review (Shields 2012) found that negotiation and perceptions by both health service providers and families influenced how family-centred care was delivered (Shields 2006). This is supported by one scoping review examining the implementation of family-centred care in the delivery of maternal and child health services for children aged less than five years (Ridgway 2021). Authors identified 13 qualitative studies and found four key themes regarding successful implementation: treating and maintaining respectful relationships; adapting and contextualising care; supporting autonomy and agency; and building a shared understanding through effective communication. One systematic review on the effect of family-centred care on the health of preterm infants and parents in the neonatal intensive care unit found a significant reduction in readmission rates (Ding 2019). Similar to our review, they also found evidence of improvement in parenting skills and knowledge of families who participated in family-centred care compared to the control group. Two additional systematic reviews on family-centred care for children with special healthcare needs (USA population only) and preterm infants and parents in the neonatal intensive care unit described improvements for children and families who participated in the intervention (Kuhlthau 2011; Segers 2019). However, both of these studies were descriptive with no formal analysis completed. Several of these reviews are now outdated, included a range of study designs, and provided no formal data analysis to support their conclusions. Other than our scoping review, we were unable to find reviews that focused on Indigenous children or children aged from birth to five years within the primary healthcare setting (McCalman 2017).

AUTHORS' CONCLUSIONS

Implications for practice

This review found very low-certainty evidence that family-centred care delivered by primary healthcare services may improve the overall health and well-being of children and their families. There was also evidence to suggest that families who participated in family-centred care increased their parenting knowledge and awareness to a small degree. However, for all other outcomes it is unclear whether family-centred care improves specific child health and well-being outcomes. We consider family-centred care to be promising, but further research is required to establish its effectiveness.

Implications for research

There is a need for research in several areas. High-quality trials are needed to generate evidence to determine whether family-centred care improves the health and well-being of Indigenous children aged less than five years. There is a need to clarify the principles and core components of family-centred care for Indigenous families and that is informed by Indigenous world views of family, which will guide greater consistency in outcome measurement and evaluation to determine the effect. There were no communication and family support interventions delivered with family-centred education the most common intervention delivered. Broadening the types of family-centred interventions to include these other styles may improve the health and well-being of Indigenous children and their families. Furthermore, no studies reported on the quality of care and the impact of family-centred care from the perspective of health service providers. These outcomes are important to determine the effectiveness of family-centred care.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Barlow 2006

Study characteristics	
Methods	Study design: RCT Study recruitment: July 2001–February 2002; follow-up 6 months' postpartum Published protocol/trial: none found
Participants	Description: pregnant American Indian adolescents aged 12–19 years at conception and at ≤ 28 weeks' gestation (intervention n = 28, comparison n = 25) Exclusion criteria: serious medical, legal, or social problems that would preclude their ability to fully participate in the intervention and assessments Indigenous population: Navajo and White Mountain Apache reservations in New Mexico and Arizona Setting: USA, reservation Place of delivery: Indian Health Service Principle health condition: negative parenting patterns Age of mother: intervention < 18 years: 16 (57%), comparison < 18 years: 17 (68%) Gender of child: not reported First child in family: intervention 21 (75%), comparison 19 (76%) Family unit: living with parents: intervention 20 (71%), comparison 16 (64%) Socioeconomic status: not reported Employment of mother: currently employed: intervention 4 (14%), comparison 3 (12%) Education of mother: still in school: intervention 16 (57%), comparison 15 (60%)
Interventions	**Intervention**

Barlow 2006 *(Continued)*

Intervention name: Family Strengthening Intervention

Intervention aim: to promote childcare knowledge, skills, and involvement among pregnant American Indian adolescents.

Theory used to develop intervention: intervention was modelled on "Healthy Families America" a national programme founded on 12 research-based principles to ensure quality of home-visiting interventions for at-risk families. The content was derived from extensive community input on what teen parents needed to learn and was based on the American Academy of Pediatrics guide to baby care: *Caring for Your Baby and Young Child: Birth to Age 5*.

Consumer and community involvement: a community-based participatory process was used to culturally adapt the programme including style, graphics, delivery, and content.

Overall grouping: education

Fees, reimbursement, or incentives: none reported

Procedures: lessons covered antenatal care, labour, delivery, breastfeeding, nutrition, parenting, home safety, immunisations, well-baby care, family planning, sexually transmitted disease prevention, and maternal goal setting for personal and family development. The curricular content was scheduled chronologically to provide key instruction at developmentally appropriate times for participants' children. The protocol included 25 home visits and 41 discrete lessons taught from 28 weeks' gestation to 6 months' postpartum (about 9 months total) by the educators using tabletop flip charts. Home visits were scheduled to last approximately 1.5 hours. Cultural adaptations, including style, graphics, delivery, and content, were achieved through a community-based participatory process (Barlow 2006, p. 1102).

Incentives, reimbursements, fees paid to individuals or organisations: none reported

Materials: not reported

Mode of delivery: individual home visits

When and how often was the intervention delivered? intervention delivered from 28 weeks' gestation to 6 months' postpartum (about 9 months in total). 25 home visits and 41 discrete lessons could be provided.

Who delivered the intervention? educators: American Indian women, bilingual, job history in health and human services, passed a background screening test, been a teen mother, or had a special interest in this group.

Was there any training provided to the people who delivered the intervention? educators participated in > 500 hours of training and were tested to ensure they had mastered lesson content and delivery strategies prior to study implementation. Educators received daily supervision at the site and weekly supervision through cross-site conference calls. Ongoing training occurred bimonthly throughout the study. Every 3 months, supervisors observed educators with participants and rated educators' professionalism, rapport, interpersonal skills, and adherence to the home-visitation protocol.

Was the study modified or adapted? none reported

Was the fidelity assessed? fidelity to dose of intervention was completed. Intervention group completed 82% of 41 lessons and 85% of 25 expected home visits. The control group completed 86% of 20 lessons and 63% of 23 expected home visits.

Comparison

Breastfeeding Education Programme

This was an education programme that was developed in 1996–1997 by Johns Hopkins Center for American Indian Health and the participating communities. Participants assigned to this arm received 23 home visits covering 20 breastfeeding lessons. Expected visit duration was 1–1.5 hours.

Fees, reimbursement, or incentives: none reported

Barlow 2006 *(Continued)*

Outcomes	Overall health and well-being: depression Family enhancing lifestyle or behaviour outcomes: family cohesion Parent/carer psychological health: depression Parenting knowledge and awareness: skills Time points: 2 and 6 months
Funding source and conflicts of interest	Funding: Substance Abuse Mental Health Services Administration, the Ford Foundation, the Annie E. Casey Foundation, and the C. S. Mott Foundation Conflict of interest: none reported
Notes	Other outcomes collected but not used within the review Mother: knowledge, involvement, family conflict, locus of control, self-esteem, drug use, social support

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation using web program. Quote: "Randomization stratified by site was determined by the Randomization.com Website prior to enrolling any study participants."
Allocation concealment (selection bias)	Low risk	Randomisation occurred after enrolment; central allocation was used. Quote: "The randomization sequence for each site was stored in Baltimore, Md, by our data manager and was concealed from the key investigators and on-site educators at all times. After each participant signed consent/assent forms and completed the baseline assessment, the educators faxed these materials to the data manager in Baltimore. The data manager checked that all assessments were properly completed, confirmed that the teen met inclusion criteria and no exclusion criteria, and then informed the educator of the participant's group assignment."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and people delivering the intervention were not blinded to the intervention. Quote: "The participants and evaluators were not blind to intervention assignment."
Blinding of outcome assessment (detection bias) All outcomes	High risk	Evaluators both delivered the intervention and completed the data collection for all mothers.
Incomplete outcome data (attrition bias) All outcomes	High risk	Intention-to-treat analysis completed. There was a higher dropout in the intervention group compared to the control group. The intervention group were more likely to be living with their parents, still in school, and be recruited earlier in their pregnancies. The authors acknowledged this limitation.
Selective reporting (reporting bias)	Unclear risk	Unable to find a protocol or trial registration.
Other bias	Low risk	No other obvious sources of bias.

Broughton 2013

Study characteristics	
Methods	Study design: RCT Study recruitment: July 2011–December 2012; follow-up 36 months' postpartum Published protocol/trial: protocol published and trial registered; ACTRN12611000111976 and ACTRN12610000422022
Participants	Description: pregnant Maori women residing within the Waikato-Tainui tribal area (intervention n = 126, control n =133) Exclusion criteria: none reported Indigenous population: Maori Setting: New Zealand, tribal area Place of delivery: primary healthcare services and dental clinics Principle health condition: early childhood caries Age of mother (years), mean: intervention 27.1 (SD 6.1), control 26.6 (SD 7.0) Gender of child: not reported First child in family: intervention 39 (32%), control 52 (40%) Family unit: none reported Socioeconomic status: held a community services card: intervention 83 (69%), control 81 (63%) Employment of mother: employed only: intervention 37 (34%), control 33 (29%); employed and benefits intervention: 11 (10%), control 10 (9%); benefits only: intervention: 51 (46%), control 58 (52%) Education of mother: up to secondary school: intervention 42 (38%), control 43 (38%); trade/polytechnic intervention: 45 (41%), control 39 (35%); university intervention: 45 (41%), control 28 (25%)
Interventions	**Intervention** Intervention 1 name: not delayed intervention Intervention aim: to reduce dental disease burden and oral health inequalities among Maori children living in the Waikato-Tainui tribal area of Aotearoa/New Zealand. Theory used to develop intervention: intervention was modelled on the Te Whare Tapa Whā model of health and well-being which compares health to the 4 walls of a house and employs a set of values, principles, philosophy, and practice that is iwi-derived and grounded in Waikato-Tainui maatauranga (knowledge). Consumer and community involvement: study conducted within the North Island Tribal area of Waikato-Tainui and was the responsibility of 2 tribally derived organisations: Raukura Hauora O Tainui and the Waikato-Tainui College for Research and Development. Both organisations worked in partnership with a research team from the University of Otago. Overall grouping: counselling Fees, reimbursement, or incentives: none reported Procedures: participants were offered 4 intervention components: 1. provision of dental care during pregnancy; 2. FV application to the teeth of children aged 6, 12, and 18 months; 3. MI; and 4. AG. The themes covered by each MI/AG phase include: 1. oral health knowledge, including teeth eruption and teething, causes and prevention of childhood dental disease, and foods, beverages, and behaviours

Broughton 2013 *(Continued)*

	that are harmful to oral tissue; 2. oral self-care – including ways to look after children's teeth, use of toothbrush, toothpaste and disclosing solution; and use of oral health services; 3. oral health protection and community water fluoridation. Materials: participants were provided with free basic dental care and support was provided for participants to access the dental clinic. Oral health packs, including toothbrushes and toothpaste, were provided to be consistent with the AG, Maori-focused oral health promotion materials, and the New Zealand oral healthcare system (fluoridation and oral health aids). Mode of delivery: individual, face-to-face sessions When and how often was the intervention delivered? dental care was arranged during pregnancy or when the participant could attend, FV was provided at 6, 12 and 18 months for children, and the MI/AG sessions were implied to be delivered at the same interval as the FV. Who delivered the intervention? oral health professional: delivered the dental care and FV component; motivational interviewer: delivered the MI/AG component. Was there any training provided to the people who delivered the intervention? none reported Was the study modified or adapted? none reported Was the fidelity assessed? none reported Intervention 2 name: delayed intervention Intervention 2 description: after 24 months the control group received the intervention described above and was named the 'Delayed intervention' group. **Comparison** Minimal dental care Basic dental care was provided that included examination, x-rays, pain relief, control of infection, scaling and prophylaxis, elimination of caries, restorations, and extractions. Fees, reimbursement, or incentives: none reported
Outcomes	Overall health and well-being: early childhood caries Child physical health and development: early childhood caries Time points: 24 and 36 months
Funding source and conflicts of interest	Funding: Te Kaunihera Rangahau Hauora O Aotearoa, the New Zealand Health Research Council (HRC ICIHRP Grant application ID 09/644) Conflict of interest: none reported
Notes	Other outcomes recorded but not used within the review Child physical health and development: other measures of early childhood caries Time points: 24 and 36 months

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Participants were randomised using envelopes.

Broughton 2013 *(Continued)*

		Quote: "Once the mother had agreed to participate in the study they were randomly allocated to either the intervention group or the delayed intervention group by choosing an envelope which contained the name of the group."
Allocation concealment (selection bias)	Unclear risk	There was little information provided about allocation concealment other than the drawing of envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and people delivering the intervention were not blinded to the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	People collecting data were blinded to the intervention. Quote: "The therapist did not know which intervention group the child had been allocated to."
Incomplete outcome data (attrition bias) All outcomes	High risk	High attrition. Outcome data were available for less than half of the intervention group and there were differences in self-reported health status and education level between those who completed the study and those who withdrew. Quote: "At the follow-up when the child was 24 months old, under half of the mothers in the intervention group were assessed."
Selective reporting (reporting bias)	High risk	A protocol was available; however, there was insufficient information to determine how the data were to be analysed. Multiple outcome measures were reported.
Other bias	Low risk	No other obvious sources of bias.

Family Spirit Nuture Part 1 2021

Study characteristics	
Methods	Study design: RCT Study recruitment: March 2017–May 2018; follow-up 12 months' postpartum Published protocol/trial: trial registered NCT03101943
Participants	Description: Navajo mothers aged ≥ 13 years with infants aged < 14 weeks living within 50 miles of the Northern Navajo Medical Center (intervention n = 68, control n = 66) Exclusion criteria: unable to fully participate or unwilling to undergo randomisation Indigenous population: Navajo Nation (New Mexico) Setting: USA, reservation Place of delivery: Indian Health Service: Northern Navajo Medical Center Principle health condition: childhood obesity Age of mother (years), mean: intervention: 27.4 (SD 6.4), control 27.5 (SD 6.1) Gender of child born: intervention 35 (52%) girls, control 35 (53%) girls Number of children in family: intervention 2.4 (SD 1.6), control 2.4 (SD 1.4) Family unit: married intervention 10 (15%), control: 15 (23%)

Family Spirit Nuture Part 1 2021 *(Continued)*

	Socioeconomic status: 1 financial hardship: intervention 13 (19%), control 19 (29%); 2–5 financial hardships: intervention 22 (32%), control 20 (30%); no financial hardship: intervention 33 (48%), control 27 (41%) Employment of mother: not employed: intervention 54 (79%), control 59 (89%); full-time: intervention 8 (12%), control 4 (6%); part-time: intervention 6 (9%), control 3 (5%) Education of mother: less than high school: intervention 8 (12%), control 14 (21%); still attending or completed high school or general equivalency diploma: intervention 27 (40%), control 19 (29%); completed more than high school: intervention 33 (49%), control 33 (50%)
Interventions	**Intervention** Intervention name: FSN Intervention aim: to address specific parent feeding practices in infancy associated risk for early childhood obesity, including SSB consumption, responsive parenting and infant feeding practices, and optimal growth through 12 months' postpartum. Theory used to develop intervention: FSN model was built on the previously published, evidence-based Family Spirit home-visiting early childhood intervention. Consumer and community involvement: the brief FSN early childhood home-visiting intervention was designed in partnership with tribal communities. Overall grouping: education Fees, reimbursement, or incentives: participants received USD 20 in gift cards and 2 gift packages worth USD 25 for the completion of assessment at baseline, 4, and 12 months. Procedures: home visit lessons were delivered between 3- and 6-months' postpartum and covered the following: 1. whole family healthy eating practices, 2. optimal infant feeding practices, 3. responsive feeding, 4. avoiding SSBs, 5. complementary feeding practices, and 6. parental healthy eating role modelling. Materials: 45-minute lessons included a warm-up, lesson content and activities, a question-and-answer period, referrals as needed and summary handouts. Mode of delivery: individual home visits When and how often was the intervention delivered? 6 lessons were delivered at specific infant age intervals at 3, 3.5, 4, 4.5, 5, and 6 months' postpartum. Who delivered the intervention? Navajo paraprofessionals Was there any training provided to the people who delivered the intervention? yes; however, the type of training was unspecified. Was the study modified or adapted? none reported Was the fidelity assessed? none reported **Comparison** Minimal education Participated in 3 injury prevention lessons at 3, 4, and 5 months' postpartum drawn from the original Family Spirit intervention but avoided confounding FSN content and outcomes. Content included childproofing, safe travel practices, and strategies to avoid abuse and neglect. Control sessions followed the same format as the FSN lessons. Fees, reimbursement, or incentives: participants received USD 20 in gift cards and 2 gift packages worth USD 25 for the completion of assessment at baseline, 4, and 12 months.
Outcomes	Overall health and well-being: infant growth

Family Spirit Nuture Part 1 2021 *(Continued)*

	Child physical health and development: infant growth Family-enhancing lifestyles or behavioural outcomes: SSB consumption Adverse events: emergency department presentations or hospital admissions Parenting knowledge and awareness: maternal SSB consumption index Time points: < 2 months and 12 months
Funding source and conflicts of interest	Funding: Navajo Area Indian Health Service, the Osprey Foundation (grant# 132271), the McCune Charitable Foundation, and a private donor Conflict of interest: none reported
Notes	Other outcomes recorded but not used within the review Child: infant growth, age at complementary food introduction, % introduced complementary food at ≥ 6 months' postpartum, SSB consumption Mother: responsive feeding Time points not used: 4, 6, and 9 months

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation lists were created using statistical software. Quote: "Two randomization lists will be created prior to study initiation using STATA statistical software."
Allocation concealment (selection bias)	Low risk	Randomisation occurred after enrolment. Quote: "Participants who completed a baseline assessment were randomized 1:1 to the FSN intervention or the IPE control. Randomization status was delivered by text message or phone call to staff who enrolled the participant."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and staff were not blinded to the intervention. Quote: "Participants and study staff were not blind to randomization status."
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is unclear who collect the study data. The protocol discussed trained staff; however, it is not clear who this was in the study and whether they were blinded to outcome assessments.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was a low level of attrition which was balanced between groups. Quote: "Follow-up assessments were completed by 92% (123 of 134) of participants at 12 months post partum."
Selective reporting (reporting bias)	High risk	Protocol available. Data were provided as per primary outcome; however, it is unclear how these data were defined (i.e. binary or continuous) both are provided. Adjusted effect sizes are only reported.
Other bias	Low risk	No other obvious sources of bias.

Family Spirit Trial 2012

Study characteristics	
Methods	Study design: RCT Study period: May 2006–September 2011; follow-up 36 months' postpartum Published protocol/trial: protocol published and trial registered; NCT00373750
Participants	Description: all pregnant American Indian adolescents aged 12–19 years at conception and at ≤ 28 weeks' gestation (intervention n = 159, comparison n = 163) Exclusion criteria: currently participating in other mental or behavioural research or if life circumstances precluded full participation in the intervention protocol, such as severe mental illness or legal status that required high-intensity residential care. Indigenous population: White Mountain Apache, San Carlos Apache Reservations, and the Tuba City and Fort Defiance communities on the Navajo Reservation in northern Arizona Setting: USA, reservations Place of delivery: Indian Health Service Principle health condition: reduce health and behavioural risks Age of mother (years), mean: intervention 18.2 (SD 1.4), control 18.1 (SD 1.6) Gender of infant: none reported First child in family: intervention 122 (76.7%), control 125 (76.7%) Family unit: lives with parents: intervention 96 (60.8%), control 95 (58.6%) Socioeconomic status: none reported Employment of mother: currently employed: 12 (7.5%), control 11 (6.8%) Education of mother: currently in school: intervention 63 (39.6%), control 68 (41.7%)
Interventions	**Intervention** Intervention name: Family Spirit Intervention + optimised standard care Intervention aim: to promote family-based protective factors and reduce behavioural health disparities among American Indian teen parents and their children. Theory used to develop intervention: the theoretical model underpinning the Family Spirit intervention was based on G.R. Patterson's developmental model, which posits parenting as the critical link between parents' personal characteristics and environmental context and their children's individual risks and ultimate outcomes. Based on this framework, the Theory of Planned Behaviour was used to inform the intervention development. Consumer and community involvement: community-based participatory research was used in the design, prioritising topic areas, and recommendations to use local paraprofessionals. Overall grouping: education Fees, reimbursement, or incentives: incentives through gift cards were given for assessments and increased with duration of participation in the study. For example, they started at USD 10 for initial assessment and increase by USD 5 per time point for maximum of USD 50 for final assessment. Procedures: the Family Spirit curriculum lessons focused on 3 domains: 1. parenting skills across early childhood (0–3 years); 2. maternal drug abuse prevention; and 3. maternal life skills and positive psychosocial development. Each visit was delivered using a flip chart. Lessons are structured to include building rapport, review of previous lesson, and past referrals, teaching of lessons and related activi-

Family Spirit Trial 2012 *(Continued)*

	ties, question/answer period and distribution of lesson summary hand-outs. The home visitor is trained to use the lesson outline to create a comfortable teaching dialogue, rather than reading points by rote. Materials: lesson summary hand-outs Mode of delivery: individual home visits or other private location When and how often was the intervention delivered? each visit lasted approximately 1 hour with 43 lessons delivered over 45 visits from. Home visits occurred weekly through to the end of pregnancy, bi-weekly until 4 months' postpartum, monthly between 4 and 12 months' postpartum, and bimonthly between 12 and 36 months' postpartum. Who delivered the intervention? Family Health Educator: local female American Indian paraprofessionals, bilingual, minimum of high school diploma, ≥ 2 years of job-related education or work experience. Was there any training provided to the people who delivered the intervention? staff received extensive training (> 80 hours) in trial protocol and policies, protection of human research subjects, and intervention delivery. Family Health Educators had to demonstrate mastery of the Family Spirit curriculum through written and oral examinations. During the first year of employment, supervisors observed educators conducting home visits on a quarterly basis and rated them on professionalism, rapport, interpersonal skills, and protocol adherence. Was the study modified or adapted? none reported Was the fidelity assessed? both Family Health Educators and Evaluators audiotaped each participant visit and a random 20% of tapes are reviewed by study co-ordinators for protocol adherence. The proportion of intervention lessons completed was recorded. **Comparison** Usual care Usual care included transportation assistance to regularly scheduled, clinic-based antenatal and well-baby visits. There were 7 antenatal visits, 9 well-baby visits during the first 3 years of life (at 1 and 2 weeks, and 2, 4, 6, 9, 12, 24, and 36 months' postpartum), and 4 social support visits between years 2 and 3. Fees, reimbursement, or incentives: incentives through gift cards given for assessments and increased with duration of participation in study (e.g. started at USD 10 for initial assessment and increased by USD 5 per time point for maximum of USD 50 for final assessment).
Outcomes	Overall health and well-being: ITSEA – competence domain Child psychological health and emotional behaviour: ITSEA – competence domain Family enhancing lifestyle or behaviour outcomes: Home Observation for Measurement of the Environment Parent/carer psychological health: depression Parenting knowledge and awareness: home safety practices, knowledge Time points: 12 and 36 months
Funding source and conflicts of interest	Funding: National Institute on Drug Abuse grant R01 DA-019042 Conflict of interest: Dr Compton has served as a consultant for Shire Pharmaceuticals, as a principal investigator on a study for Shire Pharmaceuticals, and as an associate editor for the Journal of Consulting and Clinical Psychology and the Journal of Child and Adolescent Psychopharmacology. Dr Carter receives royalties for the Infant-Toddler Social and Emotional Assessment. Dr Walkup has served as a consultant for Shire Pharmaceuticals and has received research support from, served on the advisory board of, and received travel support and honoraria from the Tourette Syndrome Association; he has

Family Spirit Trial 2012 *(Continued)*

	received free medication and placebo for NIH-funded studies from Eli Lilly and from Pfizer; and he receives royalties from Guilford Press and Oxford University Press.
Notes	Other outcomes recorded but not used within the review Child: internalising, externalising, and dysregulation behaviour Mother: substance use, parenting knowledge, home safety attitudes, parenting-related stress, self-efficacy, internalising problems, externalising problems, total behavioural and social problems, alcohol and substance abuse Time points not used: 6 months

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation using computer program. Quote: "The data manager created the randomization sequence using Stata 9.0, and the study coordinator delivered the randomization status of each individual over the telephone to the unblinded field staff member who had enrolled the participant."
Allocation concealment (selection bias)	Low risk	Randomisation occurred after enrolment; central allocation used. Quote: "The data manager created the randomization sequence using Stata 9.0, and the study coordinator delivered the randomization status of each individual over the telephone to the unblinded field staff member who had enrolled the participant."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and people delivering the intervention were not blinded to intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Independent evaluators blinded to randomisation collected data. Quote: "Independent Evaluators complete all participants' observational and interview assessments and medical chart reviews and are masked to participants' randomization assignment."
Incomplete outcome data (attrition bias) All outcomes	High risk	Intention-to-treat analysis completed. High level of attrition at end of study with a higher attrition rate in intervention than control group. Quote: "Attrition was higher in the intervention group than in the control group. Attrition in both conditions primarily occurred before 12 months, followed by relatively stable participation through 36 months. Analyses of differential attrition showed significant effects for two variables. Women in the intervention group who reported no substance use during pregnancy were more likely to drop out, and participants in the control group who reported never using cigarettes were more likely to remain in the study. Attrition did not favor the intervention group."
Selective reporting (reporting bias)	High risk	There was a protocol but no data analysis provided. Data for time points at 36 months were combined and only mean adjusted scores were given.
Other bias	Unclear risk	There was some discussion on the cultural appropriateness of the outcomes in particular the Home Observation Measurement of the Environment. No other obvious sources of bias.

Harrison 2010

Study characteristics	
Methods	Study design: cluster-RCT Study recruitment: January 2005–October 2007; follow-up 30 (SD 3) months Published protocol/trial: protocol published and trial registered; ISRCTN41467632
Participants	Description: women at 12–34 weeks of pregnancy and mothers of newborn, predentate infants from 9 communities (intervention n = 131 in 5 communities, control n = 141 in 4 communities) Exclusion criteria: any woman knowing of an impending, permanent move out of her community. Indigenous population: Quebec Cree Nation Eeyou Istchee Setting: Canada, remote Place of delivery: health clinic Principle health condition: early childhood caries Age of mother (years), mean: intervention 25.5 (SD 6.4), control 25.6 (SD 5.8) Gender of infant: none reported Number of children in family: has other children: intervention 83 (64.3%), control 92 (65.7%) Family unit: none reported Socioeconomic status: none reported Employment of primary carer: none reported Education of primary carer: none reported
Interventions	**Intervention** Intervention name: MI Intervention aim: to control caries in Indigenous children Theory used to develop intervention: follows the principles of MI, a client-centred but directive counselling style. Consumer and community involvement: 2 years of community consultation was completed. This was mainly around study design and the use of RCT. The decision to use an RCT was decided based on no health promotion programme for oral health previously being completed. Community Health Representatives who delivered the intervention modified the intervention protocol and resources (menus) to fit better with the "way of being" of the Cree. The menus were customised for various stages of infant and toddler development and were printed on flip charts that included images of local children and families. Overall grouping: counselling Fees, reimbursement, or incentives: none reported Procedures: at the counselling sessions, mothers were given the resources to enable them to adopt their selected behaviours, e.g. infant toothbrushes and fluoride toothpaste, and xylitol gum for the mother. Menus were developed at specific age ranges to reflect changes over time in each child's feeding and snacking habits, and dental development. FV was provided as a choice of care after the child's first birthday. Mothers also received a 'Privilege Card' to expedite dental care.

Harrison 2010 *(Continued)*

	Materials: mothers received resources at each MI visit to enable them to implement selected behaviours, e.g. infant toothbrushes, toothpaste, and sippy cups. Mothers also received a pamphlet explaining children's dental care practices. Mode of delivery: well-child visit provided individually to each family face-to-face with home visits as an option. When and how often was the intervention delivered? mothers were counselled once during pregnancy and up to 6 times postnatally to correspond with the 2-, 4-, 6-, 12-, 18-, and 24-month well-child visits at local clinics. Who delivered the intervention? Community Health Representatives: existing health workers and, where not available, local women were employed. Was there any training provided to the people who delivered the intervention? a 2-day training workshop for Community Health Representatives was held in the first year of the project in a community adjacent to Eeyou Istchee that was accessible by air or ground transport. An MI consultant delivered the training. The consultant presented theory and principles of MI. Explanatory notes were developed for the Community Health Representatives to guide their counselling sessions. The MI consultant followed up months later with an MI coaching conference call to problem-solve MI with and support the Community Health Representatives. A second 2-day workshop for all intervention Community Health Representatives was held in year 2 in an intervention community. Following this workshop, the Project Manager regularly visited each of the communities individually to problem-solve issues with recruiting and delivery of the counselling interventions. The Programme Manager also maintained regular telephone contact with the project's staff in each community. Was the study modified or adapted? recruitment and delivery of the intervention changed between sites. In 2/5 intervention communities and 2/4 control communities, recruitment and, for the intervention communities, delivery of the intervention was eventually completed by the Project Manager. Local women who were not Community Health Representatives completed recruitment in the remaining 2 control communities. Was the fidelity assessed? no **Comparison** Pamphlet group This was an education programme. The mothers received a culturally appropriate educational pamphlet describing healthy dental care practices for young children. Pamphlets were mailed to mothers when their child was aged 6 and 18 months. FV was available to control children at local dental clinics. Fees, reimbursement, or incentives: none reported
Outcomes	Overall health and well-being: tooth level caries Child psychological health and emotional behaviour: parent answered 'yes' to > 1 quality of life question Child physical health and development: tooth level caries Service access and utilisation: number of visits to the dentist for tooth pain Adverse events: whether there were adverse events Economic costs: cost-effectiveness Time points: 30 (SD 3) months of age
Funding source and conflicts of interest	Funding: Canadian Institute of Health Research (grant #FRN 67817) Conflict of interest: none reported
Notes	Other outcomes recorded but not used within the review

Harrison 2010 *(Continued)*

Child: data on dental caries including enamel caries, dentinal caries, pulpal caries, restorations, and absence due to caries

Mother: dental health knowledge and home care behaviours

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Communities were alphabetically ordered to receive their intervention, which was drawn from lots. Quote: "Communities were randomized in each round by alphabetical ordering of the communities' names. For example, for each round, the first name on the alphabetical list of communities was announced, followed by the drawing of an envelope from the basket; the next name was announced, followed by another draw until all envelopes were allocated."
Allocation concealment (selection bias)	Unclear risk	There was little information provided about allocation concealment other than the drawing of envelopes. Quote: "Randomization was done over community radio with two "rounds" of a constrained randomization process. Two baskets contained envelopes marked "test" or "control": one basket for large communities (2 envelopes: 1 test, 1 control) and another for smaller communities (7 envelopes: 4 test, 3 control)."
Selective cluster recruitment	High risk	Communities knew of their allocation prior to enrolment. Individuals who recruited women also delivered the intervention. There was some baseline differences in recruitment including fewer intervention mothers had already delivered at time of enrolment, had visited a dentist for toothache, and had other children with a previous tooth extraction.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and people delivering the intervention were not blinded to the intervention. Quote: "Mothers and interveners were aware of their community's allocation."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	People collecting data were blinded to the intervention. Quote: "The examiners were blinded to allocation and were unfamiliar with the intervention."
Incomplete outcome data (attrition bias) All outcomes	High risk	Intention-to-treat analysis completed. Greater loss to follow-up in control group compared to intervention group (83% vs 93%).
Selective reporting (reporting bias)	Unclear risk	Protocol available. Data provided as per definition; however, caries reported at tooth and child level and this was not distinguished in the protocol and was the primary outcome.
Other bias	Unclear risk	Deviation from intended intervention: intervention mothers were given "Privilege Cards" to allow for priority access to dental services. However, because of the turnover of dental staff, not all clinics honoured the cards. About one-third recalled using the cards; however, it is unclear how many mothers were turned away. No other obvious sources of bias.

HCSF 1 2007

Study characteristics	
Methods	Study design: RCT Study recruitment: not reported, follow-up 2 years Published protocol/trial: protocol published and trial not registered
Participants	Description: American Indian children aged 2–5 years (interventions n = 67, control n = 83) Exclusion criteria: children with presence of major physical or behavioural conditions that would preclude participation. Indigenous population: Bad River Band of Lake Superior Chippewa Indians, the Lac du Flambeau Band of Lake Superior Chippewa Indians, the Menominee Nation, and the Oneida Nation Setting: USA, reservation Place of delivery: Indian Health Service and Head Start sites Principle health condition: obesity Age of child (years), mean: intervention 4.0 (SD 0.9), control 4.0 (SD 0.9) Gender of child: intervention 34 (50.7%) girls, control 36 (43.4%) girls First child in family: none reported Family unit: none reported Primary carer of child: mother: intervention 58 (86.6%), control 70 (84.3%); father: intervention 2 (3.0%), control 1 (1.2%); grandparent/other: intervention 7 (6.0%), control 12 (14.5%) Socioeconomic status: none reported Employment of primary carer: none reported Education of primary carer: high school or less: intervention 15 (19.7%), control 16 (19.3%); some college: intervention 24 (35.8%), control 30 (36.1%); completed college and beyond: intervention 16 (23.9%), control 22 (26.5%); unknown: intervention 12 (17.9%), control 15 (18.1%)
Interventions	**Intervention** Intervention name: Mentored Health Child, Strong Families (Mentored HCSF) Intervention aim: HCSF aims to change behaviours through increased knowledge of healthy lifestyles, enhanced parenting and increased self-efficacy. Theory used to develop intervention: HCSF is based on social cognitive and family systems theories and seeks to change behaviours at the family level. Consumer and community involvement: tool kit lessons and activities were developed by the University of Wisconsin–Madison and Great Lakes Inter-Tribal Council research team and University of Wisconsin Extension specialists. Community members and tribal leaders were integral throughout the conceptualisation and planning of the intervention. HCSF's Supportive Communities component, which worked with 3 tribal communities to develop community advisory boards was aimed at assessing and eliminating environmental barriers to health. Overall grouping: education Fees, reimbursement, or incentives: gift cards to local merchants and lesson-specific incentives (non-monetary) were provided. Individual amounts varied but averaged USD 175/person.

HCSF 1 2007 *(Continued)*

	Procedures: year 1: initial contact with the family was made by telephone, and mentors were encouraged to share information to create a friendly and supportive relationship. The first in-person lesson was designed to create dialogue between the mentor and the family and to begin building a supportive rapport. During each visit, mentors reviewed the lesson with the primary carer and child, led discussions and activities to help the carer and child learn about the topic, considered behaviour change related to the topic, and assisted the family in setting goals to attempt behaviour change. Ideally, mentor-led discussions assisted the primary carer and child in progressing along the continuum of motivation towards actual behaviour change, while helping the primary carer build skills and confidence in his or her own ability to adopt healthier lifestyle choices. During year 1, intervention families were also invited with their extended family to 3 mentor-led group sessions. Year 2: intervention families participated in monthly group meetings and continued to receive a monthly newsletter with parenting tips/recipes/local programme notices to help in sustaining behaviour changes implemented in year 1. Monthly group meetings focused on topics such as basic nutrition concepts (sugar, fats, appropriate serving sizes, food choice variety) and ideas for physical activities. Monthly newsletters were disseminated for the 2 years Materials: lesson-specific incentives included an HCSF calendar to track goals and progress, cooking utensils, and physical activity items such as balls, frisbees, pedometers, exercise videos, etc. Mode of delivery: year 1: individual face-to-face home visits, year 2 group session When and how often was the intervention delivered? year 1: 12 toolkit lessons, 3 group lessons; year 2: 12 monthly group meetings Who delivered the intervention? mentors: tribal members or other people connected to the tribe. This included parents, grandparents, and respected community members who were able to deliver the intervention. Was there any training provided to the people who delivered the intervention? mentors were trained extensively by the University of Wisconsin Extension staff, tribal well-ness staff (including nurses, diabetes educators, and dieticians), knowledgeable tribal elders, and HCSF research staff. Additional training was provided on child development, nutrition, and physical activity. Mentors received a full protocol manual, yearly training, and refresher sessions. The University of Wisconsin–Madison and Great Lakes Inter-Tribal Council project co-ordinators worked with mentors, discussing issues with in-home visiting and families' lack of progress, and assessed mentor progress. Was the study modified or adapted? if at any time the home visits were unable to be scheduled or completed for participants, the intervention materials were provided by mail. This was not outlined in the protocol. Was the fidelity assessed? not reported **Comparison** Mailed group This was an education intervention. In year 1, the control families received the same 12 lessons by mail + the monthly newsletter. In year 2, the control families received only the monthly newsletter. Fees, reimbursement, or incentives: gift cards to local merchants and lesson-specific incentives (non-monetary) were provided. Individual amounts varied but averaged USD 175/person.
Outcomes	Overall health and well-being: BMI z-score Child physical health and development: BMI z-score Family enhancing lifestyle or behaviour outcomes: 12-item Short Form Survey (SF-12) Physical Health Parent/carer psychological health: SF-12 Mental Health Time points: 12 months

HCSF 1 2007 *(Continued)*

Funding source and conflicts of interest	Funding: Wisconsin Partnership Program Community–Academic Partnership Fund and the NIH (grant number U01 HL 087381). Author EJT was supported through an NIH T32 training grant to the University of Wisconsin Department of Nutritional Sciences (grant number 5T32DK007665). The funders had no role in the design, analysis, or writing of the article. Conflict of interest: none reported
Notes	Other outcomes recorded but not used within the review Child: waist circumference; fruit and vegetable servings/day; soda/sweetened drink and candy servings/day; hours physical activity/day; hours television viewing time/day; accelerometry Mother: waist circumference; height and weight; BMI; glucose tolerance; blood lipid profile; C-reactive protein level; urine microalbumin level; creatinine level; nutrition and physical activity behaviours; fruit and vegetable servings/day; soda/sweetened drink and sweets (candy) servings/day; hours of physical activity/day; hours television viewing time/day; accelerometry; health behavioural efficacy

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	It is unclear how sequence generation was completed; however, there appeared to be a sufficient process of randomisation used. Quote: "Within each stratum, half of the families were randomly assigned to the intervention condition and half to the control condition. Furthermore, within each stratum, a blocked randomization strategy was used to ensure that there was an equal number of families in the intervention and control groups."
Allocation concealment (selection bias)	Unclear risk	Randomisation occurred after enrolment; no information about allocation concealment. Quote: "Randomization at the family level was done after obtaining consent from and completing baseline measurements on participating families."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and people delivering the intervention were not blinded to the intervention.
Blinding of outcome assessment (detection bias) All outcomes	High risk	The same people who delivered the intervention also collected the data.
Incomplete outcome data (attrition bias) All outcomes	High risk	Intention-to-treat analysis completed. High level of missing data with more data missing in the intervention (83%) than in the control (67%) group; intention-to-treat analysis. Missing imputation was completed but did not account for the high attrition rate in the intervention group.
Selective reporting (reporting bias)	Low risk	Protocol available. Data provided as per definition.
Other bias	High risk	Changes in participant allocation after randomisation Participants were moved after randomisation. This could have influenced outcomes in favour of the intervention. No sensitivity analysis was completed. No other obvious sources of bias.

HCSF 1 2007 *(Continued)*

	Quote: "After randomization, participants who were unable to be scheduled for their initial mentoring visit within two months were moved to the mailed toolkit group, resulting in a higher number of participants in this group (eight families were transferred before any intervention was administered, resulting in eighty-three in the mailed only group instead of the seventy-five expected after randomization)."

HCSF 2 2017

Study characteristics	
Methods	Study design: RCT Study recruitment: January 2013–April 2015; follow-up 1 year Published protocol/trial: protocol published and trial registered; NCT01776255
Participants	Description: American Indian children aged 2–5 years and their primary carers (intervention n = 225, control n = 225) Exclusion criteria: minimal exclusion criteria applied due to community's value for inclusion in community projects. Indigenous population: American Indian/Alaska Native Setting: USA, 4 reservations and 1 urban site Place of delivery: Indian Health services, Head Start centres, and social service centres Principle health condition: obesity Age of child (months), mean: intervention 45.9 (SD 12.8), control 44.1 (SD 13.2) Gender of child: intervention 115 (51.1%), control 111 (49.3%) Number of children in family: none reported Family unit: none reported Primary carer of child: none reported Socioeconomic status: < USD 5000: intervention 69 (31.7%), control 63 (28.4%); USD 5000–19,999: intervention 61 (28.0%), control 63 (28.4%); USD 20,000–34,999: intervention 45 (20.6%), control 49 (22.1%); ≥ USD 35,000: intervention 43 (19.7%), control 47 (21.2%) Employment of primary carer: none reported Education of primary carer: high school or less: intervention 83 (36.9%), control 86 (38.2%); some college: intervention 120 (53.3%), control 115 (51.1%); completed degree or postgraduate: intervention 22 (9.8%), control 24 (10.7%)
Interventions	**Intervention** Intervention name: Wellness Journey Intervention aim: none reported Theory used to develop intervention: none reported Consumer and community involvement: each selected community vetted the final study design and provided input. Community partners (including tribal wellness staff and community advisory boards)

HCSF 2 2017 *(Continued)*

	also developed additional lessons targeting stress and sleep that were not part of the original programme (HCSF 1: see Adams 2011 under HCSF 1 2007). Overall grouping: education Fees, reimbursement, or incentives: all families received as USD 50 gift care after completing baseline, 12-month and 24-month testing. Families who were randomly chosen to complete dietary recalls also received an additional USD 25 gift card at each time point. Lesson-specific incentives, such as cooking utensils, balls, books, games, and pedometers were also provided. Procedures: each monthly toolkit included 1. printed educational lessons with information and suggestions for activities, 2. supportive items (e.g. measuring cups, recipes, pedometers, games), and 3. a children's book relating to 1 of the intervention targets to foster family interaction. There were 6 intervention targets, which included increasing fruit and vegetable consumption, decreasing sugar consumption, increasing physical activity, decreasing screen time, improving sleep habits, and decreasing stress (adult only). Wellness Journey adults were supported by social media engagement and invited invitation to an optional, site-specific Facebook group where intervention targets were discussed. Materials: each Wellness Journey lesson included a children's book related to the topic and items to support behaviour change (e.g. pedometers, apple corers, measuring cups, exercise DVDs) Mode of delivery: mailed to individuals When and how often was the intervention delivered? 12 monthly mailed lessons; twice weekly text messages and an invitation to optional site-specific Facebook group. Who delivered the intervention? local community members were employed as the project co-ordinator at each site. Was there any training provided to the people who delivered the intervention? local co-ordinators were trained in-person by the central study co-ordinator on all research protocols. Was the study modified or adapted? none reported Was the fidelity assessed? none reported **Comparison** Safety Journey This was a child safety curriculum intervention. 12 mailed safety newsletters and related materials including safety reflectors for biking and cabinet safety locks were sent to participating families. Fees, reimbursement, or incentives: all families received as USD 50 gift care after completing baseline, 12-month and 24-month testing. Families who were randomly chosen to complete dietary recalls also received an additional USD 25 gift card at each time point. Safety-focused incentives included bike reflectors, outlet covers, and books.
Outcomes	Overall health and well-being: BMI z-score Child physical health and development: BMI z-score Family enhancing lifestyle or behaviour outcomes: SF-12 Physical Health Parent/carer psychological health: SF-12 Mental Health Time points: 12 months
Funding source and conflicts of interest	Funding: National Institutes of Health, National Heart, Lung, and Blood Institute (grant number 1R01HL114912). Authors, EJT and VMG were supported through NIH T32 training grants to the University of Wisconsin Department of Nutritional Sciences (5T32DK007665) and the Department of Family Medicine and Community Health (T32HP10010), respectively, at the time of the work. Conflict of interest: none reported

HCSF 2 2017 *(Continued)*

Notes	Other outcomes recorded but not used within the review Child: waist circumference; diet screener; physical activity; 24-hour diet recall; screen time survey; physical activity, weekday sleep (hours) Mother/carer: BMI; waist circumference; diet screener; physical activity; 24-hour diet recall; screen time survey; physical activity; sleep survey; self-efficacy; safety survey, family nutrition and physical activity total score, adult perceived stress Follow-up 2 years; however, in year 2, participants crossed over and completed the alternative intervention/control. We used results from year 1 as the effectiveness trial.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation using computer program. Quote: "Randomization was conducted by the REDCap data management system (Research Electronic Data Capture data management system) using a permuted block strategy prepared by the study biostatistician."
Allocation concealment (selection bias)	Low risk	Randomisation occurred after enrolment; central allocation was used. Quote: "Randomization was conducted by a centralized study coordinator after baseline enrolment data were collected by local site coordinators at each study site."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and people delivering the intervention were not blinded to the intervention.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcomes were collected by the people delivering the intervention. People completing data entry and analyses were blinded by group assignment. Quote: "Site coordinators were not blinded to study arm for the post intervention/Year 1 data collection due to in-person delivery of intervention Lesson 1 and administration of the Wellness Journey Facebook group. Data input and analysis were conducted by study personnel who were blinded to group assignment."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intention-to-treat analysis completed. Approximately 9% of data were missing from each group.
Selective reporting (reporting bias)	Low risk	Protocol available. Data provided as per definition.
Other bias	Low risk	No other obvious sources of bias.

Johnston 2010

Study characteristics

Methods	Study design: RCT Study recruitment: December 2009–January 2012; follow-up 12 months

Johnston 2010 *(Continued)*

	Published protocol/trial: protocol published and trial registered; ACTRN12609000937213
Participants	Description: singleton or firstborn in multiple birth infants aged 0–5 weeks whose mother was aged > 16 years, Indigenous, permanent resident of the location, and currently smoked or the infant lived in a household where there was ≥ 1 other person who smoked (intervention n = 145, usual care n = 148) Exclusion criteria: infants excluded if they had serious neonatal respiratory complications, other serious neonatal complications, or had major organ abnormalities. Mothers/carers excluded in they had been previously recruited in the research study, or they lived in the same household as a mother/carer who had previously been recruited into study. Indigenous population: Maori and Aboriginal Setting: New Zealand and Australia, urban areas, Place of delivery: hospital maternity health services Manukau City (New Zealand) and Aboriginal Community Controlled Health Organisation Darwin (Australia) Principle health condition: acute respiratory illness Age of child (weeks), mean: intervention 6.3 (SD 2.7), usual care 6.0 (SD 2.7) Gender of child: intervention 40% girls, usual care 46% girls Number of children in family, mean: children in house aged < 5 years: intervention 1.9 (SD 1.0), usual care 1.9 (SD 1.0) Family unit: married/de facto/living with partner: intervention 72 (50%), usual care 91 (62%) Primary carer of child: mother: intervention 145 (100%), usual care 148 (100%) Socioeconomic status: none reported Employment of mothers: none reported Education of mothers: highest level of education – technical and further education/polytechnic/university: intervention 41 (28%), usual care 34 (23%)
Interventions	**Intervention** Intervention name: none Intervention aim: to provide information and education about the health effects of environmental tobacco smoke exposure and use behavioural 'coaching' techniques to help mothers/carers and family members implement strategies to reduce the infant's environmental tobacco smoke exposure, and identify the smokers among other household members and deliver culturally appropriate smoking cessation advice, counselling, and treatment options as requested. Theory used to develop intervention: programme about environmental tobacco smoke was framed around an Indigenous model of health promotion. This considered the psychological, physical, spiritual, and cultural well-being of the individual and the family/community, as it related to the project. In New Zealand, Te Whare Tapa Wha was used and was applied to understanding Maori smoking cessation behaviour and for guiding the development of culturally appropriate smoking cessation programmes and strategies. In Australia, the model drew on similar concepts as the New Zealand health promotion model. Consumer and community involvement: in New Zealand, the research advisory group gave support and input into the study and provided guidance as the study progressed. In Australia, the reference group monitored the study's progress and authorised publication and dissemination of findings. Overall grouping: education and counselling Fees, reimbursement, or incentives: none reported

Johnston 2010 *(Continued)*

	Procedures: an 8-week supply of free nicotine replacement therapy patches or gum was available to participants and other household members. Indigenous Health Workers provided nicotine replacement therapy with appropriate counselling and follow-up. Those who were interested also received a fax referral to Quitline with proactive call back by Quitline. Culturally appropriate resources were obtained from relevant health groups in each country who hold a repository of such resources. These were used to assist in both educational and behavioural 'coaching'. Materials: 8-week supply of free nicotine replacement therapy (patches or gum) was available to participants and other household members. Culturally appropriate resources for example flip charts, 'No Smoking' stickers, posters were also provided. Mode of delivery: individual face-to-face sessions When and how often was the intervention delivered? 3 face-to-face home visits of approximately 45–60 minutes' duration were completed over the first 3 months of the infant's life. Who delivered the intervention? Indigenous Health Workers (paraprofessional health workers) Was there any training provided to the people who delivered the intervention? Indigenous Health Workers delivered the programme after appropriate training. They completed standardised progress reports after each programme session, which was used at weekly team meetings with the health workers and study personnel for discussion and ongoing training. Was the study modified or adapted? none reported Was the fidelity assessed? a mix of quantitative and qualitative measures to assess how well the intervention programme was implemented according to protocol, e.g. number of 'coaching' activities completed, obstacles and successes in delivering programme, parent satisfaction with the programme were taken. **Comparison** Usual care Usual care through their community health provider that included routine visits for maternal and child health checks in the first 12 months of an infant's life. Fees, reimbursement, or incentives: none reported
Outcomes	Overall health and well-being: new episodes of acute respiratory disease Child physical health and development: new episodes of acute respiratory disease Family enhancing lifestyles or behavioural outcomes: in the last 7 days, infant had been around tobacco smoke; full smoking ban in the home Service access and utilisation: child rate of hospitalisations for acute respiratory infections Time points: 12 months
Funding source and conflicts of interest	Funding: National Health and Medical Research Council of Australia (545203); the Health Research Council of NZ (09/626); Cure Kids NZ (3525) and the James Russell Lewis Trust, New Zealand (13787/15734). Conflict of interest: CB has previously undertaken research on behalf of NicoNovum, but prior to the purchase of the company by RJ Reynolds. NW has provided consultancy to the manufacturers of smoking cessation medications, received honoraria for speaking at a research meeting, and received benefits in kind and travel support from a manufacturer of smoking cessation medications. MG has provided consultancy to the manufacturers of smoking cessation medications. NW, CB, MG, and VP have also undertaken two trials of very low nicotine content cigarettes, which were purchased from two different tobacco companies. The companies concerned had no role in development of the study design, data collection, data analysis, data interpretation, or writing of the trial publications.
Notes	Other outcomes recorded but not used within the review

Johnston 2010 *(Continued)*

	Child: urinary cotinine, infant was breastfed Mother/carer: self-report of smoking cessation; number quit attempts Time points not used: 4 months

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation using computer program. Quote: "Participants will be randomized by computer with stratification using permuted blocks by country (Australia, NZ) and infant age (0-5 weeks, >5-10 weeks)."
Allocation concealment (selection bias)	Low risk	Randomisation occurred after enrolment; central allocation used. Quote: "All participants (i.e. the infants) will be assigned a unique registration number allocated by a central computer following the submission of their details on a web-based form."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and people delivering the intervention were not blinded to the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Staff assessing the primary outcome were blinded to who received the intervention; however, other measures were not. The trial statistician was blinded to group assignment. Quote: "Research assistants, who will be responsible for collecting the minor outcome measures will accompany the health workers to the participants' homes for all visits and thus cannot be blinded. The primary outcome will however be a double-blinded measure."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Modified intention-to-treat analysis completed. There was a low level of attrition that was balanced between groups.
Selective reporting (reporting bias)	Low risk	Protocol available. Data provided as per definition.
Other bias	Low risk	No other obvious sources of bias.

Quissell 2014

Study characteristics

Methods	Study design: cluster-RCT Study recruitment: cohort 1 2011–2012, cohort 2 2012–2013; follow-up 1 year Published protocol/trial: protocol published and trial registered; NCT01116739
Participants	Description: Head Start children aged 3–5 years and their primary parents or carers (intervention n = 463 in 20 sites, control n = 434 in 19 sites)

Quissell 2014 *(Continued)*

Exclusion criteria: children aged < 3 years at time of Head Start enrolment, children without a consenting legal guardian, adults unable to understand English well enough to consent or to complete the computerised survey in English. In the intervention classrooms, children were excluded if they presented with an allergy to any components of the FV or if they were home-based rather than enrolled in the Head Start classroom.

Indigenous population: Navajo Nation

Setting: USA, reservation

Place of delivery: Head Start Centres

Principle health condition: early childhood caries

Age of parents (years), mean: total participating parents 32.4 (SD 9.6)

Age of child (years), mean: intervention 3.7 (SE 0.03), control 3.7 (SE 0.04)

Gender of child: intervention 236 (51.0%) girls, control 213 (49.1%) girls

Number of children in family, mean: intervention 3.0 (SD 0.1), control 2.9 (SD 0.1)

Family unit: none reported

Primary carer of child: mother: intervention 359 (77.5%), control 332 (76.5%)

Socioeconomic status, mean: intervention 4.0 (SD 0.1), control 4.0 (SD 0.2); score of 4 = an income of USD 10,000–14,999/year

Employment of primary carer: none reported

Education of primary carer (years), mean: intervention 13.7 (SD 0.2), control 13.5 (SD 0.1)

Interventions

Intervention

Intervention name: combined oral health promotion–FV intervention

Intervention aim: to reduce early childhood caries among Navajo preschool-age children

Theory used to develop intervention: none reported

Consumer and community involvement: representative of the tribe provided input into planning the research project, introducing and explaining the study to community members and tribal leaders. A Community Advisory Group reviewed all intervention activities and materials and provide ongoing community oversight, advice, and encouragement on the project.

Overall grouping: education

Fees, reimbursement, or incentives: a fruit basket raffle for enrolled carers who attended parent events.

Procedures: the intervention included the application of FV for the children and oral health promotion activities for children and carers. Community Oral Health Specialists applied FV to children's teeth in the Head Start classroom.

The Community Oral Health Specialists provided oral health promotion activities. Oral health promotion activities began with a kick-off event for carers and children that introduced the project. The first event was a kick-off to provide an opportunity for carers to learn about the project. The 3 remaining parent events included 1. an overview of the importance of primary teeth, prevention of tooth decay, consequences of tooth decay, and carers' roles in prevention; 2. 2 small-group oral health promotion activities; 3. a simple goal-setting activity; and 4. a fruit basket raffle for enrolled carers who attended. The remaining 4 child events incorporated brief, highly interactive activities into a Head Start classroom session. Topics included teeth, tooth brushing, nutrition (avoidance of sticky foods), visiting the dentist, and fluoride.

Quissell 2014 *(Continued)*

	Materials: all families received toothbrushes and toothpaste for all family members at enrolment; intervention children and participating carers received additional supplies throughout the study period. Mode of delivery: face-to-face in groups When and how often was the intervention delivered? 4 times each school year, the Community Oral Health Specialists applied FV to children's teeth. The Community Oral Health Specialists provided oral health promotion activities to children 5 times per year and to carers 4 times per year. Who delivered the intervention? American Indian community members who were hired and trained to be Community Oral Health Specialists. Was there any training provided to the people who delivered the intervention? training included an initial week of orientation to the project: instruction in oral disease and health, introduction to relevant behavioural and educational foundations, preparation for enrolment, and acquisition of required research training and credentials. The university study personnel then provided a second week of hands-on intervention and FV application training in the field, with an additional intervention training session just before initiating the programme in the field and subsequent periodic refresher sessions. The field staff dental hygienist trained the Community Oral Health Specialists to understand the function and application of FV and provided hands-on experience. Was the study modified or adapted? none reported Was the fidelity assessed? the number of adherers to the intervention was recorded. Those who received ≥ 3 child oral health promotion events, ≥ 1 carer oral health promotion event, and ≥ 3 FVs were considered to adhered (n = 247, 53.3%). **Comparison** Usual care Usual oral health care was made available by dental providers, usually by the Indian health service. Participants in the usual care arm were not prevented from having FV from other sources but did not receive it through the intervention. The usual care group also received toothbrushes and toothpaste at enrolment and data collection events. Fees, reimbursement, or incentives: none reported
Outcomes	Overall health and well-being: dental caries Child physical health and development: dental caries Family enhancing lifestyle or behaviour outcomes: oral health behaviour Time points: 12 months
Funding source and conflicts of interest	Funding: National Institute of Dental and Craniofacial Research of the National Institutes of Health under Award Number U54DE019259-01. Conflict of interest: none reported
Notes	Other outcomes recorded but not used within the review Mother: oral health knowledge Time points not used: 24 and 36 months Follow-up was for 3 years; however, we only collected data for year 1 as cohort 1 had an increased dose effect during the second year.

Risk of bias

Bias	Authors' judgement	Support for judgement

Quissell 2014 *(Continued)*

Random sequence generation (selection bias)	Low risk	Randomisation using computer program Quote: "The unit of randomization for this study is the Headstart Center (HSC), which may contain one or multiple classrooms. The HSCs were stratified by agency and by one vs. multiple classrooms. Within these strata, the HSCs were randomized into the intervention or the usual-care groups using a random number generator."
Allocation concealment (selection bias)	Unclear risk	No information is provided about allocation concealment.
Selective cluster recruitment	Unclear risk	Centres were randomised prior to enrolment; however, this did not appear to have influenced recruitment with < 1% of participants declining to participate from Head Start Centres. There were similar numbers in each group; however, there were some baseline differences.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and people delivering the intervention were not blinded to the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	People collecting data were blinded to the intervention
Incomplete outcome data (attrition bias) All outcomes	High risk	Modified intention-to-treat analysis completed. Large attrition after 1 year. It is likely this would have affected outcomes.
Selective reporting (reporting bias)	High risk	Protocol has some information; however, not very detailed. Caries reported as binary and continuous and this was not distinguished in the protocol. Adjusted analysis only provided from some outcomes.
Other bias	Low risk	No other obvious sources of bias.

Tipene-Leach 2014

Study characteristics	
Methods	Study design: RCT Study recruitment: June 2011–April 2013; follow-up 6 months' postpartum Published protocol/trial: protocol published and trial registered; ACTRN12610000993099
Participants	Description: all women booking for antenatal care from 2 midwifery practices working with mainly Maori women from low socioeconomic areas in the Hawke's Bay region (intervention n = 101, control n = 96) Exclusion criteria: babies born < 36 weeks' gestation, < 2500 g birth weight, admitted to the neonatal intensive care unit for > 3 days, severe congenital anomalies. Mothers if they had a previous unexplained sudden infant death, severe mental health problems, involved in a methadone maintenance programme. Indigenous population, n (%): Maori intervention 75 (74.3%), control 64 (66.7%) Setting: New Zealand, Urban area

Tipene-Leach 2014 *(Continued)*

Place of delivery: Maori midwifery services

Principle health condition: sudden unexpected death in infancy

Age of mother (years), mean: intervention 25.9 (SD 6.2), control 25.6 (SD 6.3)

Gender of infant: intervention 50 (49.5%) girls, control 48 (50.0%) girls

Number of children in family: first child: intervention 35 (34.7%), control 32 (33.3%)

Family unit: single: intervention 30 (29.7%), control 28 (29.2%); separated/divorced: intervention 0 (0.0%), control 5 (5.2%); married/civil union/defacto relationship: intervention 71 (70.3%), control 63 (65.6%)

Socioeconomic status: none reported

Employment of primary carer: none reported

Education of primary carer: completed primary school to year 11: intervention 46 (45.5%), control 47 (49.0%); completed year 12 (required level): intervention 19 (18.8%), control 7 (7.3%)

Interventions

Intervention

Intervention name: wahakura group

Intervention aim: none reported

Theory used to develop intervention: none reported

Consumer and community involvement: the wahakura is developed by Maori community. The wahakura is a woven flax bassinet with a thin, firm mattress. It is specifically designed to create a separate sleeping surface in the shared sleeping space.

Overall grouping: environment

Fees, reimbursement, or incentives: participants were given USD 50 grocery voucher gift after the 1-month sleep study, and USD 25 voucher on completion of each of the 3- and 6-month interviews.

Procedures: devices were provided to mothers during pregnancy with evidence-based safe sleep instructions. Mothers were recommended to always use the assigned device for their baby, regardless of location.

Materials: the wahakura and education brochures

Mode of delivery: individually face-to-face to set up the project

When and how often was the intervention delivered? mothers were recommended to use the wahakura regardless of location.

Who delivered the intervention? research nurse

Was there any training provided to the people who delivered the intervention? none reported

Was the study modified or adapted? none reported

Was the fidelity assessed? when the infant was 1 month old they were videoed overnight to see how many people were using their sleeping device.

Comparison

Bassinet group

Used a portable standing bassinet, custom designed in New Zealand for distribution to infants at high risk. Bassinet could easily be moved and transported in a car. The base contained an identical 20 mm foam sponge mattress as used in the wahakura. Families also received an education brochure.

Tipene-Leach 2014 *(Continued)*

	Fees, reimbursement, or incentives: participants were given USD 50 grocery voucher gift after the 1-month sleep study, and USD 25 voucher on completion of each of the 3- and 6-month interviews.
Outcomes	Overall health and well-being: fully breastfed Child physical and development: fully breastfed Family enhancing lifestyle or behaviour: maternal sleep quality: good; infant sleep position: back Time points: 3 and 6 months
Funding source and conflicts of interest	Funding: Health Research Council of New Zealand, and a University of Otago Research Grant Conflict of interest: none reported
Notes	Other outcomes recorded but not used within the review Child: infant health, physiological sleep study variables, dummy use, infant sleep behaviour Mother: frequency and duration bed sharing Time point not used: 1 month

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Sequence generation appeared sufficient to ensure random assignment. Quote: "The randomized order was generated by the statistician by using random length blocks."
Allocation concealment (selection bias)	Low risk	Randomisation occurred after enrolment; allocation through numbered envelopes. Quote: "Allocation will be concealed and performed, following application of inclusion/exclusion criteria and consent to participate in the study, by opening a sealed envelope opened in numbered sequence."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and people delivering the intervention were not blinded to the intervention. Quote: "Neither researchers nor participants could be blinded to the group assignment."
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is clear some outcomes were analysed blind such as video and audio recording. However, it unclear whether the interviewers at 1, 3, and 6 months were blinded to the intervention.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Intention-to-treat analysis completed. There was a low level of attrition and was balanced between groups. For binary outcomes, the events were much higher than the missing data.
Selective reporting (reporting bias)	High risk	There was a very brief description in the protocol on the analysis. Data were collected such as full, exclusive, or partial breastfeeding and only full breastfeeding data were reported.
Other bias	Low risk	No other obvious sources of bias.

Walkup 2009

Study characteristics	
Methods	Study design: RCT Study recruitment: May 2002–May 2004; follow-up 12 months' postpartum Published protocol/trial: protocol not published and trial registered; NCT00356551
Participants	Description: pregnant American Indian adolescents aged 12–22 years at conception and at ≤ 28 weeks' gestation (intervention n = 81, control n = 86). Exclusion criteria: mothers were ineligible if they had extreme medical, legal, or social problems that precluded their ability to participate in visits or assessments; mothers who were at acute risk for self or others at the time of consent Indigenous population: Navajo and White Mountain Apache reservations in New Mexico and Arizona. Setting: USA, reservation Place of delivery: Indian Health Service Principle health condition: child behavioural health problems Age of mother: aged < 18 years: intervention 36 (44%), control 43 (50%) Gender of children born: not reported First child in family: intervention 73 (90%), control 78 (91%) Family unit: living with parents: intervention 63 (78%), control 58 (67%); married: intervention 9 (11%), control 5 (6%) Socioeconomic status: not reported Employment of mother: currently employed intervention: 9 (11%), control 11 (13%) Education of mother: high school/general equivalency diploma/some college: intervention 31 (38%), control 35 (41%)
Interventions	**Intervention** Intervention name: Family Spirit Intervention Intervention aim: to address antenatal and newborn care and maternal life skills Theory used to develop intervention: curricular content for the Family Spirit intervention was based on recommendations and standards documented in the American Academy of Pediatrics' *Caring for Your Baby and Child: Birth to Age 5*. This theoretical model hypothesises that parenting is the critical link between parent domains and child domains and mediates children's outcomes. Consumer and community involvement: the Navajo and White Mountain Apache leaders and community stakeholders contributed to the design of the intervention, research protocol, and reviewed the article. Overall grouping: education Fees, reimbursement, or incentives: incentives in the form of gift cards to a local grocery store were provided to participants on completion of study assessments. Procedures: curriculum included developmentally timed antenatal and infant-care parenting lessons, as well as family planning, substance abuse prevention, and problem solving and coping-skills lessons. The Family Spirit reflects local native practices but not community-specific traditions or spiritual beliefs.

Walkup 2009 *(Continued)*

	Materials: none reported Mode of delivery: individual home visit or other private location When and how often was the intervention delivered? intervention was delivered from 28 weeks' gestation until 6 months' postpartum. 25 home visits were available each lasting approximately 1 hour. Who delivered the intervention? interventionists: local American Indian women from the community, bilingual, at least a high school degree and had work experience in health and human services Was there any training provided to the people who delivered the intervention? interventionists delivered both the intervention and control interventions to mothers. They received approximately 500 hours of training in home-visiting methods and curricular content and demonstrating mastery and fidelity to the study protocol on oral and written examinations. Interventionists also served as evaluators and were specifically trained to administer self-report and observational assessments with objectivity. Was the study modified or adapted? none reported Was the fidelity assessed? dose of intervention and control groups were collected. Treatment group mothers completed a median of 20/25 (80%) expected home visits. Control group mothers completed a median of 21/23 (91%) expected home visits (p. 598). **Comparison** Breastfeeding Nutrition Group Education programme. Control group's curricular content included a previously developed breastfeeding/nutrition education programme that included 23 home visits, each lasting approximately 1 hour. Fees, reimbursement, or incentives: gift cards to a local grocery store on completion of study assessments.
Outcomes	Overall health and well-being: ITSEA – Competence domain Child psychological health and emotional behaviour: ITSEA – Competence domain Family enhancing lifestyle or behaviour outcomes: Home Observation for Measurement of the Environment Parent carer psychological health: depression Parenting knowledge and awareness: involvement Time points: 12 months' postpartum
Funding source and conflicts of interest	Funding: Substance Abuse Mental Health Services Administration (SAMHSA I: Grant No. UD1SP08860, SAMHSA II: Grant No. UD1SP09588), and the Ford Foundation, the Annie E. Casey Foundation, and the C.S. Mott Foundation. Conflict of interest: Dr Walkup has received research grant support from Eli Lilly, Pfizer, and Abbott. He has been a consultant to GlaxoSmithKline, Eli Lilly, and the Cliff 's Communities. He has received speaker's honoraria from the Tourette Syndrome Association. The other authors report no conflicts of interest.
Notes	Other outcomes collected but not used within the review Maternal outcomes: parenting knowledge, parenting stress, substance use, social support Time points not used: 6 months' postpartum
Risk of bias	

Walkup 2009 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation using web program Quote: "The randomization sequence, generated by the Website http://randomization.com was stored confidentially by the data manager in Baltimore, MD."
Allocation concealment (selection bias)	Low risk	Randomisation occurred after enrolment; central allocation was used. Quote: "Randomization was revealed to participants after the baseline assessment."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and people delivering the intervention were not blinded to the intervention. Quote: "Neither the participants nor the interventionists were blind to study group assignment."
Blinding of outcome assessment (detection bias) All outcomes	High risk	People who delivered the intervention also collected data. Quote: "Interventionists also served as evaluators and were specifically trained to administer self-report and observational assessments with objectivity."
Incomplete outcome data (attrition bias) All outcomes	High risk	Intention-to-treat analysis completed. There was a high number of missing data by the end of the trial. In addition, the intervention group consistently had increased proportions of attrition at 2 and 6 months.
Selective reporting (reporting bias)	High risk	Trial was registered with no information provided on analysis. Only reported adjusted results and it was unclear how many confounders were included in the analysis.
Other bias	Unclear risk	There is some discussion on the cultural appropriateness of the outcomes in particular the Home Observation Measurement of the Environment outcome.

AG: anticipatory guidance; BMI: body mass index; FSN: Family Spirit Nurture; FV: fluoride varnish; HCSF: Healthy Child, Strong Families; ITSEA: Infant-Toddler Social and Emotional Assessment; MI: motivational interviewing; n: number; RCT: randomised controlled trial; SD: standard deviation; SE: standard error; SF-12: 12-item Short Form Survey; SSB: sugar-sweetened beverage; USD: US dollars.

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

Study	Reason for exclusion
Abad 2007	Wrong study design
ACTRN12608000073303	Wrong intervention
ACTRN12617000210370	Wrong intervention
ACTRN12618001079235	Wrong intervention
Adirim 2013	Wrong population
Affonso 1993	Wrong study design

Study	Reason for exclusion
Affonso 1995	Wrong study design
Ah 2016	Wrong study design
Ahmat 2012	Wrong study design
Albright 2009	Wrong population
Albright 2012	Wrong population
Albright 2014	Wrong population
Albright 2015	Wrong population
Alicata 2016	Wrong study design
Alto 1994	Wrong study population
Anand 2007	Wrong study population
Anderson 2015	Wrong study design
Anderson 2019	Wrong population
ANTaR 2007	Wrong study design
Araujo 2016	Wrong study design
Arney 2010	Wrong study design
Atkinson 2010	Wrong study design
Azur 2007	Wrong study design
Bagshaw 2006	Wrong study design
Bair-Merritt 2010	Wrong population
Baldwin 2001	Wrong study design
Barclay 2014	Wrong study design
Barlett 1988	Wrong study design
Bar-Zeev 2015	Wrong population
Batliner 2014	Wrong intervention
Batliner 2018	Wrong intervention
Benzies 2011a	Wrong study design
Benzies 2011b	Wrong study design
Berns 2017	Wrong intervention

Study	Reason for exclusion
Bernstein 2005	Wrong study design
Bertilone 2015	Wrong study design
Bertilone 2017	Wrong study design
Best 2011	Wrong study design
Best 2013	Wrong study design
BigFoot 2009	Wrong study design
BigFoot 2011	Wrong study design
Billard 2014	Wrong study design
Black 2013a	Wrong study design
Black 2013b	Wrong study design
Black 2014	Wrong study design
Blinkhorn 2012	Wrong study design
Blue 2020	Wrong intervention
Boffa 2007	Wrong study design
Bond 2009a	Wrong study design
Bond 2009b	Wrong study design
Bonnici 2008	Wrong study design
Booth-LaForce 2020	Wrong intervention
Bovill 2017	Wrong population
Bowes 2014	Wrong study design
Boychuk 1984	Wrong study design
Bradley 1994	Wrong study design
Brega 2020	Wrong intervention
Breslin 2009	Wrong study design
Brewin 2002	Wrong study design
Brewin 2004	Wrong study design
Brown 2015	Wrong study design
Brown 2016	Wrong study design

Study	Reason for exclusion
Bruerd 1989	Wrong study design
Bucharski 1999	Wrong study design
Buckskin 2013	Wrong study design
Bulterys 1990	Wrong study design
Burd 2007	Wrong study design
Burrows 2014	Wrong study design
Bussey 2013	Wrong study design
Byrnes 2020	Wrong population
Calabria 2012	Wrong study design
Carlisle 2020	Wrong study design
Chaffin 2012	Wrong intervention
Chamberlain 1998	Wrong study design
Chamberlain 2017	Wrong study design
Chambliss 2000	Wrong population
Chang 2010	Wrong study design
Chartier 2020	Wrong study design
Chi 2013	Wrong study design
Cidro 2015	Wrong study design
CIRCA 2014	Wrong study design
Cleary 2006	Wrong study design
Cresp 2016	Wrong study design
Cruz 2016a	Wrong population
Cruz 2016b	Wrong population
D'Espaignet 2003	Wrong population
Daro 1998	Wrong population
Davis 1999	Wrong study design
Davis 2001	Wrong study design
Davis 2013	Wrong population

Study	Reason for exclusion
dela Cruz 2010	Wrong study design
Department of Family and Community Services 2004	Wrong study design
Department of Family and Community Services 2005	Wrong study design
Dew 2014	Wrong study design
Dietrich 1986	Wrong study design
Dinges 1974	Wrong study design
Dionne 2009	Wrong population
Dobson 2017	Wrong study design
Douglas 2013	Wrong study design
Duffy 1994	Wrong study design
Duggan 1999	Wrong population
Duggan 2000	Wrong population
Duggan 2004a	Wrong population
Duggan 2004b	Wrong population
Eades 2004	Wrong study design
Eades 2007	Wrong study design
Eades 2012	Wrong population
El-Kamary 2004	Wrong population
Emerson 2015	Wrong study design
Engeler 1997	Wrong study design
Eni 2011	Wrong study design
Enns 2019	Wrong study design
Esquivel 2016	Wrong population
Fejo 1994	Wrong study design
Fernald 2017	Wrong population
Fialkowski 2014	Wrong study design
Fisher 2002	Wrong study design

Study	Reason for exclusion
Floden 1989	Wrong study design
Flynn 1999	Wrong study design
Frances 2011	Wrong study design
Franklin 1995	Wrong study design
Frenza 1993	Wrong study design
Frow 2010	Wrong study design
Fuddy 2002	Wrong study design
Gao 2014	Wrong study design
George 2007	Wrong study design
Gerlach 2009	Wrong study design
Ginsburg 2012	Wrong study population
Glor 1987	Wrong study design
Glover 1996	Wrong intervention
Glover 2000	Wrong intervention
Glover 2009	Wrong intervention
Glover 2015a	Wrong study design
Glover 2015b	Wrong intervention
Glover 2016	Wrong study design
Gomby 2007	Wrong study design
Gould 2013	Wrong study design
Grace 2016	Wrong study design
Gray-Donald 2000	Wrong population
Gregory 2008	Wrong study design
Guyer 2000	Wrong population
Haag 2019	Wrong intervention
Hamerton 2014	Wrong study design
Harnett 1998	Wrong study design
Harrison 2006	Wrong study design

Study	Reason for exclusion
Harvey-Berino 2003	Wrong intervention
Haswell-Elkins 2009	Wrong study design
Hewer 2006	Wrong study design
Hilferty 2010	Wrong study design
Holdaway Smith 2021	Wrong population
Homel 2006a	Wrong study design
Homel 2006b	Wrong study design
Hucul 2015	Wrong study design
Hunter 2014	Wrong population
Iglesias 2010	Wrong study design
ISRCTN41467632	Wrong intervention
Jamieson 2016	Wrong intervention
Jamieson 2018	Wrong intervention
Jamieson 2019a	Duplicate
Jamieson 2019b	Wrong intervention
Jan 2004	Wrong study design
Jersky 2016	Wrong study design
Johnson 1994	Wrong study design
Johnson 2006	Wrong study design
Johnson 2011	Wrong study design
Johnston 2011	Wrong study design
Jones 2020	Wrong study design
Jongen 2014	Wrong study design
Karanja 2010	Wrong study design
Karanja 2012	We attempted to contact multiple authors of the publication and received no reply. We decided to exclude.
Karol 2016	Wrong study design
Kegler 2003	Wrong study design

Study	Reason for exclusion
Kegler 2004	Wrong study design
Kemp 2010	Wrong population
Kemp 2018	Wrong study design
Keown 2018	Wrong intervention
Kildea 2016	Wrong study design
Kildea 2017	Wrong study design
King-Hooper 1996	Wrong study design
Kira 2016	Wrong population
Koniak-Griffin 1999	Wrong study design
Lawrence 2004	Wrong study design
Lawrence 2008	Wrong intervention
Lee 2010	Wrong study design
Lees 2014	Wrong intervention
Leijten 2016	Wrong population
Letourneau 2008	Wrong study design
Long 1995	Wrong study design
Lucero 2012	Wrong study design
Lucero 2015	Wrong study design
Macedo 2020	Wrong intervention
Mackerras 1998	Wrong study design
Madden 1984	Wrong population
Makin 2001	Wrong study design
Mares 2012	Wrong study design
Martens 2002	Wrong study design
Mathu-Muju 2016	Wrong study design
Matthews 2013	Wrong study design
Maupome 2010	Wrong study design
May 1989	Wrong study design

Study	Reason for exclusion
May 2008	Wrong study design
Mayberry 1999	Wrong study design
Mayfield 1984	Wrong study design
Mayfield 1985	Wrong study design
Mayfield 1986	Wrong study design
McIntosh 2018	Wrong intervention
McKay 2015	Wrong study design
McKenzie 1995	Wrong study design
McShane 2008	Wrong study design
Middleton 2017	Wrong study design
Mondy 2004	Wrong study design
Montag 2015	Wrong intervention
Mraz Esposito 2014	Wrong study design
Munns 2010	Wrong study design
Munns 2015	Wrong study design
Munro 2011	Wrong study design
Murphy 2012	Wrong study design
Mylant 2021	Wrong study design
Nations 2004	Unable to determine study design, contacted author but received no reply.
NCT00428805	Wrong population
NCT00435500	Wrong intervention
NCT01116726	Wrong intervention
NCT02091804	Wrong intervention
NCT03142009	Wrong population
Nguyen 2015	Wrong study design
Novotny 2013	Wrong population
Novotny 2017	Wrong study design
NSW Centre for Parenting and Research 2005	Wrong study design

Study	Reason for exclusion
Nutting 1979	Wrong study design
Oxford 2020	Wrong intervention
Patten 2012a	Wrong population
Patten 2012b	Wrong population
Phillips 2014	Wrong intervention
Poland 1991	Wrong study design
Pollack 2011	Wrong study design
Poppe 1992	Wrong study design
Prater 2002	Wrong study design
Pullon 2003	Wrong population
Ratima 1999	Wrong study design
Ratnaike 1994	Wrong study design
Reeve 2014	Wrong study design
Reeve 2016	Wrong study design
Richardson 2008	Wrong study design
Richer 2018	Wrong study design
Ricks 2015	Wrong study design
Riley 2010	Wrong study design
Ring 2007	Wrong study design
Roberts 1993	Wrong study design
Roberts-Thomson 2010	Wrong intervention
Robinson 2008	Wrong study design
Robinson 2009	Wrong study design
Robinson 2012	Wrong study design
Robinson 2013	Wrong study design
Robinson 2017	Wrong study design
Rogers 2003	Wrong study design
Ryan 2001	Wrong study design

Study	Reason for exclusion
Saggers 2009	Wrong study design
Sanghavi 2005	Wrong study design
Santos 1999	Wrong study design
Sawchuk 1998	Wrong study design
Sawyer 2014	Wrong study design
Shan 2014	Wrong study design
Simmons 2008	Wrong population
Simonet 2009	Wrong population
Sivak 2008	Wrong study design
Smith 1993	Wrong study design
Smith 2000	Wrong study design
Smith 2018	Wrong study design
Smithers 2017	Wrong intervention
Smithers 2021	Wrong intervention
Soares 2021a	Wrong intervention
Soares 2021b	Wrong intervention
Soltzberg 1997	Wrong study design
Sparrow 2011	Wrong study design
TAIHS 2003	Wrong study design
Thompson 2006	Wrong study design
Tipa 2015	Wrong study design
Trenholme 2016	Wrong intervention
Tsey 2007	Wrong study design
Turner 2007	Wrong population
Turner 2017	Wrong intervention
Valery 2007	Wrong population
Valery 2008	Wrong population
Valery 2009	Wrong population

Study	Reason for exclusion
Valery 2010	Wrong population
Vicary 2001	Wrong study design
Volpe 2014	Wrong study design
Wen 2012	Wrong population
Wilken 2013	Wrong intervention
Williams 2017	Wrong study design
Wilson 2013	Wrong population
Wilson 2018	Wrong intervention
Wright 1997	Wrong study design
Yoshimoto 2014	Wrong study design
Young 2016	Wrong study design

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

Baby Teeth Talk Study (BTT)

Study name	Preventing early childhood caries in Indigenous children: the Baby Teeth Talk study (BTT)
Methods	RCT
Participants	Pregnant women who identify as Aboriginal Peoples in Canada (First Nations, Metis, Inuit) and live in urban and on-reserve communities in Ontario and Manitoba.
Interventions	Baby Teeth Talk. MI and AG provided pre- and postnatally to mothers by community-based researchers, concerning how to care for children's teeth. Delivered at the time of tooth eruption (6–10 months), 12, 18, and 24 months. Dental care and fluoride varnish applied at time of tooth eruption, 12, 18, and 24 months. Control group received a delayed dental care programme; MI and AG, dental care, and fluoride varnish provided at 24, 30, and 36 months.
Outcomes	Outcomes assessed from preconception to 3 years' postpartum. Child dental caries as incidence and increment over 2 years; maternal/carer oral health-related knowledge, self-care, self-efficacy, and literacy; maternal/carer dental health service utilisation.
Starting date	June 2011
Contact information	Herenia P Lawrence
Notes	

Back to Basics

Study name	Back to Basics: addressing childhood obesity through traditional foods in Alaska
Methods	Randomised mixed-methods intervention trial
Participants	Alaskan Native residents from rural communities in Yukon-Kuskokwim region: children aged 0–5 years and enrolled in the RurAL CAP, Head Start, Early Head Start, or Parents as Teachers programmes.
Interventions	Back to Basics. A physical activity programme; 9-month traditional food menu programmes within Head Start programmes; home-based nutrition programme; and documentation mechanism to record traditional food important to each community. Programmes repeated annually. Control group received standard education and menu programmes.
Outcomes	Outcomes assessed annually over 4 years of intervention. BMI; traditional food content in diet.
Starting date	14 May 2018
Contact information	Timothy K Thomas
Notes	

Family Spirit Nuture Part 2 2019

Study name	Family Spirit Nurture
Methods	RCT
Participants	Pregnant Native American women living in 2 Navajo communities and the Fort Apache Indian Reservation aged 14–24 who are having their first or second baby.
Interventions	Family Spirit Nurture + optimised standard care. The Family Spirit Nurture home-visiting module consists of 36, 60-minute lessons delivered by trained local Family Health Coaches, from 28 weeks' gestation to 18 months' postpartum. Optimised standard care consists of transportation assistance to antenatal and well-baby clinic visits. These checks are recommended by the Indian Health Service and American Academy of Pediatrics. Control group will receive optimised standard care only.
Outcomes	Outcomes collected between 2 and 24 months old. Breastfeeding, complementary feeding practices, infant feeding style, toddler feeding style, consumption of fruit and vegetable intake, child physical activity levels, screen time and sedentary behaviour, BMI z-scores, maternal stress, maternal depression, maternal alcohol and drug use, infant metabolic health
Starting date	25 September 2017
Contact information	Allison Barlow
Notes	ClinicalTrials.gov Identifier: NCT03334266

Great Beginnings for Healthy Native Smiles

Study name	Great Beginnings for Healthy Native Smiles: an early childhood caries prevention project
Methods	RCT
Participants	Native American women aged > 18 years, living within 100 miles of the Hopi or Crow nations who are currently 3–7 months pregnant.
Interventions	Early Childhood Caries Prevention. Face-to-face educational sessions provided twice before childbirth then at 6, 12, 18, and 24 months provided by Community Health Workers. Children received up to 4 fluoride varnish applications during the study and MI with mothers. Control group received standard antenatal/postnatal healthy lifestyle intervention designed to improve maternal/child health knowledge.
Outcomes	Outcomes assessed through study completion at 30–36 months for the early enrolment cohort, and 24 months for the late cohort. Number of decayed, missing, or filled primary tooth surfaces or teeth (or both); maternal/carer oral health knowledge, behaviour, and attitudes.
Starting date	29 March 2021
Contact information	Julie A Baldwin, Kristan Elwell
Notes	

Infant Care Practices Study (ICP)

Study name	Infant Care Practices Study (ICP)
Methods	RCT
Participants	Pregnant American Indian women aged > 14 years, from Western South Dakota who are < 20 weeks' gestation.
Interventions	Protecting Babies While they Sleep Curriculum. 3 antenatal contacts at study site offices involving engagement with the curriculum and activities aimed to ascertain the role of carer knowledge, beliefs, and access to resources in implementation of infant safe sleep practices, led by trained study staff. Control group attend antenatal contacts and receive educational material available from local healthcare facilities.
Outcomes	Outcomes assessed at 3, 6, and 12 months postnatal. Implementation of safe sleeping practices; maternal/carer changes in Safe Sleep knowledge, beliefs, and practice.
Starting date	28 March 2018
Contact information	Amy Elliott
Notes	

LEAP-CP

Study name	LEAP-CP: Learning through Everyday Activities with Parents for Indigenous Australian infants at high risk of cerebral palsy and neurodevelopmental disabilities
Methods	RCT
Participants	Infants, aged 3 months to 2 years, assessed as a high risk of cerebral palsy/neurodevelopmental disabilities or a confirmed diagnosis of cerebral palsy with 1 or both parents identifying as Aboriginal or Torres Strait Islander in the study geographical area.
Interventions	LEAP-CP. 30 weekly 2-hour visits over 7–10 months to deliver multidisciplinary family-centred intervention, delivered through face-to-face home visits by an Indigenous Allied Health Worker. The structure of the visits followed: feedback and troubleshooting, therapeutic modules, and education modules. Carers are provided with written and pictographic programme and study-specific information to facilitate the strategies provided during the sessions. Control group received care as usual from primary and allied health programmes provided in the community.
Outcomes	Outcomes assessed at 7–10 months postintervention commencement. Parent-perceived changes in child's performance; carer depression, anxiety, and stress; infant/toddler motor skills outcomes; infant/toddler cognitive and communication skills; parent-infant emotional availability; quality and quantity of parent and home infant/toddler stimulation; infant/toddler quality of life; infant/toddler social emotional assessment; infant/toddler near vision detection; nutritional status; and infant/toddler self-care, mobility and social function.
Starting date	1 September 2019
Contact information	Katherine Benfer
Notes	

Precision Family Spirit

Study name	Precision Family Spirit: a pilot randomized implementation trial of a precision home visiting approach with families in Michigan
Methods	RCT
Participants	Native American women aged ≥ 14 years who are either pregnant or have an infant aged ≤ 2 months living in both the Lower and Upper Peninsula communities in Michigan
Interventions	Precision Family Spirit. Face-to-face home-visiting module consisting of a minimum of 25 lessons from pregnancy to 12-months' postpartum delivered by culturally matched paraprofessionals. Additional lessons, up to 41 lessons in total during the duration of enrolment, will be provided based on emergent needs assessed during home visit lessons. Control group will receive care as usual through the Michigan Family Spirit programme.
Outcomes	Outcomes are collected at 2, 6, and 12 months' postpartum. Quality of the relationship between the home visitor and the client, including satisfaction, retention, and adherence; infant feeding practices, including the introduction of SSBs; child development delays, maternal substance abuse (tobacco, alcohol, drugs); maternal depression and stress; maternal parenting knowledge, self-efficacy, and feeding practices.

Precision Family Spirit *(Continued)*

Starting date	24 June 2019
Contact information	Allison Ingalls
Notes	

Wakȟáŋyeža (Little Holy One)

Study name	Wakȟáŋyeža (Little Holy One) – an intergenerational intervention for Native American parents and children: a protocol for a randomized controlled trial with embedded single-case experimental design
Methods	RCT
Participants	Parent or carer aged > 18 years of children aged 3–5 years enrolled in Head Start class and is a member or descendent of Fort Peck Tribes, with an exposure to ≥ 1 adverse childhood event or historical trauma.
Interventions	Wakȟáŋyeža. 12 weekly 1-hour lessons provided to carers/parents. Curriculum includes lessons on cultural connection and traditions; parenting adapted from Family Spirit intervention; and stress and trauma. Control group received 6 × 1-hour lessons on nutrition over 16 weeks.
Outcomes	Outcomes were assessed at 6 and 12 weeks, 6, 12, 18, and 24 months. Change in carer trauma symptoms; change in parenting stress symptoms; change in carer depression; parent baseline assessment of stressful life events, positive childhood experiences, adverse childhood experiences, historical loss experiences, experience relating to historical trauma; changes to parental practices, control, substance use, family routines, communal mastery, tribal identity, social networks information, and suicide risk; child Head Start school attendance; child's externalisation and internalisation of symptoms.
Starting date	18 November 2019
Contact information	Teresa Brockie
Notes	

AG: anticipatory guidance; BMI: body mass index; MI: motivational interviewing; RCT: randomised controlled trial.

DATA AND ANALYSES

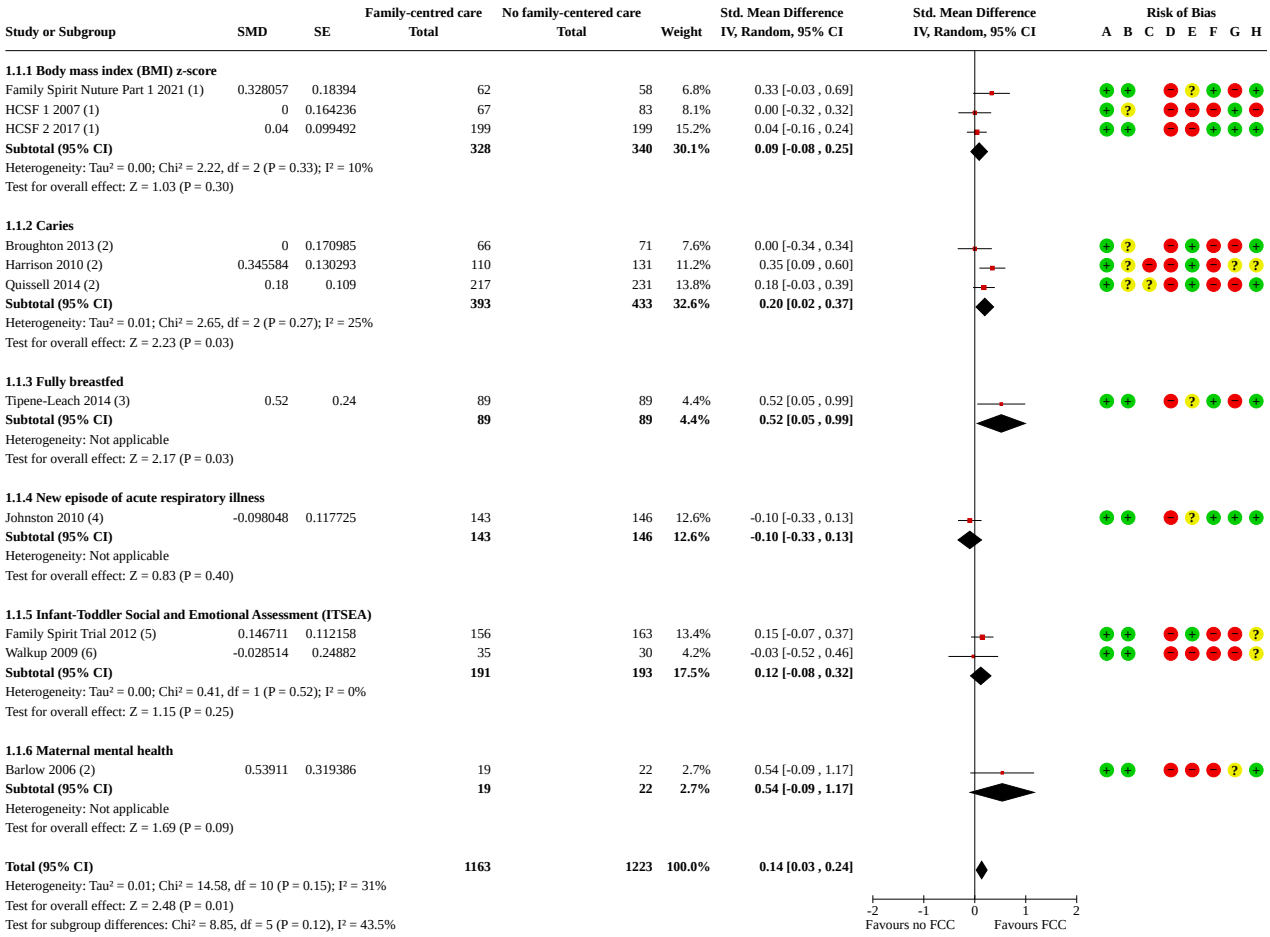
Comparison 1. Primary outcomes

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Overall health and well-being	11	2386	Std. Mean Difference (IV, Random, 95% CI)	0.14 [0.03, 0.24]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1.1 Body mass index (BMI) z-score	3	668	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-0.08, 0.25]
1.1.2 Caries	3	826	Std. Mean Difference (IV, Random, 95% CI)	0.20 [0.02, 0.37]
1.1.3 Fully breastfed	1	178	Std. Mean Difference (IV, Random, 95% CI)	0.52 [0.05, 0.99]
1.1.4 New episode of acute respiratory illness	1	289	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.33, 0.13]
1.1.5 Infant-Toddler Social and Emotional Assessment (ITSEA)	2	384	Std. Mean Difference (IV, Random, 95% CI)	0.12 [-0.08, 0.32]
1.1.6 Maternal mental health	1	41	Std. Mean Difference (IV, Random, 95% CI)	0.54 [-0.09, 1.17]
1.2 Psychological health and emotional behaviour of children	2	384	Mean Difference (IV, Random, 95% CI)	0.04 [-0.03, 0.11]
1.2.1 ITSEA	2	384	Mean Difference (IV, Random, 95% CI)	0.04 [-0.03, 0.11]
1.3 Physical health and developmental health outcomes of children	8	1961	Std. Mean Difference (IV, Random, 95% CI)	0.13 [-0.00, 0.26]
1.3.1 BMI z-score	3	668	Std. Mean Difference (IV, Random, 95% CI)	0.09 [-0.08, 0.25]
1.3.2 Caries	3	826	Std. Mean Difference (IV, Random, 95% CI)	0.19 [0.02, 0.37]
1.3.3 Fully breastfeed	1	178	Std. Mean Difference (IV, Random, 95% CI)	0.52 [0.05, 0.99]
1.3.4 New episode of acute respiratory illness	1	289	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.33, 0.13]
1.4 Family health-enhancing lifestyle or behavioural outcomes	9	1969	Std. Mean Difference (IV, Random, 95% CI)	0.16 [-0.06, 0.39]
1.4.1 Home environment	2	404	Std. Mean Difference (IV, Random, 95% CI)	0.07 [-0.13, 0.27]
1.4.2 Parent/carer general physical health	2	528	Std. Mean Difference (IV, Random, 95% CI)	-0.03 [-0.33, 0.27]
1.4.3 Family cohesion	1	41	Std. Mean Difference (IV, Random, 95% CI)	-0.15 [-0.77, 0.48]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.4.4 Maternal sleep quality	1	169	Std. Mean Difference (IV, Random, 95% CI)	0.34 [-0.24, 0.93]
1.4.5 Oral health behaviour	1	451	Std. Mean Difference (IV, Random, 95% CI)	0.23 [0.02, 0.45]
1.4.6 Full smoking ban in the home	1	254	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.62, 0.47]
1.4.7 Sugar-sweetened beverages consumption	1	122	Std. Mean Difference (IV, Random, 95% CI)	1.02 [0.64, 1.40]
1.5 Psychological health of parent/carer	5	975	Std. Mean Difference (IV, Random, 95% CI)	0.10 [-0.03, 0.22]
1.5.1 12-item Short Form Survey (SF-12) Mental Health	2	530	Std. Mean Difference (IV, Random, 95% CI)	0.01 [-0.16, 0.19]
1.5.2 Center for Epidemiologic Studies Depression Scale (CES-D)	3	445	Std. Mean Difference (IV, Random, 95% CI)	0.20 [0.01, 0.39]

Analysis 1.1. Comparison 1: Primary outcomes, Outcome 1: Overall health and well-being



Footnotes

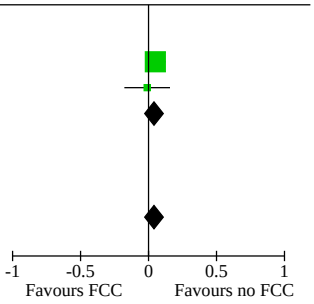
(1) A positive z-score indicates the raw score is higher than the mean. Lower score beneficial. Multiplied outcome by -1.
(2) Lower score beneficial. Multiplied outcome by -1.
(3) Converted from a log odds ratio to a standardised mean difference. Higher events beneficial.
(4) The data were provided as count data and converted to means and standard deviations. Lower score beneficial. Multiplied outcome by -1.
(5) Standard deviations derived from confidence interval of adjusted mean difference. Higher score beneficial.
(6) Higher score beneficial.

Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Selective cluster recruitment
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Analysis 1.2. Comparison 1: Primary outcomes, Outcome 2: Psychological health and emotional behaviour of children

Study or Subgroup	Family-centered care Mean	SD	Total	No family-centred care Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
1.2.1 ITSEA								
Family Spirit Trial 2012 (1)	1.07	0.34	156	1.02	0.34	163	83.5%	0.05 [-0.02 , 0.12]
Walkup 2009 (2)	0.94	0.36	35	0.95	0.33	30	16.5%	-0.01 [-0.18 , 0.16]
Subtotal (95% CI)			**191**			**193**	**100.0%**	**0.04 [-0.03 , 0.11]**
Heterogeneity: Tau² = 0.00; Chi² = 0.41, df = 1 (P = 0.52); I² = 0%								
Test for overall effect: Z = 1.15 (P = 0.25)								
Total (95% CI)			**191**			**193**	**100.0%**	**0.04 [-0.03 , 0.11]**
Heterogeneity: Tau² = 0.00; Chi² = 0.41, df = 1 (P = 0.52); I² = 0%								
Test for overall effect: Z = 1.15 (P = 0.25)								
Test for subgroup differences: Not applicable								

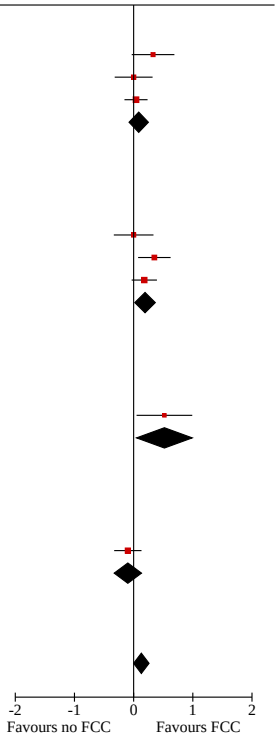


Footnotes

(1) Standard deviations derived from confidence interval of adjusted mean difference. Higher score beneficial.
(2) Higher score beneficial.

Analysis 1.3. Comparison 1: Primary outcomes, Outcome 3: Physical health and developmental health outcomes of children

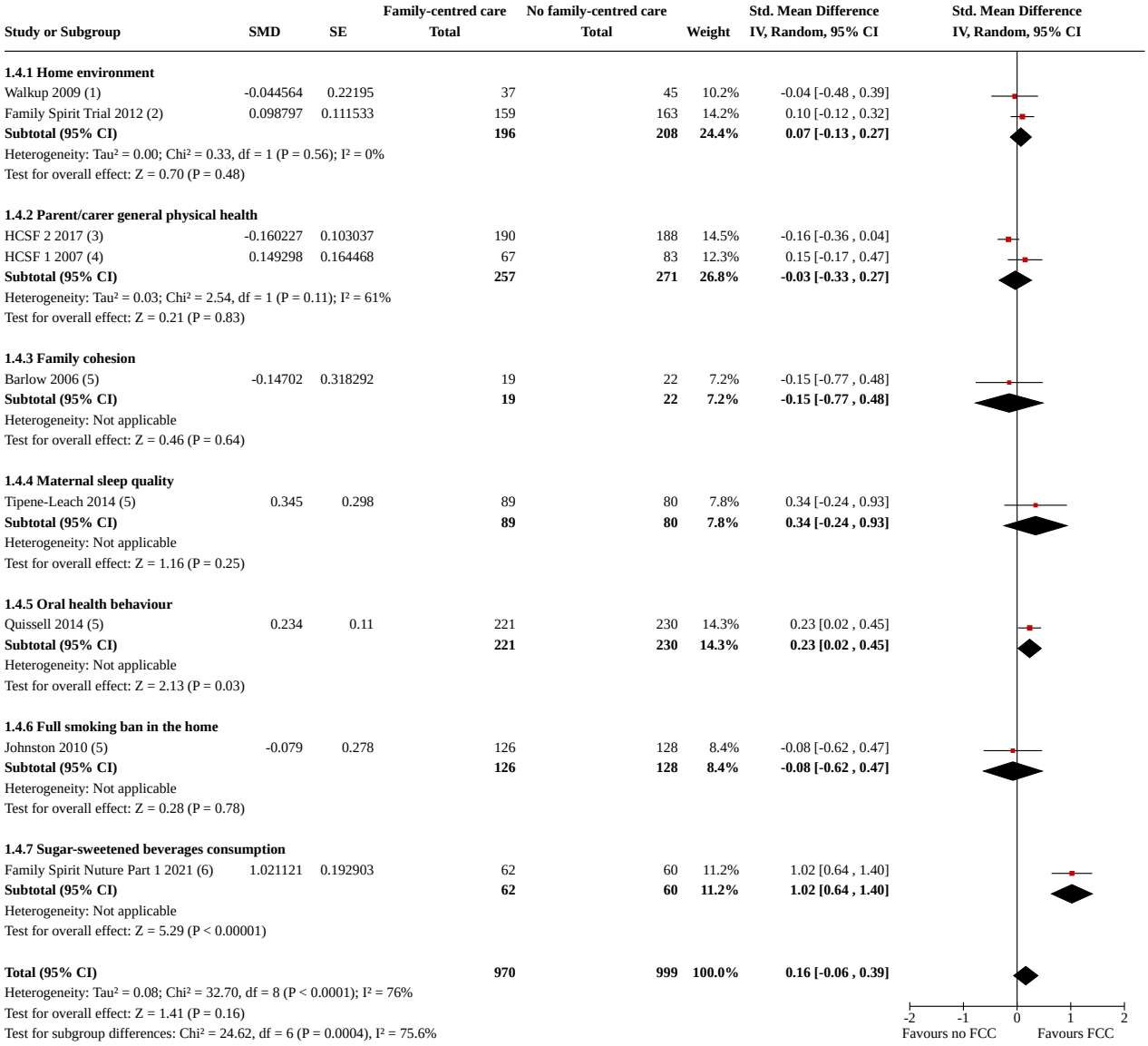
Study or Subgroup	SMD	SE	Family-centred care Total	No family-centred care Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.3.1 BMI z-score						
Family Spirit Nuture Part 1 2021 (1)	0.328057	0.18394	62	58	9.2%	0.33 [-0.03 , 0.69]
HCSF 1 2007 (1)	0	0.163268	67	83	10.8%	0.00 [-0.32 , 0.32]
HCSF 2 2017 (1)	0.04	0.099492	199	199	18.2%	0.04 [-0.16 , 0.24]
Subtotal (95% CI)			**328**	**340**	**38.2%**	**0.09 [-0.08 , 0.25]**
Heterogeneity: Tau² = 0.00; Chi² = 2.22, df = 2 (P = 0.33); I² = 10%						
Test for overall effect: Z = 1.03 (P = 0.30)						
1.3.2 Caries						
Broughton 2013 (2)	0	0.170985	66	71	10.1%	0.00 [-0.34 , 0.34]
Harrison 2010 (2)	0.35	0.14	110	131	13.0%	0.35 [0.08 , 0.62]
Quissell 2014 (2)	0.18	0.109	217	231	16.9%	0.18 [-0.03 , 0.39]
Subtotal (95% CI)			**393**	**433**	**40.0%**	**0.19 [0.02 , 0.37]**
Heterogeneity: Tau² = 0.01; Chi² = 2.55, df = 2 (P = 0.28); I² = 21%						
Test for overall effect: Z = 2.18 (P = 0.03)						
1.3.3 Fully breastfeed						
Tipene-Leach 2014 (3)	0.52	0.24	89	89	6.1%	0.52 [0.05 , 0.99]
Subtotal (95% CI)			**89**	**89**	**6.1%**	**0.52 [0.05 , 0.99]**
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.17 (P = 0.03)						
1.3.4 New episode of acute respiratory illness						
Johnston 2010 (4)	-0.098048	0.117725	143	146	15.7%	-0.10 [-0.33 , 0.13]
Subtotal (95% CI)			**143**	**146**	**15.7%**	**-0.10 [-0.33 , 0.13]**
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.83 (P = 0.40)						
Total (95% CI)			**953**	**1008**	**100.0%**	**0.13 [-0.00 , 0.26]**
Heterogeneity: Tau² = 0.01; Chi² = 12.15, df = 7 (P = 0.10); I² = 42%						
Test for overall effect: Z = 1.95 (P = 0.05)						
Test for subgroup differences: Chi² = 7.00, df = 3 (P = 0.07), I² = 57.1%						



Footnotes

(1) A positive z-score indicates the raw score is higher than the mean. Lower score beneficial. Multiplied outcome by -1.
(2) Lower score beneficial. Multiplied outcome by -1.
(3) Converted from a log odds ratio to a standardised mean difference. Higher events beneficial.
(4) The data were provided as count data and converted to means and standard deviations. Lower score beneficial. Multiplied outcome by -1.

Analysis 1.4. Comparison 1: Primary outcomes, Outcome 4: Family health-enhancing lifestyle or behavioural outcomes

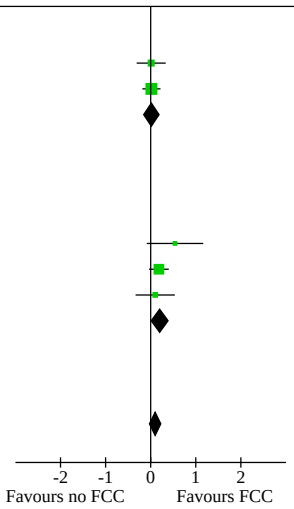


Footnotes

(1) Measured using the Home Observation Measurement of the Environment scale. Higher score beneficial.
(2) Measured using the Home Observation Measurement of the Environment scale. Standard deviation derived from confidence interval of adjusted mean difference. Higher score beneficial.
(3) Measured using the SF-12 - Physical health component. Higher score beneficial.
(4) Measured using the SF-12 - Physical health component. Higher score beneficial
(5) Higher score beneficial.
(6) Lower score beneficial. Multiplied by -1.

Analysis 1.5. Comparison 1: Primary outcomes, Outcome 5: Psychological health of parent/carer

Study or Subgroup	Family-centred care Mean	SD	Total	No family-centred care Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.5.1 12-item Short Form Survey (SF-12) Mental Health								
HCSF 1 2007 (1)	46.1	9.2	67	46	9.2	83	15.3%	0.01 [-0.31 , 0.33]
HCSF 2 2017 (1)	48.87	9.84	190	48.71	9.82	190	39.2%	0.02 [-0.18 , 0.22]
Subtotal (95% CI)			**257**			**273**	**54.5%**	**0.01 [-0.16 , 0.19]**
Heterogeneity: Tau² = 0.00; Chi² = 0.00, df = 1 (P = 0.98); I² = 0%								
Test for overall effect: Z = 0.17 (P = 0.87)								
1.5.2 Center for Epidemiologic Studies Depression Scale (CES-D)								
Barlow 2006 (2)	-8.4	10	19	-14.2	11	22	4.0%	0.54 [-0.09 , 1.17]
Family Spirit Trial 2012 (3)	-12.46	5.21	159	-13.41	5.21	163	33.1%	0.18 [-0.04 , 0.40]
Walkup 2009 (4)	3.1	9.7	37	2	11.8	45	8.4%	0.10 [-0.34 , 0.54]
Subtotal (95% CI)			**215**			**230**	**45.5%**	**0.20 [0.01 , 0.39]**
Heterogeneity: Tau² = 0.00; Chi² = 1.36, df = 2 (P = 0.51); I² = 0%								
Test for overall effect: Z = 2.09 (P = 0.04)								
Total (95% CI)			**472**			**503**	**100.0%**	**0.10 [-0.03 , 0.22]**
Heterogeneity: Tau² = 0.00; Chi² = 3.39, df = 4 (P = 0.50); I² = 0%								
Test for overall effect: Z = 1.53 (P = 0.13)								
Test for subgroup differences: Chi² = 2.03, df = 1 (P = 0.15), I² = 50.8%								



Footnotes

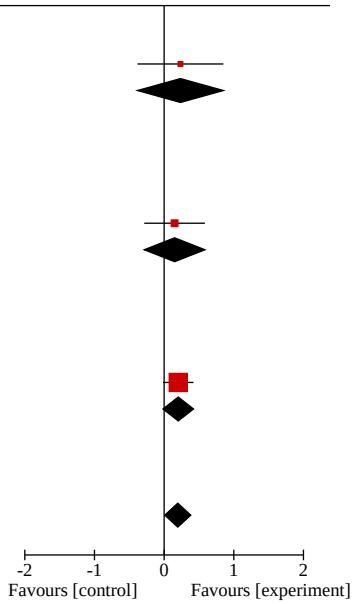
(1) Measured using the SF-12 Mental health component. Higher score beneficial.
(2) Measured using the CES-D. Lower score beneficial. Multiplied outcome by -1.
(3) Measured using the CES-D. Standard deviations derived from confidence interval of adjusted mean difference. Lower score beneficial. Multiplied outcome by -1.
(4) Measured using the CES-D. Data change from baseline measure (baseline to 12 months postpartum). Lower score beneficial. Multiplied outcome by -1.

Comparison 2. Secondary outcomes

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Parenting knowledge and awareness	3	445	Std. Mean Difference (IV, Random, 95% CI)	0.20 [0.01, 0.38]
2.1.1 Skills	1	41	Std. Mean Difference (IV, Random, 95% CI)	0.23 [-0.38, 0.85]
2.1.2 Involvement	1	82	Std. Mean Difference (IV, Random, 95% CI)	0.15 [-0.29, 0.59]
2.1.3 Home safety practices	1	322	Std. Mean Difference (IV, Random, 95% CI)	0.20 [-0.02, 0.42]
2.2 Service access and utilisation	2	530	Std. Mean Difference (IV, Random, 95% CI)	-0.12 [-0.54, 0.30]

Analysis 2.1. Comparison 2: Secondary outcomes, Outcome 1: Parenting knowledge and awareness

Study or Subgroup	SMD	SE	Experimental Total	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
2.1.1 Skills						
Barlow 2006 (1)	0.23429	0.314367	19	22	9.2%	0.23 [-0.38 , 0.85]
Subtotal (95% CI)			**19**	**22**	**9.2%**	**0.23 [-0.38 , 0.85]**
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.75 (P = 0.46)						
2.1.2 Involvement						
Walkup 2009 (2)	0.150199	0.222247	37	45	18.3%	0.15 [-0.29 , 0.59]
Subtotal (95% CI)			**37**	**45**	**18.3%**	**0.15 [-0.29 , 0.59]**
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.68 (P = 0.50)						
2.1.3 Home safety practices						
Family Spirit Trial 2012 (3)	0.202649	0.111753	159	163	72.5%	0.20 [-0.02 , 0.42]
Subtotal (95% CI)			**159**	**163**	**72.5%**	**0.20 [-0.02 , 0.42]**
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.81 (P = 0.07)						
Total (95% CI)			**215**	**230**	**100.0%**	**0.20 [0.01 , 0.38]**
Heterogeneity: Tau² = 0.00; Chi² = 0.06, df = 2 (P = 0.97); I² = 0%						
Test for overall effect: Z = 2.06 (P = 0.04)						
Test for subgroup differences: Chi² = 0.06, df = 2 (P = 0.97), I² = 0%						

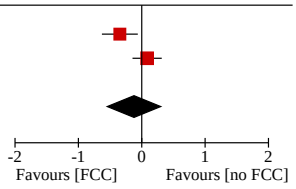


Footnotes

(1) Higher score beneficial.
(2) Data change from baseline measure (baseline to 12 months postpartum). HIgher score beneficial.
(3) Standard deviations derived from confidence interval of adjusted mean difference. Higher score beneficial.

Analysis 2.2. Comparison 2: Secondary outcomes, Outcome 2: Service access and utilisation

Study or Subgroup	SMD	SE	Family-centred care Total	No family-centred care Total	Weight	Std. Mean Difference IV, Random, 95% CI
Harrison 2010 (1)	-0.345584	0.144417	110	131	48.1%	-0.35 [-0.63 , -0.06]
Johnston 2010 (1)	0.084892	0.117707	143	146	51.9%	0.08 [-0.15 , 0.32]
Total (95% CI)			**253**	**277**	**100.0%**	**-0.12 [-0.54 , 0.30]**
Heterogeneity: Tau² = 0.08; Chi² = 5.34, df = 1 (P = 0.02); I² = 81%						
Test for overall effect: Z = 0.57 (P = 0.57)						
Test for subgroup differences: Not applicable						



Footnotes

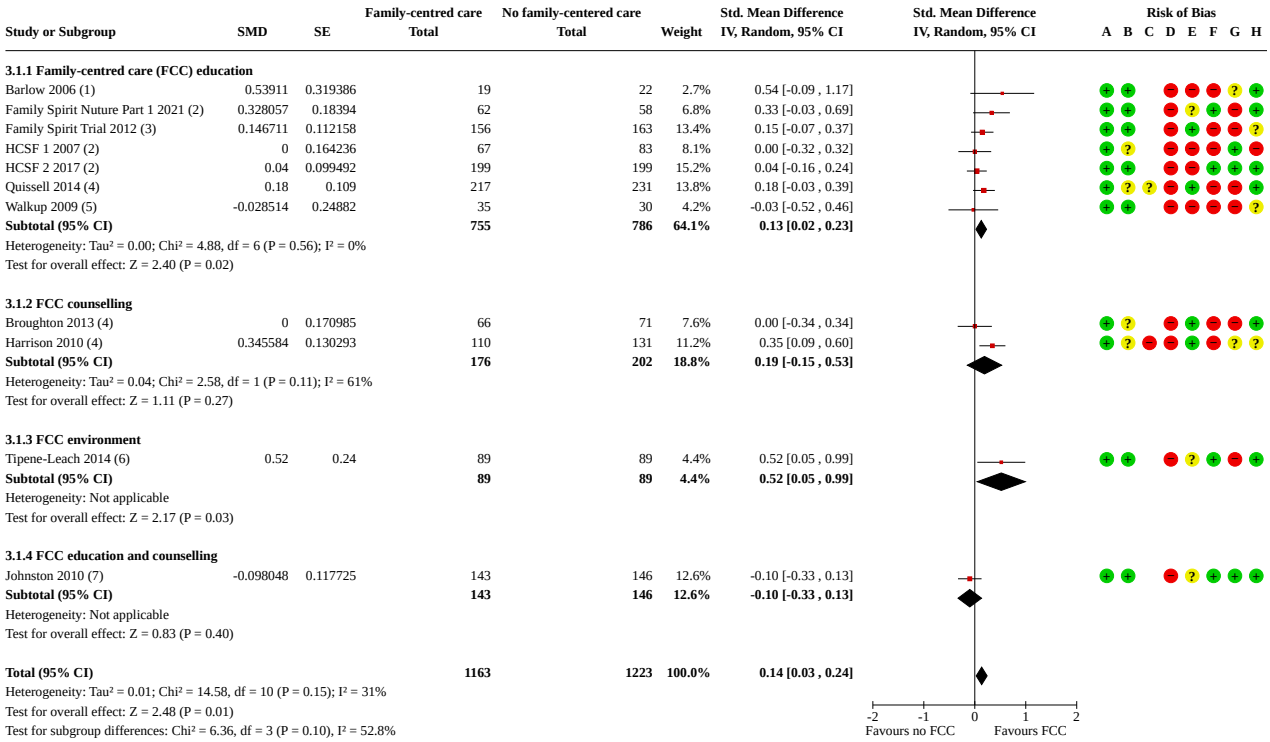
(1) The data were provided as count data and converted to means and standard deviations. Lower score beneficial.

Comparison 3. Subgroup analysis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Overall health and well-being	11	2386	Std. Mean Difference (IV, Random, 95% CI)	0.14 [0.03, 0.24]
3.1.1 Family-centred care (FCC) education	7	1541	Std. Mean Difference (IV, Random, 95% CI)	0.13 [0.02, 0.23]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1.2 FCC counselling	2	378	Std. Mean Difference (IV, Random, 95% CI)	0.19 [-0.15, 0.53]
3.1.3 FCC environment	1	178	Std. Mean Difference (IV, Random, 95% CI)	0.52 [0.05, 0.99]
3.1.4 FCC education and counselling	1	289	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.33, 0.13]
3.2 Physical health and developmental health outcomes of children	8	1961	Std. Mean Difference (IV, Random, 95% CI)	0.13 [-0.00, 0.26]
3.2.1 FCC education	4	1116	Std. Mean Difference (IV, Random, 95% CI)	0.11 [-0.01, 0.24]
3.2.2 FCC counselling	2	378	Std. Mean Difference (IV, Random, 95% CI)	0.19 [-0.15, 0.53]
3.2.3 FCC environment	1	178	Std. Mean Difference (IV, Random, 95% CI)	0.52 [0.05, 0.99]
3.2.4 FCC education and counselling	1	289	Std. Mean Difference (IV, Random, 95% CI)	-0.10 [-0.33, 0.13]
3.3 Family health-enhancing lifestyle or behavioural outcomes	9	1969	Std. Mean Difference (IV, Random, 95% CI)	0.16 [-0.06, 0.39]
3.3.1 FCC education	7	1546	Std. Mean Difference (IV, Random, 95% CI)	0.17 [-0.09, 0.43]
3.3.2 FCC environment	1	169	Std. Mean Difference (IV, Random, 95% CI)	0.34 [-0.24, 0.93]
3.3.3 FCC education and counselling	1	254	Std. Mean Difference (IV, Random, 95% CI)	-0.08 [-0.62, 0.47]

Analysis 3.1. Comparison 3: Subgroup analysis, Outcome 1: Overall health and well-being



Study or Subgroup	SMD	SE	Family-centred care Total	No family-centered care Total	Weight	Std. Mean Difference IV, Random, 95% CI
3.1.1 Family-centred care (FCC) education						
Barlow 2006 (1)	0.53911	0.319386	19	22	2.7%	0.54 [-0.09 , 1.17]
Family Spirit Nuture Part 1 2021 (2)	0.328057	0.18394	62	58	6.8%	0.33 [-0.03 , 0.69]
Family Spirit Trial 2012 (3)	0.146711	0.112158	156	163	13.4%	0.15 [-0.07 , 0.37]
HCSF 1 2007 (2)	0	0.164236	67	83	8.1%	0.00 [-0.32 , 0.32]
HCSF 2 2017 (2)	0.04	0.099492	199	199	15.2%	0.04 [-0.16 , 0.24]
Quissell 2014 (4)	0.18	0.109	217	231	13.8%	0.18 [-0.03 , 0.39]
Walkup 2009 (5)	-0.028514	0.24882	35	30	4.2%	-0.03 [-0.52 , 0.46]
Subtotal (95% CI)			**755**	**786**	**64.1%**	**0.13 [0.02 , 0.23]**
Heterogeneity: Tau² = 0.00; Chi² = 4.88, df = 6 (P = 0.56); I² = 0%						
Test for overall effect: Z = 2.40 (P = 0.02)						
3.1.2 FCC counselling						
Broughton 2013 (4)	0	0.170985	66	71	7.6%	0.00 [-0.34 , 0.34]
Harrison 2010 (4)	0.345584	0.130293	110	131	11.2%	0.35 [0.09 , 0.60]
Subtotal (95% CI)			**176**	**202**	**18.8%**	**0.19 [-0.15 , 0.53]**
Heterogeneity: Tau² = 0.04; Chi² = 2.58, df = 1 (P = 0.11); I² = 61%						
Test for overall effect: Z = 1.11 (P = 0.27)						
3.1.3 FCC environment						
Tipene-Leach 2014 (6)	0.52	0.24	89	89	4.4%	0.52 [0.05 , 0.99]
Subtotal (95% CI)			**89**	**89**	**4.4%**	**0.52 [0.05 , 0.99]**
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.17 (P = 0.03)						
3.1.4 FCC education and counselling						
Johnston 2010 (7)	-0.098048	0.117725	143	146	12.6%	-0.10 [-0.33 , 0.13]
Subtotal (95% CI)			**143**	**146**	**12.6%**	**-0.10 [-0.33 , 0.13]**
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.83 (P = 0.40)						
Total (95% CI)			**1163**	**1223**	**100.0%**	**0.14 [0.03 , 0.24]**
Heterogeneity: Tau² = 0.01; Chi² = 14.58, df = 10 (P = 0.15); I² = 31%						
Test for overall effect: Z = 2.48 (P = 0.01)						
Test for subgroup differences: Chi² = 6.36, df = 3 (P = 0.10), I² = 52.8%						

Footnotes

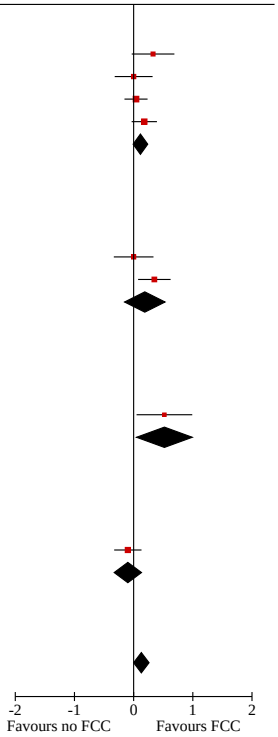
(1) Maternal mental health: Lower score beneficial. Multiplied outcome by -1.
(2) BMI z-score: A positive z-score indicates the raw score is higher than the mean. Lower score beneficial. Multiplied outcome by -1.
(3) Standard deviations derived from confidence interval of adjusted mean difference. Higher score beneficial.
(4) Caries: Lower score beneficial. Multiplied outcome by -1.
(5) ITSEA: Higher score beneficial.
(6) Fully breastfed: Converted from a log odds ratio to a standardised mean difference. Higher events beneficial.
(7) New episode of acute respiratory illness: The data were provided as count data and converted to means and standard deviations. Lower score beneficial. Multiplied outcome by -1.

Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Selective cluster recruitment
(D) Blinding of participants and personnel (performance bias)
(E) Blinding of outcome assessment (detection bias)
(F) Incomplete outcome data (attrition bias)
(G) Selective reporting (reporting bias)
(H) Other bias

Analysis 3.2. Comparison 3: Subgroup analysis, Outcome 2: Physical health and developmental health outcomes of children

Study or Subgroup	SMD	SE	Family-centred care Total	No family-centred care Total	Weight	Std. Mean Difference IV, Random, 95% CI
3.2.1 FCC education						
Family Spirit Nuture Part 1 2021 (1)	0.328057	0.18394	62	58	9.2%	0.33 [-0.03 , 0.69]
HCSF 1 2007 (1)	0	0.163268	67	83	10.8%	0.00 [-0.32 , 0.32]
HCSF 2 2017 (1)	0.04	0.099492	199	199	18.2%	0.04 [-0.16 , 0.24]
Quissell 2014 (2)	0.18	0.109	217	231	16.9%	0.18 [-0.03 , 0.39]
Subtotal (95% CI)			**545**	**571**	**55.0%**	**0.11 [-0.01 , 0.24]**
Heterogeneity: Tau² = 0.00; Chi² = 2.76, df = 3 (P = 0.43); I² = 0%						
Test for overall effect: Z = 1.82 (P = 0.07)						
3.2.2 FCC counselling						
Broughton 2013 (2)	0	0.170985	66	71	10.1%	0.00 [-0.34 , 0.34]
Harrison 2010 (2)	0.35	0.14	110	131	13.0%	0.35 [0.08 , 0.62]
Subtotal (95% CI)			**176**	**202**	**23.2%**	**0.19 [-0.15 , 0.53]**
Heterogeneity: Tau² = 0.04; Chi² = 2.51, df = 1 (P = 0.11); I² = 60%						
Test for overall effect: Z = 1.08 (P = 0.28)						
3.2.3 FCC environment						
Tipene-Leach 2014 (3)	0.52	0.24	89	89	6.1%	0.52 [0.05 , 0.99]
Subtotal (95% CI)			**89**	**89**	**6.1%**	**0.52 [0.05 , 0.99]**
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.17 (P = 0.03)						
3.2.4 FCC education and counselling						
Johnston 2010 (4)	-0.098048	0.117725	143	146	15.7%	-0.10 [-0.33 , 0.13]
Subtotal (95% CI)			**143**	**146**	**15.7%**	**-0.10 [-0.33 , 0.13]**
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.83 (P = 0.40)						
Total (95% CI)			**953**	**1008**	**100.0%**	**0.13 [-0.00 , 0.26]**
Heterogeneity: Tau² = 0.01; Chi² = 12.15, df = 7 (P = 0.10); I² = 42%						
Test for overall effect: Z = 1.95 (P = 0.05)						
Test for subgroup differences: Chi² = 6.20, df = 3 (P = 0.10), I² = 51.6%						



Footnotes

(1) BMI z-score: A positive z-score indicates the raw score is higher than the mean. Lower score beneficial. Multiplied outcome by -1.

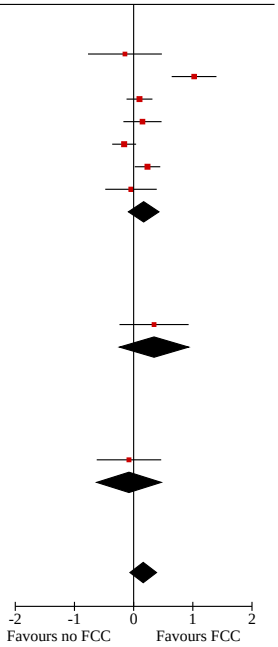
(2) Caries: Lower score beneficial. Multiplied outcome by -1.

(3) Fully breastfeed: Converted from a log odds ratio to a standardised mean difference. Higher events beneficial.

(4) New episode of acute respiratory illness: The data were provided as count data and converted to means and standard deviations. Lower score beneficial. Multiplied outcome by -1.

Analysis 3.3. Comparison 3: Subgroup analysis, Outcome 3: Family health-enhancing lifestyle or behavioural outcomes

Study or Subgroup	SMD	SE	Family-centred care Total	No family-centred care Total	Weight	Std. Mean Difference IV, Random, 95% CI
3.3.1 FCC education						
Barlow 2006 (1)	-0.14702	0.318292	19	22	7.2%	-0.15 [-0.77 , 0.48]
Family Spirit Nuture Part 1 2021 (2)	1.021121	0.192903	62	60	11.2%	1.02 [0.64 , 1.40]
Family Spirit Trial 2012 (3)	0.098797	0.111533	159	163	14.2%	0.10 [-0.12 , 0.32]
HCSF 1 2007 (4)	0.149298	0.164468	67	83	12.3%	0.15 [-0.17 , 0.47]
HCSF 2 2017 (5)	-0.160227	0.103037	190	188	14.5%	-0.16 [-0.36 , 0.04]
Quissell 2014 (6)	0.234	0.11	221	230	14.3%	0.23 [0.02 , 0.45]
Walkup 2009 (7)	-0.044564	0.22195	37	45	10.2%	-0.04 [-0.48 , 0.39]
Subtotal (95% CI)			**755**	**791**	**83.9%**	**0.17 [-0.09 , 0.43]**
Heterogeneity: Tau² = 0.09; Chi² = 31.61, df = 6 (P < 0.0001); I² = 81%						
Test for overall effect: Z = 1.29 (P = 0.20)						
3.3.2 FCC environment						
Tipene-Leach 2014 (8)	0.345	0.298	89	80	7.8%	0.34 [-0.24 , 0.93]
Subtotal (95% CI)			**89**	**80**	**7.8%**	**0.34 [-0.24 , 0.93]**
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.16 (P = 0.25)						
3.3.3 FCC education and counselling						
Johnston 2010 (9)	-0.079	0.278	126	128	8.4%	-0.08 [-0.62 , 0.47]
Subtotal (95% CI)			**126**	**128**	**8.4%**	**-0.08 [-0.62 , 0.47]**
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.28 (P = 0.78)						
Total (95% CI)			**970**	**999**	**100.0%**	**0.16 [-0.06 , 0.39]**
Heterogeneity: Tau² = 0.08; Chi² = 32.70, df = 8 (P < 0.0001); I² = 76%						
Test for overall effect: Z = 1.41 (P = 0.16)						
Test for subgroup differences: Chi² = 1.13, df = 2 (P = 0.57), I² = 0%						



Footnotes

(1) Family cohesion: Higher score beneficial.
(2) Sugar-sweetened beverages consumption: Lower score beneficial. Multiplied by -1.
(3) Home environment: Measured using the Home Observation Measurement of the Environment scale. Standard deviation derived from confidence interval of adjusted mean difference. Higher score b
(4) Parent/caregiver general physical health: Measured using the SF-12 - Physical health component. Higher score beneficial
(5) Parent/caregiver general physical health: Measured using the SF-12 - Physical health component. Higher score beneficial.
(6) Oral health behaviour: Higher score beneficial.
(7) Home environment: Measured using the Home Observation Measurement of the Environment scale. Higher score beneficial.
(8) Maternal sleep quality: Higher score beneficial.
(9) Full smoking ban in the home: Higher score beneficial.

ADDITIONAL TABLES

Table 1. Comparison of interventions of included studies

Study	Participants	Indigenous status	Country	Primary focus of intervention	Intervention	Broad category of intervention	Length of intervention	Control
Barlow 2006	Pregnant adolescents aged 12–19 years at conception and at ≤ 28 weeks' gestation.	Navajo reservation (New Mexico) and White Mountain Apache reservation (Arizona)	USA	Negative parenting patterns	Home visits covering antenatal care, labour, delivery, breastfeeding, nutrition, parenting, home safety, immunisations, well-baby care, family planning, sexually transmitted disease prevention, and maternal goal setting for personal and family development.	Education	9 months: from 28 weeks' gestation to 6 months' postpartum; 25 home visits and 31 discrete lessons	Education: breastfeeding programme delivered in 23 home visits and 20 lessons.
Broughton 2013	Pregnant women	Maori residing within the Waikato-Tainui tribal area	New Zealand	Early childhood caries	Participants offered 4 intervention components: 1. provision of dental care during pregnancy; 2. FV application to teeth of children aged 6, 12, and 18 months; 3. MI, and 4. AG. The 3 themes covered by MI and AG are oral health knowledge, oral self-care and oral health protection and community water fluoridation.	Counselling	18 months: 1 intervention component delivered during pregnancy and 3 more at age 6, 12, and 18 months.	Minimal dental care: examination, x-rays, pain relief, control of infection, scaling and prophylaxis, elimination of caries, restorations, and extractions. Counselling delayed: intervention sessions were delivered after the infant was 24 months old.
Family Spirit Nuture Part 1 2021	Women aged ≥ 13 years with infants aged < 14 weeks	Navajo Nation (New Mexico)	USA	Early childhood obesity	Family Spirit Nuture curriculum lessons focus on: optimal infant feeding practices, responsive feeding, avoiding SSBs, optimal complementary feeding practices, and whole family healthy eating practices.	Education	3 months: 6 lessons delivered from 3 to 6 months' postpartum	Education: 3 injury prevention lessons including childproofing, safe travel and outings with an infant, and strategies to avoid abuse and neglect.
Harrison 2010	Women between weeks 12	Cree Nation Eey-	Canada	Early childhood caries	Mothers received MI aimed at reducing child caries. FV was offered after the infant was 1 year old.	Counselling	24 months: 1 counselling session dur-	Education: mothers received 2 mailed culturally

Table 1. Comparison of interventions of included studies *(Continued)*

	and 34 of pregnancy and mothers of newborn, predentate infants	ou Istchee (Quebec)					ing pregnancy and up to 6 more sessions postnatally until their child's second birthday.	appropriate educational pamphlet describing healthy dental care practices for young children. FV was available to children in control group at local dental clinics.
Johnston 2010	Infants aged 0–5 weeks	Maori and Australian Aboriginal	New Zealand and Australia	Acute respiratory illness	An 8-week supply of free nicotine replacement therapy was available to participants and other household members. Counselling and follow-up was provided. A fax referral to Quitline was offered, with proactive call back by Quitline. Resources were provided to support educational and behavioural coaching.	Education and counselling	3 months: 3 home visits	Usual care
HCSF 1 2007	Children aged 2–5 years	Bad River Band of Lake Superior Chippewa Indians, the Lac du Flambeau Band of Lake Superior Chippewa Indians, the Menominee Nation, and the Oneida Nation	USA	Obesity	Year 1: mentor-led lessons with the primary carer and child, discussions and activities to help the carer and child learn about the topic, behaviour change related to the topic, and goal setting to attempt behaviour change. Families attended 3 mentor-led group sessions. Year 2: monthly group meetings focused on topics such as basic nutrition concepts and ideas for physical activities. Monthly newsletters were disseminated for the 2 years	Education	2 years: year 1: 12 toolkit lessons and 3 group lessons; year 2: 12 monthly group lessons	Education: year 1: same 12 lessons by mail + monthly newsletter. year 2: only monthly newsletter
Family Spirit Trial 2012	Pregnant adolescents aged 12–19 years at conception and at ≤ 28	White Mountain Apache reservation (Arizona), San Carlos Apache Reserva-	USA	Reduce health and behavioural risks	The Family Spirit curriculum lessons focused on 3 domains: 1. parenting skills across early childhood (0–3 years); 2. maternal drug abuse prevention; and 3. maternal life skills and positive psychosocial development.	Education	3 years: home visits occurred weekly through the end of pregnancy, biweekly until 4 months' postpartum,	Optimised standard care: visits include 7 antenatal visits, 9 well-baby visits during the first 3 years of life, and 4 social sup-

Table 1. Comparison of interventions of included studies *(Continued)*

	weeks' gestation.	tions (Arizona), Fort Defiance communities on the Navajo Reservation (Arizona)					monthly between 4 and 12 months' postpartum, and bimonthly between 12 and 36 months' postpartum; 45 home visits and 43 lessons	port visits between years 2 and 3.
Quissell 2014	Head Start children aged 3–5 years and their primary carers	Navajo Nation	USA	Early childhood caries	The application of FV for children and oral health promotion activities for children and carers.	Education	1 year: 4 times for FV; oral health promotion was 5 for children and 4 times for adults.	Usual care: usual oral health care made available by dental providers usually the Indian Health Service. FV was available at clinics.
Tipene-Leach 2014	Women booking for antenatal care	Maori	New Zealand	Sudden unexpected death in infancy	The provision of the wahakura a traditional sleeping device.	Environment	Single provision	A portable standing bassinet
HCSF 2 2017	American Indian children aged 2–5 years and their primary carers	American Indian/Alaska Native	USA	Obesity	12 monthly mailed healthy lifestyle lessons, items, and children's books addressing 6 intervention targets. Adults were supported by social media engagement via 2 weekly text messages and invitation to an optional, site-specific Facebook group	Education	1 year: 12 monthly mail outs; 2 weekly text messages	Education: child safety curriculum delivered in 12 mailed safety newsletters and related materials
Walkup 2009	Pregnant adolescents aged 12–22 years at conception and at ≤ 28 weeks' gestation	Navajo reservation (New Mexico) and White Mountain Apache reservation (Arizona)	USA	Behavioural health problems	Home visits providing developmentally timed antenatal and infant-care parenting lessons, as well as family planning, substance abuse prevention, and problem-solving and coping-skills lessons.	Education	9 months: from 28 weeks' gestation to 6 months' postpartum; 25 home visits	Education: breastfeeding and nutrition programme delivered in 23 home visits.

AG: anticipatory guidance; FV: fluoride varnish; MI: motivational interviewing; SSB: sugar sweetened beverage.

Table 2. Comparison of outcomes for inclusion in review

Study	Control group	Family-centred care intervention category	Type of outcome	Name of outcome	Outcome measured on	Name of validated survey, questionnaire, or instrument?	Short term	Medium term	Long term	Included in a meta-analysis
Primary outcomes										
Overall health and well-being										
Walkup 2009	Minimal education	Education	Continuous	Competence domain	Child	ITSEA	—	X	—	X
Family Spirit Trial 2012	Usual care	Education	Continuous	Competence domain	Child	ITSEA	—	X	—	X
HCSF 2 2017	Minimal education	Education	Continuous	BMI z-score	Child	BMI; scale and measure	—	X	—	X
HCSF 1 2007	Minimal education	Education	Continuous	BMI z-score	Child	BMI; scale and measure	—	X	—	X
Family Spirit Nuture Part 1 2021	Minimal education	Education	Continuous	BMI z-score	Child	BMI; scale and measure	—	X	—	X
Quissell 2014	Usual care	Education	Continuous	Caries: decayed, missing, or filled spaces	Child	NA	—	X	—	X
Barlow 2006	Minimal education	Education	Continuous	Depression	Mother	CES-D	—	X	—	X
Tipene-Leach 2014	Usual care	Environment	Binary	Fully breastfed: yes	Child	No	—	X	—	X

Table 2. Comparison of outcomes for inclusion in review *(Continued)*

Johnston 2010	Usual care	Education and counselling	Count	New episodes of acute respiratory illness	Child	Yes	—	X	—	X
Harrison 2010	Minimal education	Counselling	Continuous	Caries: tooth level caries prevalence (d2-4efs > 0)	Child	NA	—	—	X	X
Broughton 2013	Minimal dental care	Counselling (not delayed)	Continuous	Caries: decayed, missing, or filled spaces	Child	NA	—	—	X	X
Psychological health and emotional behaviour of children										
Walkup 2009	Minimal education	Education	Continuous	Competence domain	Child	ITSEA	—	X	—	X
Family Spirit Trial 2012	Usual care	Education	Continuous	Competence domain	Child	ITSEA	—	X	—	X
Harrison 2010	Minimal education	Counselling	Binary	Parent reported 'dental caries-related' child quality of life. Answered "yes" to > 1 quality of life question.	Child	Yes: in-house with a previous survey involving 301 children	—	—	X	—
Family Spirit Trial 2012	Usual care	Education	Continuous	Competence domain	Child	ITSEA	—	—	X	—
Physical health and developmental outcomes of children										
Family Spirit Nuture Part 1 2021	Minimal education	Education	Continuous	BMI z-score	Child	BMI; scale and measure	X	—	—	—
Tipene-Leach 2014	Usual care	Environment	Binary	Fully breastfed: yes	Child	No	X	—	—	—
HCSF 2 2017	Minimal education	Education	Continuous	BMI z-score	Child	BMI; scale and measure	—	X	—	X

Table 2. Comparison of outcomes for inclusion in review *(Continued)*

HCSF 1 2007	Minimal education	Education	Continuous	BMI z-score	Child	BMI; scale and measure	—	X	—	X
Family Spirit Nuture Part 1 2021	Minimal education	Education	Continuous	BMI z-score	Child	BMI; scale and measure	—	X	—	X
Quissell 2014	Usual care	Education	Continuous	Caries: decayed, missing, or filled spaces	Child	NA	—	X	—	X
Tipene-Leach 2014	Usual care	Environment	Binary	Fully breastfeeding: yes	Child	No	—	X	—	X
Johnston 2010	Usual care	Education and counselling	Count	New episodes of acute respiratory illness	Child	Yes	—	X	—	X
Harrison 2010	Minimal education	Counselling	Continuous	Caries: tooth level caries prevalence (d2-4efs > 0)	Child	NA	—	—	X	X
Broughton 2013	Minimal dental care	Counselling (not delayed)	Continuous	Caries: decayed, missing, or filled spaces	Child	NA	—	—	X	X
Broughton 2013	Counselling (delayed)[a]	Counselling (not delayed)	Continuous	Caries: decayed, missing, or filled spaces	Child	NA	—	—	X	—
Family enhancing lifestyle or behaviour outcomes										
Barlow 2006	Minimal education	Education	Continuous	Cohesion	Family	Not reported	X	—	—	—
Tipene-Leach 2014	Usual care	Environment	Binary	Maternal sleep quality: good	Mother	No	X	—	—	—
Tipene-Leach 2014	Usual care	Environment	Binary	Infants sleep position: back position	Child	No	X	—	—	—
HCSF 1 2007	Minimal education	Education	Continuous	SF-12: Physical Health component	Carer	SF-12	—	X	—	X

Table 2. Comparison of outcomes for inclusion in review *(Continued)*

HCSF 2 2017	Minimal education	Education	Continuous	SF-12: Physical Health component	Carer	SF-12	—	X	—	X
Walkup 2009	Minimal education	Education	Continuous	HOME	Mother	HOME	—	X	—	X
Barlow 2006	Minimal education	Education	Continuous	Cohesion	Family	Not reported	—	X	—	X
Family Spirit Trial 2012	Usual Care	Education	Continuous	HOME	Mother	HOME	—	X	—	X
Family Spirit Nuture Part 1 2021	Minimal education	Education	Continuous	Infant SSB consumption	Child	Adapted Pre-School Beverage Intake Questionnaire	—	X	—	X
Quissell 2014	Usual care	Education	Continuous	Oral health behaviour	Carer	Not reported	—	X	—	X
Tipene-Leach 2014	Usual care	Environment	Binary	Maternal sleep quality: good	Mother	No	—	X	—	X
Tipene-Leach 2014	Usual care	Environment	Binary	Infants sleep position: back position	Child	No	—	X	—	—
Johnston 2010	Usual care	Education and counselling	Binary	Full smoking ban in home	Family	No	—	X	—	X
Johnston 2010	Usual care	Education and counselling	Binary	In last 7 days, infant has been around tobacco smoke	Child	No	—	X	—	—
Family Spirit Trial 2012	Usual care	Education	Continuous	HOME	Mother	HOME	—	—	X	—
Psychological health of parent/carer										

Table 2. Comparison of outcomes for inclusion in review *(Continued)*

Barlow 2006	Minimal education	Education	Continuous	Depression	Mother	CES-D	X	—	—	—
Walkup 2009	Minimal education	Education	Continuous	Depression	Mother	CES-D	X	—	—	—
Family Spirit Trial 2012	Usual care	Education	Continuous	Depression	Mother	CES-D	X	—	—	—
Barlow 2006	Minimal education	Education	Continuous	Depression	Mother	CES-D	—	X	—	X
Walkup 2009	Minimal education	Education	Continuous	Depression	Mother	CES-D	—	X	—	X
HCSF 1 2007	Minimal education	Education	Continuous	SF-12: Mental Health component	Carer	SF-12	—	X	—	X
HCSF 2 2017	Minimal education	Education	Continuous	SF-12: Mental health component	Carer	SF-12	—	X	—	X
Family Spirit Trial 2012	Usual care	Education	Continuous	Depression	Mother	CES-D	—	X	—	X
Family Spirit Trial 2012	Usual care	Education	Continuous	Depression	Mother	CES-D	—	—	X	—
Adverse events										
Harrison 2010	Minimal education	Counselling	Unclear	Adverse events related to the intervention. Unclear what specific events were included	Child	NA	—	—	X	—
Family Spirit Nuture Part 1 2021	Minimal education	Education	Unclear	Emergency department presentations and hospital admissions were recorded as potential adverse events	Child	NA	—	—	X	—
Secondary outcomes										

Table 2. Comparison of outcomes for inclusion in review *(Continued)*

Parenting knowledge and awareness										
Barlow 2006	Minimal education	Education	Continuous	Skills	Mother	No	X	—	—	—
Barlow 2006	Minimal education	Education	Continuous	Skills	Mother	No	—	X	—	X
Walkup 2009	Minimal education	Education	Continuous	Involvement	Mother	Parent Involvement Scale from the Substance Abuse and Mental Health Services Administration measure	—	X	—	—
Family Spirit Trial 2012	Usual care	Education	Continuous	Home safety practices	Mother	No	—	X	—	X
Family Spirit Nuture Part 1 2021	Minimal education	Education	Continuous	Maternal SSB knowledge index	Mother	No	—	X	—	—
Family Spirit Trial 2012	Usual care	Education	Continuous	Knowledge	Mother	No	—	—	X	X
Service access and utilisation										
Johnston 2010	Usual care	Education and counselling	Count	Hospitalisation for acute respiratory illness	Child	Yes	—	X	—	—
Harrison 2010	Minimal education	Counselling	Count	Number of visits to dentist for tooth pain	Child	Yes	—	—	X	—
Economic costs										

Table 2. Comparison of outcomes for inclusion in review *(Continued)*

Harrison 2010	Minimal education	Counselling	Cost	Cost-effectiveness	Health system	NA	—	—	X	—

[a]When control children were aged 24 months, they received the intervention for one year and are called the delayed intervention group.
BMI: body mass index; CES-D: Center for Epidemiologic Studies Depression Scale; HOME: Home Observation for Measurement of the Environment; ITSEA: Infant Toddler Social Emotional Assessment; NA: not applicable; SF-12: 12-item Short Form Survey; SSB: sugar-sweetened beverage.

APPENDICES

Appendix 1. Criteria for family-centredness

Family-centredness rating score (13 elements)

Rating 0, 1, 2, 3, or 4

	Barlow 2006	Broughton 2013	Family Spirit Nuture Part 1 2021	Family Spirit Trial 2012	Harrison 2010	HCSF 1 2007	HCSF 2 2017	Johnston 2010	Quissell 2014	Tipene-Leach 2014	Walkup 2009
C1: family as a constant											
Family as a constant in child's life	2	4	3	2	4	2	4	4	1	4	3
Recognising family strengths	2	4	2	2	3	2	4	2	1	4	2
Parent/professional collaboration	4	4	4	4	4	4	3	2	4	3	4
Needs-based family support	3	4	2	3	3	4	4	4	3	2	4
Flexible provision of health care	3	4	2	3	3	4	4	2	3	4	4
Sharing information with families	4	4	4	4	4	4	4	4	4	3	4
C2: culturally responsive											
Culturally competent health care	3	4	4	3	3	4	4	4	4	4	4
Respecting family diversity	3	4	2	3	2	2	3	3	2	3	4
Providing financial support	0	0	0	0	0	0	0	0	0	0	0
C3: supporting family individuality and need for different types of family support											
Respecting family coping methods	1	3	1	1	1	4	4	1	2	2	2
Providing emotional support	3	4	2	3	0	3	3	2	1	1	4
Family-to-family support	1	1	0	1	0	2	2	0	0	1	4
Attending to the developmental needs of children and families	3	4	2	3	3	2	3	0	3	3	4
Total score	32 (62%)	44 (85%)	28 (54%)	32 (62%)	30 (58%)	37 (72%)	43 (83%)	28 (54%)	28 (54%)	34 (65%)	43 (83%)

(Exclude studies with family-centredness score < 26 or 50%)
0: article included 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 included a minimal amount of implicit evidence that the author(s) advanced adoption or support of the elements of family-centred care.
2: article included numerous instances of implicit evidence that the author(s) advanced adoption or support of the elements of family-centred care.
3: article included a minimal amount of explicit evidence that the author(s) advanced adoption or support of the elements of family-centred care.
4: article included 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.

Appendix 2. CENTRAL search strategy

#1(aborigin* or indigen*):ti,ab,kw
#2("first nation*" or "native people*"):ti,ab,kw
#3"oceanic ancestry group":kw
#4("first australian*" or "torres strait* islander*" or tiwi or maori* or "tangata whenua"):ti,ab,kw
#5((american* or canadian) near/2 indian*):ti,ab,kw
#6tribes:kw
#7([mh "united states"] or [mh canada] or [mh "new zealand"] or ("united states" or america* or canad* or alaska* or "new zealand*"):ti,ab,kw) and native*:ti,ab,kw
#8(amerind* or metis or navajo or ojibw* or chippewa or algonquin or cree or arikara or iroquois or cherokee or mohawk or muscogee or choctaw or seminole or zuni or lakota or sioux or hopi or pima or tohono or yaqui):ti,ab,kw
#9(aleut* or eskimo* or inuit* or inupiat* or yupik* or hawai*):ti,ab,kw
#10{or #1-#9}
#11(family or families or father* or mother* or husband* or wife* or paternal or maternal or grandparent* or guardian* or parent or parents or parental or parenting or "child rearing" or childrearing):ti,ab,kw
#12[mh "health personnel"]
#13(((general or family) next (doctor* or practitioner* or physician*)) or ((health* or medical) near/2 (service* or personnel or organi*ation*)) or nurse* or nursing or provider* or worker* or aide or aides):ti,ab,kw
#14((primary near/2 (care or health*)) or "patient cent*red"):ti,ab,kw
#15#10 and (#11 or #12 or #13 or #14)
#16[mh pregnancy]
#17pregnan*:ti,ab,kw
#18[mh "maternal health services"]
#19"maternal welfare":kw
#20[mh infant]
#21[mh "child development"]
#22"child development":ti,ab,kw
#23(embryo* or fetus* or foetus* or "unborn child*" or prenatal or pre-natal or perinatal or peri-natal or postnatal or post-natal or postpartum or post-partum or obstetric* or midwife* or baby or babies or newborn or neonat* or neo-nat* or childbirth or birth or infant* or toddler* or preschool* or pre-school* or "nursery school*" or kindergarten or "early child*"):ti,ab,kw
#24[mh "pregnancy complications"]
#25[mh "infant newborn diseases"]
#26[mh "neurodevelopmental disorders"]
#27((*developmental* or learning or "child behavio*") next (disorder* or disease* or disab*)):ti,ab,kw
#28[mh "child health services"]
#29(child* and (health* or care or welfare or wellbeing or "well being")) or (family next (centred or centered or based or focused or focussed))
#30"early intervention*":ti,ab,kw
#31((family or families or parent* or mother* or father* or maternal or paternal or guardian*) near/5 (educat* or teach* or instruct* or train* or coach* or counsel* or advis* or advice* or inform* or support* or program* or intervention*)):ti,ab,kw
#32{or #16-#31}
#33#15 and #32

Appendix 3. MEDLINE search strategy

1. (aborigin* or indigen*).ti,ab,kf.

2. (first nation* or native people*).ti,ab,kf.

3. oceanic ancestry group/

4. (first australian* or torres strait* islander* or tiwi).ti,ab,kf.

5. (maori* or tangata whenua).ti,ab,kf.

6. american native continental ancestry group/

7. indians north american/

8. ((american* or canadian) adj2 indian*).ti,ab,kf.

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,kf.

10. (amerind* or metis or navajo or ojibw* or chippewa or algonquin or cree or arikara or iroquois or cherokee or mohawk or muscogee or choctaw or seminole or zuni or lakota or sioux or hopi or pima or tohono or yaqui).ti,ab,kf.

11. inuits/

12. (aleut* or eskimo* or inuit* or inupiat* or yupik* or hawai*).ti,ab,kf.

13. or/1-12

14. (family or families).mp.

15. (father* or mother* or husband* or wife* or paternal or maternal or grandparent* or guardian*).mp.

16. parenting/

17. exp child rearing/

18. (parent or parents or parental or parenting or child rearing or childrearing).ti,ab,kf.

19. exp health personnel/

20. (((general or family) adj (doctor* or practitioner* or physician*)) or ((health* or medical) adj2 (service* or personnel or organi#ation*)) or nurse* or nursing or provider* or worker* or aide or aides).ti,ab,kf.

21. ((primary adj2 (care or health*)) or patient cent?red).mp.

22. or/14-21

23. 13 and 22

24. exp pregnancy/

25. pregnan*.mp.

26. exp maternal health services/

27. exp "embryonic and fetal development"/

28. exp fetus/

29. exp infant/

30. child preschool/

31. exp child development/

32. (embryo* or fetus or foetus or "unborn child*" or prenatal or pre-natal or perinatal or peri-natal or postnatal or post-natal or postpartum or post-patum or baby or babies or newborn or neonat* or neo-nat* or childbirth or birth or obstetric* or midwife* or infant* or toddler* or preschool* or pre-school* or "nursery school*" or kindergarten or "early child*").mp.

33. exp pregnancy complications/

34. exp infant newborn diseases/

35. exp neurodevelopmental disorders/

36. ((developmental* or learning or child behavio*) adj (disorder* or disease* or disab*)).ti,ab,kf.

37. "early intervention (education)"/

38. exp child health services/

39. child health/

40. child welfare/

41. ((child* and (health* or care or welfare or wellbeing or well being)) or (family adj (cent?red or based or focus?ed))).mp.

42. ((family or families or parent* or mother* or father* or maternal or paternal or guardian*) adj5 (educat* or teach* or instruct* or train* or coach* or counsel* or advis* or advice* or inform* or support* or program* or intervention*)).ti,ab,kf.

43. or/24-42

44. 23 and 43

45. randomized controlled trial.pt.

46. controlled clinical trial.pt.

47. random*.tw.

48. placebo*.tw.

49. trial.tw.

50. groups.ab.

51. clinical trial.pt.

52. evaluation studies.pt.

53. research design/

54. follow up studies/

55. prospective studies/

56. cross over studies/

57. comparative study.pt.

58. controlled before after studies/

59. interrupted time series analysis/

60. (experiment* or intervention*).tw.

61. (pre test or pretest or post test or posttest).tw.

62. (preintervention or postintervention).tw.

63. time series.tw.

64. (cross over or crossover or factorial* or latin square).tw.

65. (assign* or allocat* or volunteer*).tw.

66. (control* or compar* or prospectiv*).tw.

67. (impact* or effect? or chang* or evaluat*).tw.

68. or/45-67

69. 44 and 68

Appendix 4. Embase search strategy

1. exp indigenous people/

2. (aborigin* or indigen*).ti,ab,kw.

3. (first nation* or native people*).ti,ab,kw.

4. oceanic ancestry group/

5. exp australian aborigine/

6. (first australian* or torres strait* islander* or tiwi).ti,ab,kw.

7. "maori (people)"/

8. (maori* or tangata whenua).ti,ab,kw.

9. exp amerind people/

10. ((american* or canadian) adj2 indian*).ti,ab,kw.

11. (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.

12. (amerind* or metis or navajo or ojibw* or chippewa or algonquin or cree or arikara or iroquois or cherokee or mohawk or muscogee or choctaw or seminole or zuni or lakota or sioux or hopi or pima or tohono or yaqui).ti,ab,kw.

13. exp eskimo-aleut people/

14. native hawaiian/

15. (aleut* or eskimo* or inuit* or inupiat* or yupik* or hawai*).ti,ab,kw.

16. or/1-15

17. (family or families).mp.

18. (father* or mother* or husband* or wife* or paternal or maternal or grandparent* or guardian*).mp.

19. (parent or parents or parental or parenting or child rearing or childrearing).mp.

20. health care personnel/

21. (((general or family) adj (doctor* or practitioner* or physician*)) or ((health* or medical) adj2 (service* or personnel or organi#ation*)) or nurse* or nursing or provider* or worker* or aide or aides).ti,ab,kw.

22. ((primary adj2 (care or health*)) or patient cent?red).mp.

23. or/17-22

24. 16 and 23

25. exp pregnancy/

26. pregnan*.mp.

27. exp prenatal development/

28. human embryo/

29. fetus/

30. exp childbirth/

31. exp infant/

32. toddler/

33. preschool child/

34. child development/

35. (embryo* or fetus or foetus or "unborn child*" or prenatal or pre-natal or perinatal or peri-natal or postnatal or post-natal or postpartum or post-patum or baby or babies or newborn or neonat* or neo-nat* or childbirth or birth or obstetric* or midwife* or infant* or toddler* or preschool* or pre-school* or "nursery school*" or kindergarten or "early child*").mp.

36. maternal child health care/

37. exp newborn care/

38. infant welfare/

39. exp pregnancy complication/

40. exp newborn disease/

41. exp infant disease/

42. developmental disorder/

43. exp autism/

44. exp behavior disorder/

45. exp learning disorder/

46. ((developmental* or learning or child behavio*) adj (disorder* or disease* or disab*)).ti,ab,kw.

47. child health/

48. child health care/

49. ((child* and (health* or care or welfare or wellbeing or well being)) or (family adj (cent?red or based or focus?ed))).mp.

50. early childhood intervention/

51. early intervention/

52. parent counseling/

53. ((family or families or parent* or mother* or father* or maternal or paternal or guardian*) adj5 (educat* or teach* or instruct* or train* or coach* or counsel* or advis* or advice* inform* or support* or program* or intervention*)).ti,ab,kw.

54. or/25-53

55. 24 and 54

56. randomized controlled trial/

57. controlled clinical trial/

58. single blind procedure/ or double blind procedure/

59. crossover procedure/

60. random*.tw.

61. trial.tw.

62. placebo*.tw.

63. ((singl* or doubl*) adj (blind* or mask*)).tw.

64. (experiment* or intervention*).tw.

65. epidemiology/

66. controlled study/

67. (pre test or pretest or post test or posttest).tw.

68. (preintervention or postintervention).tw.

69. (cross over or crossover or factorial* or latin square).tw.

70. (assign* or allocat* or volunteer*).tw.

71. (control* or compar* or prospectiv*).tw.

72. (impact* or effect? or chang* or evaluat*).tw.

73. time series analysis/

74. time series.tw.

75. or/56-74

76. 55 and 75

77. limit 76 to embase

78. limit 76 to conference abstracts

79. or/77-78

Appendix 5. PsycINFO search strategy

1. exp indigenous populations/

2. (aborigin* or indigen*).ti,ab,id.

3. (first nation* or native people*).ti,ab,id.

4. (first australian* or torres strait* islander* or tiwi).ti,ab,id.

5. (maori* or tangata whenua).ti,ab,id.

6. ((american* or canadian) adj2 indian*).ti,ab,id.

7. tribes/

8. ((america* or canad* or alaska* or new zealand*) and native*).ti,ab,id.

9. (amerind* or metis or navajo or ojibw* or chippewa or algonquin or cree or arikara or iroquois or cherokee or mohawk or muscogee or choctaw or seminole or zuni or lakota or sioux or hopi or pima or tohono or yaqui).ti,ab,id.

10. (aleut* or eskimo* or inuit* or inupiat* or yupik*).ti,ab,id.

11. hawai*.ti,ab,hw,id.

12. or/1-11

13. (family or families).ti,ab,hw,id.

14. (father* or mother* or husband* or wife* or paternal or maternal or grandparent* or guardian*).ti,ab,hw,id.

15. (parent or parents or parental or parenting or child rearing or childrearing).ti,ab,hw,id.

16. health personnel/

17. (((general or family) adj (doctor* or practitioner* or physician*)) or ((health* or medical) adj2 (service* or personnel or organi#ation*)) or nurse* or nursing or provider* or worker* or aide or aides).ti,ab,id.

18. ((primary adj2 (care or health*)) or patient cent?red or client cent?red).ti,ab,hw,id.

19. or/13-18

20. 12 and 19

21. ("120" or "140" or "160").ag.

22. exp pregnancy/

23. pregnan*.ti,ab,hw,id.

24. exp prenatal development/

25. exp prenatal care/

26. exp birth/

27. exp early childhood development/

28. exp preschool students/

29. kindergarten students/

30. (embryo* or fetus* or foetus* or unborn child* or prenatal or pre-natal or perinatal or peri-natal or postnatal or post-natal or postpartum or post-patum or baby or babies or newborn or neonat* or neo-nat* or childbirth or birth or obstetric* or midwife* or infant? or toddler* or preschool* or pre-school* or nursery school* or kindergarten or early child*).ti,ab,hw,id.

31. exp obstetrical complications/

32. exp neonatal disorders/

33. exp developmental disabilities/

34. ((developmental* or neurodevelopmental* or learning or child behavio*) adj (disorder* or disease* or disab*)).ti,ab,hw,id.

35. early intervention/

36. ((child* and (health* or care or welfare or wellbeing or well being)) or (family adj (cent?red or based or focus?ed))).ti,ab,hw,id.

37. family life education/

38. parent training/

39. ((family or families or parent* or mother* or father* or maternal or paternal or guardian*) adj5 (educat* or teach* or instruct* or train* or coach* or counsel* or advis* or advice* or inform* or support* or program* or interven*)).ti,ab,id.

40. or/21-39

41. 20 and 40

42. random*.ti,ab,hw,id.

43. (experiment* or intervention*).ti,ab,hw,id.

44. trial*.ti,ab,hw,id.

45. placebo*.ti,ab,hw,id.

46. ((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)).ti,ab,hw,id.

47. treatment effectiveness evaluation/

48. mental health program evaluation/

49. (pre test or pretest or post test or posttest).ti,ab,hw,id.

50. (preintervention or postintervention).ti,ab,hw,id.

51. (cross over or crossover or factorial* or latin square).ti,ab,hw,id.

52. (assign* or allocat* or volunteer*).ti,ab,hw,id.

53. (control* or compar* or prospectiv*).ti,ab,hw,id.

54. (impact* or effect? or chang* or evaluat*).ti,ab,hw,id.

55. time series.ti,ab,hw,id.

56. exp experimental design/

57. ("0430" or "0450" or "0451" or "1800" or "2100").md.

58. or/42-57

59. 41 and 58

Appendix 6. CINAHL search strategy

S26 s25 Limiters - Exclude MEDLINE records

S25 s9 and s24

S24 s10 or s11 or s12 or s13 or s14 or s15 or s16 or s17 or s18 or s19 or s20 or s21 or s22 or s23

S23 "early intervention*" or ((family or families or parent* or mother* or father* or maternal or paternal or guardian*) N5 (educat* or teach* or instruct* or train* or coach* or counsel* or advis* or advice* or inform* or support* or program* or intervention*))

S22 (child* and (health* or care or welfare or wellbeing or "well being")) or (family N1 (cent#red or based or focus#ed))

S21 MH child health services+

S20 (developmental* or learning or "child behavio*") N1 (disorder* or diasease* or disab*)

S19 MH mental disorders diagnosed in childhood+

S18 MH infant, newborn, diseases+

S17 MH pregnancy complications+

S16 embryo* or fetus* or foetus* or "unborn child*" or prenatal or pre-natal or perinatal or peri-natal or postnatal or post-natal or postpartum or post-patum or baby or babies or newborn or neonat* or neo-nat* or childbirth or birth or obstetric* or midwife* or infant* or toddler* or preschool* or pre-school* or "nursery school*" or kindergarten or "early child*"

S15 "child development*"

S14 MH infant+

S13 MH (maternal health services+ or maternal-child care+ or maternal-child welfare+)

S12 MH fetus+

S11 MH embryo+

S10 (MH pregnancy+) or pregnan*

S9 s7 and s8

S8 family or families or father* or mother* or husband* or wife* or paternal or maternal or grandparent* or guardian* or parent or parents or parental or parenting or "child rearing" or childrearing or ((general or family) N1 (doctor* or practitioner* or physician*)) or ((health* or medical) N2 (service* or personnel or organi?ation*)) or nurse* or nursing or provider* or worker* or aide or aides or (primary N2 (care or health*)) or "patient centred" or "patient centered" or MH health personnel+

S7 s1 or s2 or s3 or s4 or s5 or s6

S6 aleut* or eskimo* or inuit* or inupiat* or yupik* or hawai*

S5 amerind* or metis or navajo or ojibw* or chippewa or algonquin or cree or arikara or iroquois or cherokee or mohawk or muscogee or choctaw or seminole or zuni or lakota or sioux or hopi or pima or tohono or yaqui

S4 ((MH (united states+ or canada+)) or ("united states" or america* or canad* or alaska* or "new zealand*")) and native*

S3 ((american* or canadian*) N2 indian*) or tribes

S2 "first australian*" or "torres strait* islander*" or tiwi or maori* or "tangata whenua"

S1 aborigin* or indigen* or "first nation*" or "native people*"

Appendix 7. Informit search strategy

Indigenous Collection 14 databases: A+Education, AGIS Plus Text, Asia Collection, Australian Public Affairs (APAFT), Business Collection, EduTV, Engineering Collection, Families & Society Collection, Health Collection, Humanities & Social Sciences Collection, Indigenous Collection, Literature & Culture Collection, New Zealand Collection, TVNews

(family OR families OR father* OR mother* OR husband* OR wife* OR paternal OR maternal OR grandparent* OR guardian* OR parent*)

AND

(pregnan* OR embryo* OR fetus* OR foetus* OR "unborn child*" OR prenatal OR "pre-natal" OR perinatal OR "peri-natal" OR postnatal OR "post-natal" OR postpartum OR "post-partum" OR obstetric* OR midwife* OR baby OR babies OR newborn OR neonat* OR "neo-nat*" OR childbirth OR birth OR infant* OR toddler* OR preschool* OR "pre-school*" OR "nursery school*" OR kindergarten OR "early child*" OR "child develoment" OR "newborn disease*" OR "infant disease*" OR "early childhood disease*" OR developmental OR "learning disorder*" OR "child behavio*" OR "early intervention*" OR (child* AND (health* OR care OR welfare OR wellbeing OR "well being")))

AND

(random* OR control* OR trial OR assign* OR allocat* OR volunteer* OR experiment* OR intervention* OR compar* OR prospectiv* OR assess* OR impact* OR effect* OR chang* OR evaluat* OR blind* OR "cross over" OR crossover OR factorial OR "latin square" OR "time series")

Appendix 8. CENTRAL search strategy (scoping)

#1(aborigin* or indigen*):ti,ab,kw (Word variations have been searched)
#2(first nation* or native people*):ti,ab,kw (Word variations have been searched)
#3MeSH descriptor: [Oceanic Ancestry Group] explode all trees
#4(first australian* or torres strait* islander*):ti,ab,kw (Word variations have been searched)
#5maori*:ti,ab,kw (Word variations have been searched)
#6MeSH descriptor: [American Native Continental Ancestry Group] explode all trees
#7MeSH descriptor: [Indians, North American] explode all trees
#8((american* or canadian) near/1 indian*)
#9MeSH descriptor: [United States] explode all trees
#10MeSH descriptor: [Canada] explode all trees
#11MeSH descriptor: [New Zealand] explode all trees
#12(america* or canad* or alaska* or new zealand*):ti,ab,kw (Word variations have been searched)
#13native*:ti,ab,kw (Word variations have been searched)
#14(#9 or #10 or #11 or #12) and #13
#15(metis or cherokee* or chippewa* or choctaw* or navajo* or sioux):ti,ab,kw (Word variations have been searched)
#16MeSH descriptor: [Inuits] explode all trees
#17(inuit* or eskimo* or inupiat* or yupik*):ti,ab,kw (Word variations have been searched)
#18hawai*:ti,ab,kw (Word variations have been searched)
#19#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #14 or #15 or #16 or #17 or #18
#20(family or families):ti,ab,kw (Word variations have been searched)
#21(father* or mother* or husband* or wife* or paternal or maternal or grandparent* or guardian*):ti,ab,kw (Word variations have been searched)
#22MeSH descriptor: [Parenting] explode all trees
#23(parent or parents or parental or parenting):ti,ab,kw (Word variations have been searched)
#24MeSH descriptor: [Maternal Health Services] explode all trees
#25(prenatal or perinatal or postnatal or postpartum):ti,ab,kw (Word variations have been searched)
#26#20 or #21 or #22 or #23 or #24 or #25
#27#19 and #26
#28MeSH descriptor: [Pregnancy] explode all trees
#29pregnan*:ti,ab,kw (Word variations have been searched)
#30MeSH descriptor: [Embryonic and Fetal Development] explode all trees
#31MeSH descriptor: [Fetus] explode all trees
#32MeSH descriptor: [Infant] explode all trees

#33MeSH descriptor: [Child, Preschool] explode all trees
#34(fetus* or foetus* or unborn child* or baby or babies or newborn or neonat* or infant? or toddler* or preschool* or preschool* or kindergarten or early child*):ti,ab,kw (Word variations have been searched)
#35MeSH descriptor: [Pregnancy Complications] explode all trees
#36MeSH descriptor: [Infant, Newborn, Diseases] explode all trees
#37MeSH descriptor: [Neurodevelopmental Disorders] explode all trees
#38MeSH descriptor: [Early Intervention (Education)] explode all trees
#39#28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38
#40#27 and #39

HISTORY

Protocol first published: Issue 12, 2016

CONTRIBUTIONS OF AUTHORS

NS: assisted with drafting the protocol, completed first screening, full-text screening and data extracting, assessed levels of family-centredness, carried out the analysis, interpreted the analysis, completed risk of bias, drafted and revised the final manuscript. NS will take responsibility of updating the review.

CC: assisted with drafting the protocol, assisted with full-text screening and data extraction, assessed levels of family-centredness, provided systematic review expertise, drafted and revised the final manuscript.

SC: assisted with drafting the protocol, completed full-text screening, assessed levels of family-centredness, interpreted the analysis, completed risk of bias, revised the final manuscript.

LS: assisted with drafting the protocol, completed full-text screening, assessed levels and advised on family-centredness, interpreted the analysis, completed risk of bias, revised the final manuscript.

RB: assisted with drafting the protocol, completed full-text screening, assessed levels of family-centredness, interpreted the analysis, revised the final manuscript.

CA: completed first screening and data extracting, revised and edited the final manuscript.

KE: provided advice about the clinical relevance of outcomes and revise the final manuscript.

RM: provided advice about the clinical relevance of outcomes and revise the final manuscript.

JM: completed the protocol, contributed to full-text screening and assessed levels of family centredness, interpreted the analysis, completed risk of bias, revised the final manuscript.

DECLARATIONS OF INTEREST

Where review authors had published papers that might be included in the review, the review author/s in question were not involved in assessing the study for inclusion, or extracting or analysing data from that study.

NS: none.

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

SC: none.

LS: none.

RB: none.

CA: none.

MW: none.

KE: none.

RM: none.

JM: none.

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Internal sources

- No sources of support provided, Other

  No sources of support provided

External sources

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  ISAC provided a grant of USD 21,107 to Apunipima Cape York Health Services to produce the Cochrane protocol and a review of family-centred interventions for Indigenous early childhood health. Apunipima contracted James Cook University researchers to complete the protocol and a review.
- Poche Centre for Indigenous Health at the University of Western Australia, Australia

  Provided funds for evidence synthesis activities to support the completion of the review.
- Catherine Chamberlain, Australia

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- Roxanne Bainbridge, Australia

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- Janya McCalman, Australia

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Types of participants

If the population had both Indigenous and non-Indigenous children, we included studies that had more than 50% Indigenous children. If studies included children aged five years or older, we included studies that had more than 50% of children aged less than five years old or where the mean of the children's age was five years or less.

All studies were required to be implemented or led from primary healthcare services. In the USA, child wellness promotion and healthcare services delivered in rural reservations are often run in collaboration with Indian Health services or tribal health services, and early childhood centres. As a result, we decided to include trials from rural reservations in the USA where primary healthcare services were not the sole source of implementing or leading the family-centred care but did so in collaboration with other services.

Types of outcome measures

Primary outcome

We included an additional primary outcome named 'overall health and well-being'. Although we built in specific outcomes, we did not consider a broader outcome that could answer the aim of whether family-centred care interventions were effective in improving the health and well-being of Indigenous children and their families. We developed this outcome based on the guidance provided in Chapter 3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (McKenzie 2021). To determine which outcomes would be included we used a stepwise approach. The first step was the inclusion of a study outcome by order of priority of the second to fifth primary outcomes as listed under Primary outcomes. The outcomes were included if they were measured using administrative data followed by a validated question and where neither were available, a subjective outcome. The longest time point was used in the analysis and if data were not available, then the next longest data point until a primary outcome was chosen for each study.

Selection of outcomes reported

As anticipated, there was more than one outcome assigned to each outcome category. Review authors JM, RB, SC, LS, and CC were provided with a spreadsheet of all outcomes with each outcome assigned to its respective outcome category and no results. Led by review author NS, each outcome was determined by the group for inclusion into the review. Outcomes were included based on objective versus subjective measures, their overall relevance to family centred-care interventions and from a strengths-based rather than deficit perspective. After outcomes were determined for inclusion, they were cross-checked within each category to determine if there were any outcomes that were similar across studies. The final outcomes included from each paper in each category were based on decision rules by the review team or the most frequently reported outcome, or both.

Timing of outcome assessment

We grouped timing of assessment into short-, medium-, and long-term time points with no more than one time interval for each outcome from each study selected. If there were multiple time points in each time point period, we chose the time point that was closest to the end of the time interval. For example, for medium-term outcomes from greater than three to 12 months when trials gave outcomes at six and 12 months, we used the 12-month time point. This was determined by the review team before any results were seen.

Main outcomes for summary of findings table

We decided to include all primary outcomes in the summary of findings table. This included the addition of the overall health and well-being and the physical health and developmental health of Indigenous children outcomes.

Measures of treatment effect

When analysing continuous data, we multiplied data by −1 for scales that were in the opposite direction. For outcomes that had both continuous and dichotomous data, we combined both outcomes in the meta-analysis and calculated the standardised mean difference (SMD) and 95% confidence interval (CI) using the general inverse variance method (Deeks 2021). For count data, we considered the outcomes to be common and, therefore, calculated these data as continuous (i.e. means and standard deviations). We then converted these data into SMDs using methods outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021b). We included the longest time point for each outcome in the analysis.

Dealing with missing data

For missing data, we used the methods outlined in Chapter 6 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021b). We used these methods to determine standard deviations for continuous data. For cluster-RCTs, we converted the individual means and standard deviations to SMDs using the methods outlined in Chapter 23 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2021c; White 2005).

Sensitivity analysis

Where available, we included an additional sensitivity analysis by excluding outcomes that were subjective and not from validated questionnaires or tools, or were not administrative data (i.e. hospital records).

NOTES

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

INDEX TERMS

Medical Subject Headings (MeSH)

*Child Rearing; Health Services; *Parenting; Parents; Primary Health Care

MeSH check words

Child; Child, Preschool; Humans