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[1]School of Health Sciences, University of Dundee, Dundee, UK
[2]School of Nursing and Midwifery, Queen's University Belfast, Belfast, UK
[3]Breastfeeding Network, UK
[4]Department of Nursing and Midwifery, University of Huddersfield, Huddersfield, UK
[5]School of Health, Wellbeing and Social Care, The Open University, Milton Keynes, UK
[6]Population, Policy and Practice, Great Ormond Street Institute of Child Health, London, UK
[7]Department of Psychology, University of Limerick, Castletroy, Ireland

[*]Corresponding author

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Abstract

Lessons for the UK on implementation and evaluation of breastfeeding support: evidence syntheses and stakeholder engagement

Anna Gavine,[1*] Albert Farre,[1] Fiona Lynn,[2] Shona Shinwell,[1] Phyllis Buchanan,[3] Joyce Marshall,[4] Sara Cumming,[1] Louise Wallace,[5] Angie Wade,[6] Elayne Ahern,[7] Laura Hay,[1] Marianne Cranwell[1] and Alison McFadden[1]

[1]School of Health Sciences, University of Dundee, Dundee, UK
[2]School of Nursing and Midwifery, Queen's University Belfast, Belfast, UK
[3]Breastfeeding Network, UK
[4]Department of Nursing and Midwifery, University of Huddersfield, Huddersfield, UK
[5]School of Health, Wellbeing and Social Care, The Open University, Milton Keynes, UK
[6]Population, Policy and Practice, Great Ormond Street Institute of Child Health, London, UK
[7]Department of Psychology, University of Limerick, Castletroy, Ireland

[*]Corresponding author a.gavine@dundee.ac.uk

Background: Breastfeeding impacts positively on multiple health outcomes, but < 50% of UK women breastfeed at 8 weeks. Women with long-term conditions face additional challenges in breastfeeding.

Objectives: To synthesise global and UK evidence to co-create an implementation and evaluation toolkit for cost-effective breastfeeding support in the NHS.

Design: Evidence syntheses with stakeholder engagement.

Review methods: Systematic reviews examined effectiveness of breastfeeding support for (1) healthy women and (2) women with long-term conditions using Cochrane Pregnancy and Childbirth Group methods. Mixed-methods systematic reviews synthesised process evaluations of effective breastfeeding support interventions for healthy women and experiences of receiving/providing support for breastfeeding women with long-term conditions. Cross-study synthesis integrated qualitative and quantitative findings. Systematic reviews synthesised evidence on the incremental costs and cost-effectiveness of breastfeeding support following National Institute for Health and Care Excellence guidance. All searches were conducted from May 2021 to October 2022. Stakeholder engagement and toolkit development comprised online discussions, a modified Delphi study, focus groups and four workshops. Participants were 23 stakeholders, 16 parents in the parents' panels, 15 women in the focus groups and 87 stakeholders who attended the workshops.

Results: We found considerably more interventions designed for healthy women (review 1) than aimed at women with long-term conditions (reviews 1 and 4); approximately half of the studies were targeted at groups at higher risk of poor breastfeeding outcomes, and the impact of support may be different in these populations. Despite this, studies from review 2 found that women perceived the provision of support as positive, important and needed. Studies from review 5 echoed a range of suggestions from participants regarding potential strategies to improve breastfeeding support, with the most widely reported being the need to acknowledge the role and influence of other sources of support (e.g. partners, family, friends, peers, external professionals, web-based resources) and involving these sources

in the provision of breastfeeding support for women with long-term conditions. In reviews 3 and 6, there was uncertainty about the cost-effectiveness of breastfeeding support interventions due to the limited number of studies and lack of good-quality evidence.

Limitations: There was a lack of evidence for the effectiveness and cost-effectiveness of breastfeeding interventions in the UK. There was often insufficient information reported about intervention characteristics.

Conclusions: 'Breastfeeding only' support probably reduces the number of women stopping any or exclusive breastfeeding. The evidence for 'breastfeeding plus' interventions is less consistent, but these may reduce the number of women stopping exclusive breastfeeding at 4–6 weeks and at 6 months. We found no evidence of differential intervention effects regarding mode of provision or provider. Cost-effectiveness is uncertain due to the lack of good-quality evidence. Key enablers of successful implementation were responsiveness and tailoring of interventions to both women's and supporters' needs. Breastfeeding support as delivered in the included studies probably has little to no effect on breastfeeding outcomes for women with long-term conditions. The mixed-methods synthesis and stakeholder work identified that existing interventions may not address the complex needs of these women. The main study output is a co-produced toolkit to guide implementation and evaluation of breastfeeding support services in the UK.

Future work: Evaluation of breastfeeding support for all women, particularly those at risk of poor breastfeeding outcomes (e.g. long-term conditions, deprivation). This could involve tailoring the toolkit to local contexts via implementation and effectiveness studies or using quality improvement studies.

Study registration: This study is registered as PROSPERO CRD42022337239, CRD42021229769 and CRD42022374509. The reviews of economic evidence were not registered; however, the review protocol can be accessed via the repository held by Queen's University Belfast Research Portal (https://pure.qub.ac.uk/).

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Report Supplementary Material 1 Ranked strategies and number of times selected

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/DGTP5702).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

aOR	adjusted odds ratio
BFHI	baby-friendly hospital initiative
BMI	body mass index
CFIR	Consolidated Framework for Implementation Research
CI	confidence interval
DCE	discrete choice experiment
GBP	Great British pounds
GDM	gestational diabetes mellitus
GP	general practitioner
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HIC	high-income country
HIV	human immunodeficiency virus
ICER	incremental cost-effectiveness ratio
LMIC	low- and middle-income country
LTC	long-term condition
MLTC	multiple long-term conditions
NHS EED	NHS Economic Evaluation Database
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OECD	Organisation for Economic Cooperation and Development
OR	odds ratio
PPI	patient and public involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QALY	quality-adjusted life-year
RCT	randomised controlled trial
RR	relative risk
WHO	World Health Organization
WTP	willingness-to-pay

Plain language summary

What was the question?

We know that breastfeeding is good for the health of mothers and babies, yet many mothers experience difficulties and stop breastfeeding before they want to. This is noticeable among women living in disadvantaged areas where there are low rates of breastfeeding. Good support may help women overcome difficulties so that they can continue to breastfeed. Women with chronic illnesses such as diabetes and depression face additional challenges in breastfeeding. We wanted to understand how to improve breastfeeding support for UK women.

What did we do?

We brought together previous scientific studies to learn about what works. We also spoke with parents and service providers. We combined all our findings into a toolkit to help the NHS improve breastfeeding support for women.

What did we find?

We found that, for healthy women, some forms of breastfeeding support can probably help reduce the number of women stopping breastfeeding and help them breastfeed exclusively. For women with chronic illnesses, we found that the types of support used in the studies probably did not help women to breastfeed. Most of the evidence did not come from the UK. We identified barriers to providing breastfeeding support for all women, especially those who are disadvantaged. We identified strategies that could help the NHS overcome these barriers. There was a lack of evidence on how cost-effective these interventions are compared with usual care, but parents and providers saw the value of paying for breastfeeding support.

What does this mean?

Giving women targeted breastfeeding support will help them to breastfeed; however, we need to test if this support works in the NHS. We also need to develop additional services for women with chronic illnesses. The NHS could use our findings to improve support for all breastfeeding women by identifying specific barriers and using evidence-based strategies to overcome them.

Scientific summary

Background

Breastfeeding impacts positively on multiple health outcomes across the lifespan. Global and UK infant recommendations are that infants should receive breastmilk exclusively for 6 months and as part of a mixed diet until 2 years. However, fewer than half of UK women are breastfeeding at 6–8 weeks, with a marked social gradient.

Objectives

This study aimed to synthesise global and UK evidence in order to co-create with stakeholders a framework to guide the implementation and evaluation of cost-effective breastfeeding support interventions in the NHS:

1. Update the Cochrane review 'Support for healthy breastfeeding mothers with healthy term babies' (McFadden A, Gavine A, Renfrew MJ, Wade A, Buchanan P, Taylor JL, *et al.* Support for healthy breastfeeding mothers with healthy term babies. *Cochrane Database Syst Rev* 2017;**2**:CD001141).
2. Synthesise process evaluations of breastfeeding support interventions.
3. Conduct an economic evaluation of interventions to enable women to breastfeed.
4. Conduct a systematic review of breastfeeding support interventions for women with long-term conditions (LTCs).
5. Synthesise evidence of barriers to and facilitators of breastfeeding support for women with LTCs.
6. Conduct a systematic review of economic evaluations of breastfeeding support interventions.
7. Co-create a NHS-tailored implementation and evaluation strategy framework to increase breastfeeding rates in the UK.
8. Contribute to methodological development on involving stakeholders in systematic reviews.

Design

The study comprised two meta-analyses of breastfeeding support interventions, two mixed-methods evidence syntheses and two economic evaluations with embedded stakeholder engagement, including parents' panels, stakeholder working groups, focus groups and workshops. Stakeholders interpreted and adapted the international evidence to ensure its relevance to UK settings and co-produced the toolkit.

Review methods

Review 1: update of Cochrane review 'Support for healthy breastfeeding mothers with healthy term babies'

The Cochrane Pregnancy and Childbirth Group's Trials Register was searched in May 2021. Healthy women and babies were those who did not require additional medical care. Interventions could be delivered as standalone breastfeeding support interventions ('breastfeeding only') or as part of a wider maternal and newborn health intervention ('breastfeeding plus') where additional services (e.g. vaccination, intrapartum care) are provided. Primary outcomes were stopping any or exclusive breastfeeding at 6 months and 4–6 weeks postpartum. We used standard Cochrane methods for data extraction, risk-of-bias assessment and statistical analysis. We used meta-regression to investigate statistical heterogeneity.

Review 2: mixed-methods review of process evaluations linked to effective breastfeeding support interventions

Six electronic databases were searched in March 2022. Eligible studies reported the views and experiences of delivering or receiving effective breastfeeding support interventions. Qualitative and quantitative findings were synthesised separately and then integrated into a theoretically informed cross-study synthesis.

Review 3: economic evaluation review

This review, with searches conducted in February 2021, considered value for money by appraising and synthesising the evidence of incremental costs and cost-effectiveness in comparison with a control. The eligibility criteria were the same as those of review 1, with the addition of relevant economic outcomes such as incremental cost-effectiveness ratios (ICERs). Quality assessment followed National Institute for Health and Care Excellence (NICE) guidance. Consistency between studies in evidence of cost-effectiveness was reviewed.

Review 4: effectiveness of breastfeeding support for women with long-term conditions

Searches were conducted in August 2022. Included studies involved women with a long-term physical or mental health condition. Primary outcomes were stopping any or exclusive breastfeeding at 4–8 weeks and 6 months. We used standard Cochrane methods for data extraction, risk-of-bias assessment and statistical analysis.

Review 5: mixed-methods review of experiences of breastfeeding support for women with long-term conditions

Searches were conducted in October 2022. Included studies reported primary research on the views and experiences of breastfeeding women with LTCs and/or support providers. Qualitative and quantitative findings were synthesised separately and then integrated into a theoretically informed cross-study synthesis.

Review 6: review of economic evidence for breastfeeding support for women with long-term conditions

The search strategy for review 3 was used for this review, with modification of the inclusion criteria for women with LTCs. Searches were conducted in August 2022. Quality assessment followed the NICE guidance.

Stakeholder engagement

Stakeholder engagement and toolkit development comprised online discussions, a modified Delphi study, face-to-face focus groups and four workshops. Participants were 23 stakeholders (health service providers and representatives of third-sector organisations), 16 parents in the parents' panels and 15 women from a deprived and diverse locality in the focus group discussions.

Results

We found considerably more interventions designed for healthy women (review 1) than aimed at women with LTCs (review 2). 'Breastfeeding only' interventions probably have a small effect in reducing the number of healthy women stopping breastfeeding. However, 'breastfeeding plus' and interventions for women with LTCs probably have little or no effect on breastfeeding outcomes. In both reviews, approximately half of the studies were targeted at groups at higher risk of poor breastfeeding outcomes, and it is possible that the impact of support is different in these populations. Despite this, studies from review 2 found that women perceived the provision of support as positive, important and needed. Studies from review 5 echoed participants' suggestions of potential strategies to improve breastfeeding support, the most widely reported being the need to involve wider sources of support (e.g. partners, family, friends, peers, external professionals, web-based resources) in supporting women with LTCs to

breastfeed. In reviews 3 and 6, there was uncertainty in the cost-effectiveness of breastfeeding support interventions due to the limited number of studies and lack of good-quality evidence.

More specific findings from each review are presented below.

Review 1

This updated review includes 125 interventions reported in 116 trials with more than 98,816 mother–infant pairs. Ninety-one interventions were 'breastfeeding only' and 34 were 'breastfeeding plus'.

The overall risk of bias of trials included in the review was mixed. Blinding of participants and personnel is not feasible in such interventions, and, as studies used self-report breastfeeding data, there is also a risk of bias in outcome assessment.

Moderate-certainty evidence indicated that 'breastfeeding only' support probably reduced the number of women stopping breastfeeding for all primary outcomes: stopping any breastfeeding at 6 months [relative risk (RR) 0.93, 95% confidence interval (CI) 0.89 to 0.97]; stopping exclusive breastfeeding at 6 months (RR 0.90, 95% CI 0.88 to 0.93); stopping any breastfeeding at 4–6 weeks (RR 0.88, 95% CI 0.79 to 0.97); and stopping exclusive breastfeeding at 4–6 weeks (RR 0.83, 95% CI 0.76 to 0.90).

The evidence for 'breastfeeding plus' was less consistent. Interventions may have a beneficial effect on reducing the number of women stopping exclusive breastfeeding at 4–6 weeks (RR 0.73, 95% CI 0.57 to 0.95, *very uncertain evidence*) and 6 months (RR 0.79, 95% CI 0.70 to 0.90, *moderate-certainty evidence*). However, 'breastfeeding plus' support probably results in little to no difference in other breastfeeding outcomes.

We conducted meta-regression to explore substantial heterogeneity for the primary outcomes. Minimal differential effects were found except for a schedule of four to eight visits possibly associated with more beneficial effects. There was a lack of evidence for UK effective interventions.

Review 2

We included 16 studies linked to 10 effective interventions. The quality of the included studies was mixed, but all studies' findings were judged to be at least fairly well supported by data. The synthesis identified 18 factors affecting implementation of interventions and data-driven analytical themes. Mapping to the Consolidated Framework for Implementation Research resulted in three overarching themes: (1) assessing the needs of those delivering and receiving breastfeeding support interventions, (2) assessing the context and optimising delivery and engagement with breastfeeding support interventions and (3) reflecting and evaluating the success of implementing and providing breastfeeding support. Included studies identified implementation challenges relating to the needs, preferences and priorities of intervention providers and recipients. Overall, breastfeeding women perceived support as positive, important and needed. Breastfeeding supporter training enabled implementation teams to address breastfeeding supporters' needs. Studies reported contextual factors (e.g. alignment with local policies) affecting the implementation and delivery of breastfeeding support interventions as well as tailoring strategies (e.g. community involvement, use of lay language, responsive support content/information) to address contextual factors. Reports about implementation success focused on key implementation outcomes such as satisfaction, fidelity or usefulness.

Review 3

We included 39 economic evaluations, nine of which were deemed directly or partially applicable to the UK system. For 'breastfeeding only' support, evidence from one study suggested that the intervention was unlikely to be cost-effective [£56,074.98 per quality-adjusted life-year gained at 2022 Great British pounds (GBP) prices]. There was evidence for the incremental cost per additional woman breastfeeding (any or exclusive), with ICERs ranging from £67 to £112 from 2 weeks up to 8 weeks postpartum, and from £2446 to £4226 up to 6 months postpartum. Without willingness-to-pay thresholds, value for

money is unclear. Evidence for 'breastfeeding plus' support suggests that this is not cost-effective; however, there was a lack of good-quality evaluations, with inconsistency in results. Where evidence of sensitivity analysis was reported for handling uncertainty, ICERs were upheld. Scenario analyses from the base case did show changes in costing the intervention, which suggested that costs were sensitive. Eight studies were deemed to have potentially very serious limitations due to short time horizons and a lack of extrapolation beyond within-trial data. These limitations affect conclusions about cost-effectiveness.

Review 4

Twenty-two studies of 23 interventions were included. The meta-analyses included 5048 mother–infant pairs. The most common condition, in nine studies, was overweight and obesity. A further three studies were of women with gestational diabetes mellitus. Five studies included women with human immunodeficiency virus (HIV). Two studies were of women with substance misuse problems, and one was of women with anxiety and depression. Interventions varied in whether they provided breastfeeding support only or if they also provided support for the LTC.

The overall risk of bias of trials was generally high. Blinding of participants and personnel is not feasible in such interventions. About half of the studies were rated as being at high or unclear risk of allocation concealment and incomplete outcome data. All studies were rated as being at high or unclear risk of selective outcome reporting.

There was little to no difference between intervention and control for any of the primary outcomes. We judged these outcomes to be of low and moderate certainty.

Review 5

We included 24 studies. The health conditions covered were HIV, obesity and overweight, substance use, diabetes in pregnancy, disabilities and a rare genetic disorder. The overall quality of included studies was mixed. Four key themes were identified: (1) additional breastfeeding support needs for women with LTCs; (2) variable or insufficient availability of breastfeeding support for mothers with LTCs; (3) experiences of breastfeeding support of mothers with LTCs suggesting complex breastfeeding journeys; and (4) suggestions from participants of potential strategies to improve breastfeeding support.

Review 6

We included five economic evaluations. The conditions assessed were HIV, obesity, prenatal opioid use and medically high risk (maternal hypertension and diabetes prior to birth). Each intervention assessed in full economic evaluations was deemed cost-effective for the base case. However, each study failed to meet one or more applicability criteria, which is likely to change the conclusions about cost-effectiveness.

Embedded stakeholder engagement and patient and public involvement

Two stakeholder working groups with 23 members and two parents' panels with 16 members met virtually several times throughout. The main study stakeholder group and parents' panel discussed the realities of breastfeeding, ranked intervention transferability criteria, highlighted barriers to accessing and providing breastfeeding support and prioritised implementation strategies to overcome barriers. Six focus group discussions involving 23 participants from an area of high socioeconomic disadvantage represented the perspectives of communities who are less likely to breastfeed. The other stakeholder working group and parents' panel provided first-hand accounts of breastfeeding, and of providing breastfeeding support for women with multimorbidities. They discussed adapting interventions identified in the main study to meet the needs of women with LTCs. The views and suggestions of all stakeholders and parents guided all stages of the project and directly influenced the co-production workshops.

Four workshops across the UK were attended by 87 participants representing parents and third-sector organisations, healthcare practitioners, service managers and commissioners, policy-makers and

academics. The workshop output was a toolkit for implementing breastfeeding support interventions in the UK. The toolkit comprises evidence-based recommendations for breastfeeding support services, prioritised criteria for adapting the evidence-based recommendations to local services, and guidance on implementing new breastfeeding support services, planning the implementation strategy and evaluating the breastfeeding support services. A discrete choice experiment showed that participants valued additional breastfeeding support and were willing to pay £89.91 per woman to achieve a 1% reduction in the number of women stopping any breastfeeding at 6 weeks, and £105.04 for a 1% reduction in stopping exclusive breastfeeding.

Conclusions

'Breastfeeding only' support can increase the duration and exclusivity of breastfeeding in healthy women. For 'breastfeeding plus' and interventions for women with LTCs the evidence is less certain and there is probably little effect on breastfeeding outcomes. As the mixed-methods synthesis and stakeholder work identified that women with LTCs face additional challenges when breastfeeding, more research is needed to develop effective and cost-effective support. Evidence for the effectiveness and cost-effectiveness of breastfeeding support interventions in the UK is lacking.

Implications for health care

Decision-makers and frontline practitioners can use the toolkit to inform implementation efforts, to overcome barriers specific to their settings and to tailor evidence-based interventions to their populations. Key to success will be addressing health system barriers and enhancing the skills, knowledge and confidence of practitioners. Regarding women with LTCs, stakeholder engagement suggested health services could integrate infant-feeding specialists with the multidisciplinary team to give infant feeding a higher profile in obstetric and medical care.

Recommendations for research (numbered in priority order):

1. Development and evaluation of breastfeeding support interventions for women with LTCs and multimorbidities, particularly mental health conditions, overweight/obesity and gestational diabetes.
2. Focus on understanding the components of breastfeeding support interventions that make them effective, including which components would be more effective in populations at risk of poorer breastfeeding outcomes (e.g. areas of high socioeconomic deprivation), and understanding why 'breastfeeding plus' interventions are less effective.
3. Implementing and evaluating effective breastfeeding support in the UK for all women. This could evaluate the prototype intervention proposed in this report tailored to local contexts via implementation and effectiveness and cost-effectiveness studies or using quality improvement methodology.

Study registration

This study is registered as PROSPERO CRD42022337239, CRD42021229769 and CRD42022374509. The reviews of economic evidence were not registered; however, the review protocol can be accessed via the repository held by Queen's University Belfast Research Portal (https://pure.qub.ac.uk/).

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Chapter 1 Background

Importance of breastfeeding

Breastfeeding has a significantly positive impact on multiple health outcomes across the lifespan. For children, this includes fewer deaths and hospital admissions for infectious diseases[1–4] and reduced incidence of obesity, diabetes mellitus and dental disease.[5–7] Breastfeeding has been linked to improved educational and behavioural outcomes.[8–10] For women, breastfeeding is associated with a lower risk of cardiovascular disease, breast and ovarian cancer and diabetes mellitus.[11–13] The impact of breastfeeding on health outcomes applies across settings and population groups, including in high-income countries (HICs) such as the UK. Globally, the scaling up of breastfeeding to near-universal level could prevent 823,000 deaths of children under 5 years old and 20,000 annual deaths of women from breast cancer.[14] To optimise population health, global and UK infant recommendations are that infants should be breastfed (or receive breastmilk) exclusively for about 6 months and that this should continue as part of a mixed diet until 2 years or beyond.[15,16]

Increased breastfeeding has the potential to reduce healthcare costs.[17,18] In addition to the important effects on health for women and children, breastfeeding has wider health system and societal impacts, including cost savings for the NHS and environmental benefits. The cost to the global economy of not breastfeeding has been estimated at £242B, and, in the UK, estimates are that £23.6M in additional treatment costs could be saved each year by increased breastfeeding.[17] A further cost to the NHS is the increasing number of prescriptions for specialist formula to treat cow's milk protein allergy.[19] The environmental impact of not breastfeeding (i.e. feeding with infant formula) is significant, for example from plastics and resources used by the dairy industry.[20,21] Therefore, significant health, societal and environmental gains are to be had from increasing breastfeeding duration and exclusivity.

UK breastfeeding patterns

The UK has low breastfeeding rates. Following the cessation of the quinquennial UK-wide Infant Feeding Surveys, comprehensive, robust data on breastfeeding rates are lacking. For England, the most recent data (2020/21 data), reported by NHS trusts, showed a 72% initiation rate and 49% prevalence of breastfeeding at 6–8 weeks.[22] The comparative figures were 60% initiation and 45% prevalence at 6–8 weeks for Wales (2016 data)[23] and 65% initiation and 43% prevalence at 6–8 weeks for Scotland (2018/19 data).[24] In Northern Ireland (2020 data), the initiation rate was 62% and prevalence at 6 weeks was 40%.[25] Rates of exclusive breastfeeding are much lower in all four countries. Throughout the UK, there is a marked social gradient in breastfeeding rates whereby women from socioeconomically deprived groups, those with lower education levels and adolescent women are least likely to breastfeed.[26] For example, in Scotland (2018/19 data),[24] breastfeeding prevalence at 6–8 weeks was 62% in the wealthiest quintile compared with 28% in the most deprived quintile. The differences were starker by mother's age, with breastfeeding prevalence at 6–8 weeks of 58% among mothers aged 40 years and 13% among mothers aged under 20 years.[24] In the UK, women from non-white ethnic groups had higher rates of breastfeeding initiation, prevalence and duration than white women; rates of exclusive breastfeeding after 1 week were similar.[26] Women and babies from the most deprived backgrounds and younger mothers have most to gain from the health benefits conferred by breastfeeding. It has also been reported that around 80% of women in the UK stop breastfeeding before they intended, causing distress[26] and potentially leading to poorer mental health.[27,28]

Comparing breastfeeding rates between the four countries of the UK, and with countries internationally, is fraught with difficulty, as data are collected in different ways, at different time points and for different years. Nevertheless, rates of breastfeeding in the UK are consistently reported to be lower

than those in other European countries. For example, in 2015, a survey of European countries found that breastfeeding initiation rates ranged from 80% in the Netherlands to 98% in Norway and that breastfeeding prevalence at 2 months ranged from 64% in the Netherlands to 89% in Norway (both outcomes were reported by 6 of 11 countries).[29] The exception is Ireland, which has similar rates to the UK with a breastfeeding initiation rate of 64%[30] and breastfeeding prevalence at 3 months of 35%.[29]

Breastfeeding support

In the UK, formal breastfeeding support, comprising practical, informational, emotional and social support may be provided by healthcare practitioners, voluntary organisations and peer supporters. Women may also receive informal breastfeeding support from families and friends. However, many women report feeling unsupported by healthcare providers and their social networks, especially in the early weeks following birth.[31] This was exacerbated by the impact of COVID-19 on breastfeeding support services, which were already being reduced.[32,33]

There is evidence that women living in deprived areas face multiple barriers to breastfeeding and accessing appropriate breastfeeding support. Common barriers include pain, the perception that they do not produce sufficient milk to meet their baby's needs,[34] embarrassment about breastfeeding in public and negative societal attitudes to breastfeeding.[34,35] While these barriers affect all women, they can be particularly challenging in settings where family and friends lack knowledge and experience of breastfeeding.[35] Women from disadvantaged backgrounds may value particularly the experiential knowledge and skills adapted to local contexts provided by peer support.[36] However, survey data suggested that coverage of breastfeeding peer support across the UK was variable and not accessed by socially disadvantaged women.[33] Additional barriers for women from minority ethnic groups, for example Bangladeshi women, include diverse cultural influences of their heritage and their areas of residence in the UK[37] and cultural stereotypes held by healthcare providers.[38] There is strong global evidence that, for healthy women and babies, breastfeeding support is effective at increasing partial and exclusive breastfeeding.[39–42] However, these reviews combine evidence from high-, middle- and low-income countries, with most of the HIC evidence coming from the USA. Interventions tested in trials are heterogeneous and generally undertheorised. The extent to which global evidence is transferable to the UK setting is unclear. Previous evidence from UK-based trials is limited and has not demonstrated efficacy of interventions.[43–45] Feasibility studies in the UK show that peer support interventions are acceptable[46,47] but effectiveness has not been established.

Women with multimorbidities

The prevalence of maternal chronic conditions is rising,[48] which is in part due to increasing maternal age and the improved management of long-term conditions (LTCs).[49] For instance, UK data show that 2.3% of women have been diagnosed with diabetes either prior to or during pregnancy,[50] 0.5% have a diagnosis of inflammatory bowel disease,[51] 0.5–1.0% have a diagnosis of epilepsy,[52] 18.4% have a postnatal diagnosis of anxiety[53] and 11.4% have a postnatal diagnosis of depression.[53] Moreover, the rates of gestational diabetes in pregnant women in the UK range from 1.2% to 24.2% depending on maternal characteristics and diagnostic method,[54] and this increases the risk of developing type 2 diabetes 10-fold.[55]

The prevalence of multiple long-term conditions (MLTC) in the UK is also rising, particularly among working-age adults.[56] Within a general adult population, the onset of MLTC happens 10–15 years earlier in those living in the most deprived areas than in those living in more affluent areas.[57] The MuM-PreDiCT study sought to identify the prevalence of multimorbidities specifically during pregnancy and reported that between 19.8% and 46.2% of pregnant women experience two or more LTCs.[58] LTCs were defined as conditions that had a significant impact on patients, and the specific 79 conditions

included in the study were determined in consultation with stakeholders.[59] Unlike in the general adult population, it is not currently clear if the prevalence of MLTC is higher among women from areas of high socioeconomic deprivation. The MuM-PreDiCT study did not find higher odds of multimorbidities in women from areas of high socioeconomic deprivation or in any specific ethnic group.[58] Post hoc analysis explored whether this was being impacted by the health conditions used to define multimorbidity, as some conditions, such as irritable bowel syndrome, anxiety and polycystic ovarian syndrome, were higher in more affluent areas.[58] When a shortened list of conditions was used, socioeconomic deprivation was associated with multimorbidities after adjusting for maternal age and gravidity [adjusted odds ratio (aOR) 1.30, 95% confidence interval (CI) 1.08 to 1.57].[58] However, this was no longer significant once body mass index (BMI) and smoking status were also adjusted for (aOR 1.05, 95% CI 0.87 to 1.27). MLTC were more common in mothers aged 45–49 years (aOR 1.8, 95% CI 1.0 to 3.20), and this remained significant when adjusted for other characteristics.

Living with MLTC can have a significant impact on mental well-being and can make engaging in other activities difficult.[60] Within the context of maternal health, experiencing a LTC during pregnancy is associated with mental health conditions in the postpartum period such as post-traumatic stress.[61] Mothers with LTCs are also more likely to experience other adverse determinants of health, such as intimate partner violence, smoking, living in poverty and a lack of educational qualifications.[62]

There is some evidence for the management of single conditions during pregnancy and the postnatal period, for example diabetes,[63] epilepsy,[64] and depression,[65] that is focused on the treatment modalities for that single condition. However, there is a complete lack of evidence on MLTC in mothers. Postnatal care, in particular, has been universally described as poor due to a lack of follow-up care and help for women to care for their babies.[66] Breastfeeding could present a challenge to women with MLTC, as is evidenced by significantly lower breastfeeding rates among women with single LTCs.[62,67] For instance, a study comparing UK women with lifelong limiting conditions found that breastfeeding rates at 3 months were lower in this group than among women without any conditions (25.6% vs. 33.4%);[62] however, rates of initiation were similar. Data from Canada showed that although women with chronic diseases had similar odds of initiating breastfeeding, they were more likely to cease breastfeeding early than women in the general population (aOR 2.48, 95% CI 1.49 to 4.12).[68] Data from other countries also suggest that breastfeeding rates are lower among women with a range of specific conditions such as insulin-dependent diabetes (aOR 0.49, 95% CI 0.27 to 0.89), epilepsy (aOR 0.42, 95% CI 0.26 to 0.68)[69] and rheumatoid arthritis (any breastfeeding at 3 months in women with rheumatoid arthritis = 26% vs. 46% of general population). There is currently a complete lack of evidence on breastfeeding rates in women with MLTC.[70]

There are several reasons why women with LTCs may have additional difficulties breastfeeding, including a physiological delay in milk release to 72 hours after birth, an increased risk of early separation from the infant as a result of caesarean section and/or requirement for the infant to be placed in neonatal intensive care unit facilities, fatigue, and poor and inconsistent advice about the safety of medications.[68] Anecdotal evidence from the Breastfeeding Network has also identified a lack of joined-up care as a barrier to breastfeeding. As breastfeeding can confer significant health benefits to both mother and infant,[14] there is a need for breastfeeding support interventions to provide effective support to all women that is tailored to their individual needs.[71]

Economic impact

Breastfeeding in itself is considered a cost-effective intervention.[17,72] Increased breastfeeding has the potential to reduce healthcare costs.[17,18] In addition to the important effects on the health of women and children, breastfeeding has wider health system and societal impacts, including cost savings for the NHS and environmental benefits. The cost to the global economy of not breastfeeding has been estimated at US$570B (£396B) each year, with estimates indicating that 0.75% of gross national income in HICs

is lost from not breastfeeding.[73] With a UK gross national income of £2505B in 2022,[74] this equates to a value to the UK economy of £18.8B. For the UK health system, estimates are that £23.6M of additional treatment costs each year could be saved by increased breastfeeding.[17] This cost to the NHS is considered a conservative estimate, as a limited number of maternal and child-related illnesses were included in the analysis. A further cost to the NHS is the increasing number of prescriptions for specialist formula to treat cow's milk protein allergy.[19] For example, an 800 g tin of specialised formula (Aptamil Pepti® 1 powder, Nutricia, Trowbridge, UK) prescribed for cow's milk allergy, which would feed a baby under 6 months old for 1 week, costs the NHS £19.72 at 2023 prices.[75] The environmental impact of not breastfeeding (i.e. feeding with infant formula) is significant. For example, plastics and resources used by the dairy industry have a cost in carbon dioxide emissions equivalent to 50,000–77,500 cars on the road each year and a water footprint of 4700 l/kg.[20,21] Therefore, significant health, societal and environmental gains are to be had from increasing breastfeeding duration and exclusivity. In choosing a breastfeeding support intervention to implement into a health system, policy-makers need to understand not only the evidence of effect and contextual factors that should be considered but also the evidence of cost-effectiveness. With pressure on NHS resources, service managers need to ensure that any investment yields a positive return both in the short term, with increased breastfeeding, and in the long term, with reduced health service resource use and subsequent cost savings.

Why this research is needed

There is a need to find out what works to support women in the UK to meet their infant-feeding goals, to breastfeed for longer, and to increase rates of exclusive breastfeeding. This involves understanding the characteristics and components of breastfeeding support interventions that are likely to be effective and cost-effective in the UK, as well as how to implement and evaluate such interventions. This is particularly the case for populations where breastfeeding rates are low, including young mothers, women of low socioeconomic status, those from marginalised groups, and those with multimorbidities. Although this has been a policy aspiration in the UK for several decades, there is a gap in evidence regarding effective interventions. At a time when the NHS is struggling to meet demand, and life expectancy is stalling, cost-effective public health interventions targeted to disadvantaged communities are vital.

Chapter 2 Research design including stakeholder engagement

Aim and objectives

The aim was to synthesise global and UK evidence to co-create with stakeholders a framework to guide the implementation and evaluation of cost-effective breastfeeding support interventions in the NHS.

Objectives

1. Update the Cochrane review 'Support for healthy breastfeeding mothers with healthy term babies'[41] to identify effective breastfeeding support interventions (see *Chapter 3*).
2. Conduct a theoretically informed mixed-methods synthesis of process evaluations of UK-relevant breastfeeding support interventions (see *Chapter 4*).
3. Conduct an economic evaluation of interventions to enable women to breastfeed (see *Chapter 5*).
4. Conduct a systematic review to identify effective interventions that provide breastfeeding support for women with LTCs (see *Chapter 6*).
5. Conduct a mixed-methods synthesis of barriers to and facilitators of breastfeeding support in women with LTCs (see *Chapter 7*).
6. Conduct a systematic review of economic evaluations of breastfeeding support interventions for women with single LTCs (see *Chapter 8*).
7. Co-create a NHS-tailored implementation and evaluation strategy framework to address contextual barriers and inform transferability of cost-effective interventions to increase breastfeeding rates among healthy women and those with LTCs in the UK (see *Chapter 9*).
8. Contribute to methodological development of involving stakeholders in co-creation of systematic reviews and synthesising process evaluations to support the transferability and applicability of global evidence to local health service contexts (see *Chapter 10*).

Objectives 1–3, 7 and 8 were in the original proposal (referred to throughout this report as the main study). Objectives 4–6 were added when additional funding was awarded to address the needs of women with multimorbidities. The focus of objectives 4–6 is on single LTCs because of the lack of evidence relevant to multimorbidities. The primary focus of our work was support for healthy women to breastfeed, addressing inequities in health outcomes. This included women from diverse ethnic and socioeconomic groups. The work on MLTC was an add-on. However, we were also interested in multimorbidities as a contributing factor to health inequities. Objective 7 was modified from the original proposal to incorporate the findings of the additional work. To increase usability, we reframed the main output as a toolkit instead of a framework.

Study design

The study comprised evidence syntheses and economic evaluations with embedded stakeholder engagement, including patient and public involvement (PPI). We used principles of co-creation to ensure that study outputs were relevant to the NHS context. The main study comprised four interlinked work packages with a cross-cutting strand of stakeholder engagement and PPI, as shown in *Figure 1*. The main study took place over 2 years and the additional work took place over 9 months.

The methods for each evidence synthesis are described in the relevant chapters. In this chapter we present our approach to stakeholder engagement and PPI.

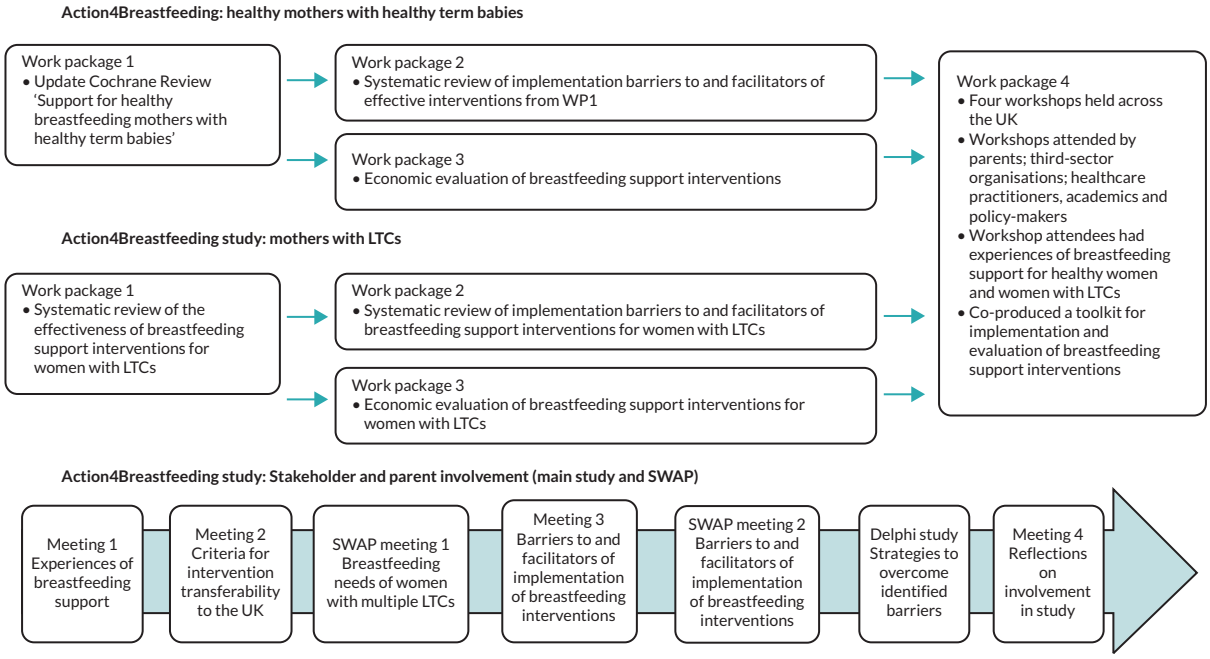

FIGURE 1 Study flow diagram.

Stakeholder and parent engagement: main study

To ensure joint ownership,[76] our approach was 'active involvement', defined as 'the contribution of any person who would be a knowledge user but whose primary role is not research', throughout the process of evidence synthesis, including planning, production and dissemination.[77] Involvement and co-creation were essential to enhance the quality and relevance of the evidence syntheses.[78,79] Stakeholders and parents were involved in three ways: a co-investigator (PB) from a breastfeeding support organisation represented service user views; the stakeholder working group, parents' panel and focus group discussions ensured that the experiences of breastfeeding women and service providers were represented in key decisions; and attendees at four workshops co-created the study outputs. Here we describe the participants, activities and outcomes of the stakeholder working group, parents' panel and focus group discussions. See *Chapter 9* for details of the workshops.

Participants

The stakeholder working group comprised 11 members representing third-sector organisations [Breastfeeding Network, Association of Breastfeeding Mothers, La Leche League, National Childbirth Trust (NCT)]; health professionals [general practitioner (GP), midwife, health visitor]; breastfeeding support workers; community breastfeeding support services; national infant-feeding networks; and national policy bodies. Two members also had roles with UNICEF-UK Baby Friendly Initiative. There were representatives from the four nations of the UK. Members of the stakeholder working group were selected to represent areas of high deprivation and/or ethnically diverse populations. For example, the health visitor covered deprived areas in Manchester; the midwife was from the north-east of England, where breastfeeding rates are low; the GP worked in inner-city Glasgow; and the community breastfeeding lead worked in an ethnically diverse area of London.

The parents' panel comprised nine parents, seven mothers with recent and varied breastfeeding experience and two fathers whose partners had breastfed and who were members of a third-sector organisation. The mothers were recruited via a national third-sector organisation Facebook group. We acknowledge that this approach can lead to the recruitment of parents from higher-income and more educated backgrounds. One member of the parents' panel was a Gypsy/Traveller, one of the most

marginalised and deprived communities in the UK. For this reason, we supplemented the parents' panel with focus group discussions.

Focus group discussions were held to reach parents from socially disadvantaged backgrounds who were less likely to participate in larger group meetings and who represented groups least likely to breastfeed. The participants were recruited via a not-for-profit organisation providing peer support (not specific to infant feeding) to parents living in economically deprived, ethnically diverse populations in West Yorkshire. Fifteen women participated in the focus group discussions.

Activities and outcomes

The stakeholder working group and parents' panel each met four times and also participated in an online consensus-building exercise. The consensus-building exercise drew on modified Delphi study methodology.[80] All meetings were held virtually due to COVID-19 restrictions. Focus group discussions were held at three time points, with both a virtual and in-person option provided; there were six focus groups in total. *Table 1* shows the main activities at each meeting. Between meetings, a newsletter was circulated to all members to update them on the progress of the study. At the fourth meeting, the stakeholder working group and parents' panel reflected on their experiences of engaging with the study. Their views are included in *Chapter 10*.

Stakeholder and parent engagement (multiple long-term conditions)

Participants

The MLTC stakeholder working group comprised 12 members representing third-sector organisations [Breastfeeding Network, La Leche League, Lactation Consultants of Great Britain and the British Human Immunodeficiency Virus (HIV) Association] and a wide range of healthcare professionals (consultant physician, consultant psychiatrist, GP, pharmacist, health visitor, specialist midwife, infant-feeding co-ordinator and diabetes specialist nurse) involved with caring for women with MLTC who may breastfeed. Stakeholder working group members were from England, Scotland and Wales and were selected for their experience in supporting women with a wide range of long-term physical and mental health conditions to breastfeed.

One-to-one discussions with condition-specific experts including a consultant endocrinologist and an HIV breastfeeding specialist were also undertaken.

The MLTC parents' panel comprised seven parents with MLTC and recent breastfeeding experience. Parents' panel members were from across the four UK nations and had lived experience of a wide range of physical and mental health conditions, including diabetes, lupus, fibromyalgia, inflammatory bowel disease, multiple sclerosis, hypertension, kidney disease, connective tissue disorders, asthma, chronic fatigue syndrome, anxiety and depression. Parents were recruited via third-sector organisation Facebook groups.

Activities and outcomes

The MLTC stakeholder working group and parents' panel met twice during the 9-month study. These meetings mirrored the first and third meetings of the main study stakeholder working group and parents' panel. The first meeting of the parents' panel was focused mainly on giving parents opportunities to tell their stories of breastfeeding alongside coping with multimorbidities. The first meeting of the stakeholder working groups was focused on participants' experiences of providing breastfeeding support to women with MLTC and the barriers to and facilitators of providing support. In the second meeting, the stakeholder working group and parents' panel discussed the same five effective interventions used in the main study, this time focusing on whether and how these interventions could be adapted to meet the needs of women with multimorbidities. The findings from the MLTC stakeholder engagement contributed to the workshop activities as described in *Chapter 9*.

TABLE 1 Main study stakeholder engagement participants, activities and outcomes

Meeting (number of participants)	Description of activity	Outcomes/impact on study
SWG 1 (11)	Getting to know each other and setting ground rules. Presentation of project and bite-size training on systematic reviews. Assessing the transferability of breastfeeding interventions to the UK (breakout discussions)	Early discussions of criteria for assessing transferability developed for SWG 2
PP 1 (6)	Getting to know each other and setting ground rules. Presentation of project and bite-size training on systematic reviews. Reflections on personal experiences of breastfeeding support	Factors viewed as important to satisfaction with breastfeeding support influenced Cochrane review (review 1) meta-analysis (e.g. selection of outcome time points)
FGD 1 (8: 5 online, 3 face to face)	Topic guide covered personal experiences of breastfeeding support, and views of important components of support including who, where, when and how	Factors viewed as important to satisfaction with breastfeeding support influenced Cochrane review (review 1) meta-analysis (e.g. selection of outcome time points)
SWG 2 (7)	Interactive exercise to score and rank transferability criteria from the PIET-T process model[81]	Top 3 ranked criteria (1, population's acceptability of the intervention; 2, quality of the primary evidence available; 3, sustainability of the intervention) used to select examples of effective interventions from the Cochrane review (review 1) for discussion of implementation barriers and facilitators
PP 2 (4)	The PIE-T model explained. Results of the SWG ranking exercise presented. Discussion of the 12 highest-scoring criteria	Parents' views of transferability criteria informed decision not to exclude any effective interventions, as any intervention could be transferred to the UK with adaptations and resources
FGD 2 (6: 3 online, 3 face to face)	Visual materials in plain language covering the key transferability criteria presented. Participants asked to discuss important factors to take into account when transferring interventions from another country to a UK setting	Discussions of barriers to and facilitators of accessing breastfeeding support and informed consideration of transferability
SWG 3 (6)	Five effective interventions from the Cochrane review (review 1) presented and discussed to identify implementation barriers and strategies	Identified barriers and facilitators included in the consensus-building exercise study
PP 3 (4)	Five effective interventions from the Cochrane review (review 1) presented and parents discussed positive and negative aspects, barriers to access and strategies to overcome the barriers	Identified barriers to access and strategies included in the consensus-building exercise
Consensus-building exercise 1 (10)	Respondents (SWG and PP) presented with 18 barriers (from previous meetings) and asked to recommend strategies from 10 themes from the Expert Recommendations for Implementing Change (ERIC) framework[82]	For each barrier, strategy themes with > 70% consensus were taken forward to round 2. Due to lack of consensus on strategies, one barrier was excluded from round 2
Consensus-building exercise 2 (8)	For each of the 17 barriers, respondents asked to rank in order of importance individual strategies from the themes that reached consensus in round 1 (34 strategies)	Due to low response rate (no parents responded) and lack of consensus, 34 strategies were taken forward to the workshops
FGD 3 (9: 6 online, 3 face to face)	Five effective interventions from the Cochrane review (review 1) discussed to identify implementation barriers and strategies	Identified barriers and facilitators compared with findings from SWG, PP and workshops to illuminate considerations that might be needed when adapting for communities with low breastfeeding rates

FGD, focus group discussions; PIET-T, population-intervention-environment-transfer model of transferability; PP, parents' panel; SWG, stakeholder working group.

Role of stakeholder engagement

The main purpose of the stakeholder working groups, the parents' panel and the focus group discussion was to adapt the international evidence, that is, the findings of the reviews, to ensure relevance to the UK context and the NHS, and to coproduce the toolkit. The stakeholder engagement therefore influenced the interpretation and adaptation to the UK setting of the review findings rather than their methods. The exception to this was in influencing the decision on outcome time points and variables for the meta-regression for review 1.

Chapter 3 Effective interventions for breastfeeding support for healthy women with healthy term babies

Introduction

This chapter contains a summary of the methods and results section from the updated Cochrane review on breastfeeding support for healthy term women with healthy term babies.[83] The full review including table of characteristics, forest plots and risk of bias assessments is published in the Cochrane Library.[83] Parts of this chapter have been reproduced with permission from Wiley. Copyright © 2022 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Objectives

1. To describe types of breastfeeding support for healthy breastfeeding women with healthy term babies.
2. To examine the effectiveness of different types of breastfeeding support interventions focusing on breastfeeding support provided on its own or breastfeeding support in combination with a wider maternal and child health intervention.
3. To examine the effectiveness of the following intervention characteristics on breastfeeding support:
    a. type of support (e.g. face to face, telephone, digital technologies, group or individual support, proactive or reactive)
    b. intensity of support (i.e. number of postnatal contacts)
    c. person delivering the intervention (e.g. healthcare professional, lay person)
    d. to examine whether the impact of support varied between high- and low- and middle-income countries.

Methods

Criteria for considering studies for this review

Inclusion criteria

Types of studies
All randomised or quasi-randomised controlled trials (RCTs), with or without blinding, were included. Cluster-RCTs were also eligible for inclusion.

Types of participants
Participants were healthy pregnant women considering or intending to breastfeed their baby, or healthy women who were breastfeeding healthy babies. Healthy women and babies were considered those who did not require additional medical care. Studies of women requiring additional medical care (e.g. women with diabetes, women with HIV/AIDS, overweight or obese) were excluded. The inclusion criteria were amended in this update to include women undergoing caesarean section.

Types of interventions
We defined breastfeeding support as contact with an individual or individuals (either professional or volunteer) offering support that is supplementary to the standard care offered in that setting.

Interventions could be delivered as standalone breastfeeding support interventions (breastfeeding only), or breastfeeding support could be delivered as part of a wider maternal and newborn health intervention (breastfeeding plus) where additional services are also provided (e.g. vaccination, intrapartum care, well-baby clinics).

'Support' interventions eligible for this review could include elements such as reassurance, praise, information, and the opportunity to discuss and to respond to the mother's questions and could also include staff training to improve the supportive care given to women. It could be offered by health professionals or lay people, trained or untrained, in hospital and community settings. It could be offered to groups of women or one-to-one, including mother-to-mother support, and it could be offered proactively by contacting women directly, or reactively, by waiting for women to get in touch.

This update now also includes support provided via digital technologies as well as support provided over the telephone.

Support could involve only one contact or regular, ongoing contact over several months. Studies were included if the intervention occurred in the postnatal period alone or also included an antenatal component.

Types of outcome measures

Primary outcomes

1. Stopping any breastfeeding at 6 months postpartum.
2. Stopping exclusive breastfeeding at 6 months postpartum.
3. Stopping any breastfeeding at 4–6 weeks postpartum.
4. Stopping exclusive breastfeeding at 4–6 weeks postpartum.

Secondary outcomes

1. Stopping any breastfeeding at 2, 3–4 and 12 months postpartum.
2. Stopping exclusive breastfeeding at 2 and 3–4 months postpartum.
3. Maternal satisfaction with care.
4. Maternal satisfaction with feeding method.
5. All-cause infant or neonatal morbidity (including infectious illness rates).
6. Maternal mental health.

Exclusion criteria

Types of studies

Any study that did not involve the random allocation of participants was excluded (non-RCTs; quasi-experimental studies; one group before-and-after studies; cohort studies; case–control studies; case reports; or qualitative studies).

Types of participants

Studies that focused specifically on women or infants with additional care needs were excluded. For mothers this could mean coexisting medical problems (e.g. diabetes, HIV) or pregnancy-related complications (e.g. pre-eclampsia). For infants this could include preterm birth, low birthweight or additional care in a neonatal unit.

Types of interventions

Interventions taking place in the antenatal period alone were excluded from this review, as were interventions described as solely educational or promotional in nature.

Additional limitations

We did not exclude studies based on language or date of publication. Abstracts were eligible for inclusion if they provided sufficient information for data to be extracted. If they did not provide sufficient information, they were recorded as ongoing studies.

Search methods for identification of studies

The Cochrane Pregnancy and Childbirth Group's Trials Register was searched by its information specialist in May 2021. This includes results of searches of CENTRAL, MEDLINE, EMBASE, CINAHL, ClinicalTrials.gov, and the World Health Organization (WHO) International Clinical Trials Registry Platform (11 May 2021).

We also searched the reference lists of retrieved studies and the list of excluded studies from the previous version of this review to identify any studies that met the new inclusion criteria.[41]

Data collection and analysis

We used standard Cochrane Pregnancy and Childbirth Group methods. Two review authors independently selected trials, extracted data and assessed risk of bias using Covidence software.[84] The certainty of the evidence was assessed by two reviewers using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.[85]

We then assessed study trustworthiness using the new approach implemented by the Cochrane Pregnancy and Childbirth Group to identify and manage potentially untrustworthy studies.[86] All full texts meeting the inclusion criteria and studies included in the previous update of this review were evaluated against the following criteria.

Research governance

- No prospective trial registration for studies published after 2010 without plausible explanation.
- When requested, trial authors refuse to provide/share the protocol and/or ethics approval letter.
- Trial authors refuse to engage in communication with the Cochrane review authors.
- Trial authors refuse to provide individual patient data upon request with no justifiable reason.

Baseline characteristics

- Characteristics of the study participants being too similar [distribution of mean (standard deviation) excessively narrow or excessively wide].

Feasibility

- Implausible numbers (e.g. 500 women with severe cholestasis of pregnancy recruited in 12 months).
- (Close to) zero losses to follow-up without plausible explanation.

Results

- Implausible results (e.g. massive risk reduction for main outcomes with small sample size).
- Unexpectedly even numbers of women 'randomised' including a mismatch between the numbers and the methods, for example if they say no blocking was used but still end up with equal numbers, or they say they used blocks of four but the final numbers differ by six.

Any studies classed as potentially high risk for any of these criteria were referred back to the Cochrane Pregnancy and Childbirth Group, who contacted the study authors for more information. If we did not receive adequate information, the study remained 'awaiting classification'.

Data synthesis

We used methods outlined in the Cochrane Handbook for statistical analysis.[87] In this update of the review, we grouped interventions into two different categories for meta-analysis. The first group, 'breastfeeding only', were interventions that only contained breastfeeding support. In the second group, breastfeeding support was one part of a larger intervention that also aimed to provide other health benefits for the mother or her infant (e.g. vaccinations, new-baby care).

We used meta-regression to further assess statistical heterogeneity for the four primary outcomes when a sufficient number of studies were included in the analyses (i.e. at least 10 observations per characteristic modelled).[88] The following four categories were selected for the meta-regression in conjunction with stakeholders:

1. by type of supporter (professional vs. lay person, or both)
2. by mode of support (face to face vs. telephone support vs. digital vs. combination)
3. by intensity of support [low (fewer than four) vs. moderate (four to eight) vs. high (nine or more)]
4. by income status of country [high-income country vs. low- and middle-income country (LMIC)].

We performed sensitivity analyses based on risk of bias for allocation concealment and incomplete outcome data. Additionally, sensitivity analyses were conducted to investigate the effect of including cluster-randomised trials where no adjustment was possible.

Results

A total of 590 trial reports were assessed for inclusion in this update (see Gavine *et al.*[83] for full details). This included 560 studies from the updated search, 16 trial reports that were awaiting classification in the previous version of the review, 8 studies that were ongoing in the last version of the review and 6 previously excluded studies that were reassessed due to the change in inclusion criteria. Of these, 72 met the inclusion criteria.

All studies (100 previously included and 72 newly identified studies) were assessed against Cochrane's criteria for trustworthiness. Of the 100 previously included studies, we requested further information for 38, and of the new studies identified in this update, we required clarification for 43. In total, we received satisfactory responses for 27 studies. In total, 54 studies were reclassified to 'awaiting classification'. The remaining studies were included, and this updated review includes 116 trials, of which 103 contribute data to the analyses.

In total, 249 studies were excluded with reasons (this comprises 139 reports from the updated search and 110 reports from previous versions of the review). The majority of studies (n = 136) were excluded as the intervention was not relevant to the review, for example interventions that were focused on education and/or promotion only and did not offer any support, interventions that were focused on other aspects of postnatal care, and antenatal-only interventions. We excluded any study that was not a RCT (n = 53). A further 49 studies were excluded because they did not focus on healthy mothers (e.g. coexisting medical conditions requiring additional care) or babies (e.g. preterm, low birthweight). Eleven studies were excluded because the comparator was not either standard care or an alternative non-breastfeeding intervention. Finally, four studies were excluded as they were not research papers. For full details, see Gavine *et al.*[83] for characteristics of the excluded studies.

Description of included studies

This updated review includes 116 trials, of which 103 contribute data to the analyses. The 116 studies comprise 83 individually randomised trials and 33 cluster-randomised trials. Most are two-arm RCTs; however, 20 studies are either three- or four-arm RCTs. In total, 125 interventions with more than 98,816 mother–infant pairs were included. See Gavine *et al.*[83] for further details and tables of characteristics.

Participants

Participants living in 42 countries are included in the review. Using the World Bank classification of countries by income, 21 of the new included studies in the review were conducted in HICs, 6 in upper-middle-income countries, 16 in LMICs and 5 in low-income countries (LICs). Participants were women from the general healthy population of their countries. However, 52 studies recruited women from groups at high risk of health inequalities or health inequities in their country. Most of these studies were conducted in HICs (*n* = 33). These included women defined as low-income or living in a disadvantaged area (*n* = 18), women with a non-white ethnic background (*n* = 9) and young mothers (*n* = 6).

Interventions

Of the 125 interventions included in the review, 91 interventions comprised only breastfeeding support components. The remaining 34 interventions aimed to increase breastfeeding rates as part of a multicomponent intervention, which aimed to improve other aspects of child health, such as vaccination rates, or sleep.

Women received breastfeeding support proactively in 85 interventions. In 32 studies, women had access to both proactive and reactive support, and in 6 studies only reactive support was offered. Just over half of the studies included an antenatal component.

Most interventions provided one-to-one support (*n* = 115). However, in 19 of these 115 interventions, additional group support was also available to women. Eight studies consisted of only group support and two studies provided support to partners. The majority of interventions were provided by professionals (*n* = 74). Thirty-five interventions were provided by a lay person (usually a peer supporter), and 14 had both lay and professional input. The majority of studies reported that the person providing the support had undergone training in breastfeeding (*n* = 97).

Face-to-face support was a component of the majority of interventions (*n* = 104). In 64 of the 104 interventions, face-to-face support was the only mode of support available. In 36 interventions, face-to-face support was complemented with telephone support. Telephone support alone was evaluated in 14 studies. Only five studies used fully digital approaches (e.g. social media, messaging services), and two studies used only two-way text messaging.

Intervention intensity was grouped as follows: low intensity (three or fewer contacts), moderate intensity (four to eight contacts) and high intensity (nine or more contacts). Twenty-one interventions were specified as low intensity, 41 were specified as moderate intensity, and 44 were specified as high intensity. The intensity of the remaining 19 interventions was not specified.

In 97 studies, the control groups were described as receiving the standard care for the study population. However, there are large differences in standard care provision both between and within countries. Thirteen studies compared the study intervention against either an active control arm or a control group that offered participants additional care to the standard care available to non-participants. In six studies the care received by the control group is either not reported or unclear.

Risk-of-bias assessments

We considered that the overall risk of bias of trials included in the review was mixed. Blinding of participants and personnel is not feasible in such interventions, and, as studies utilised self-report breastfeeding data, there is also a risk of bias in outcome assessment.

For full details of the risk-of-bias assessments, see Gavine *et al.*[83] A summary of the judgements is detailed in *Figure 2*.

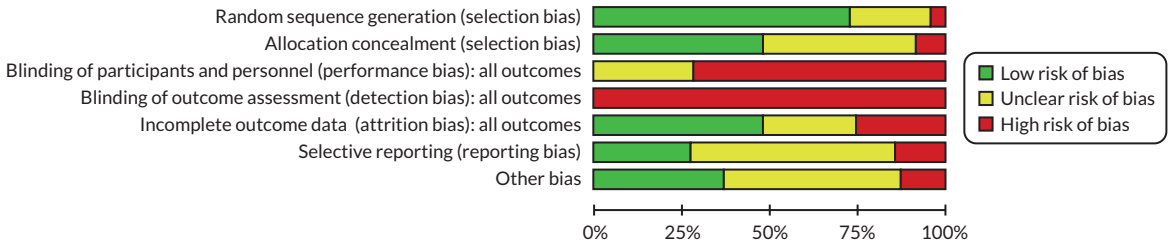

FIGURE 2 Risk-of-bias graph: review authors' judgements about each risk-of-bias item presented as percentages across all included studies (Gavine *et al.*[83]).

Effects of interventions

Tables 2 and *3* provide the summary of findings. For full details of effects of interventions, including forest plots and funnel plots, see Gavine *et al.*[83]

Primary outcomes

Moderate-certainty evidence indicated that 'breastfeeding only' support probably reduced the number of women stopping breastfeeding for all primary outcomes: stopping any breastfeeding at 6 months [relative risk (RR) 0.93, 95% CI 0.89 to 0.97]; stopping exclusive breastfeeding at 6 months (RR 0.90, 95% CI 0.88 to 0.93); stopping any breastfeeding at 4–6 weeks (RR 0.88, 95% CI 0.79 to 0.97); and stopping exclusive breastfeeding at 4–6 weeks (RR 0.83 95% CI 0.76 to 0.90). Sensitivity analyses excluding studies rated as being at high or unclear risk of bias for allocation concealment and incomplete outcome reporting found similar or more beneficial treatment effects.

The evidence for 'breastfeeding plus' was less consistent. For primary outcomes there was some evidence that 'breastfeeding plus' support probably reduced the number of women stopping any breastfeeding (RR 0.94, 95% CI 0.91 to 0.97, *moderate-certainty evidence*) or exclusive breastfeeding at 6 months (RR 0.79, 95% CI 0.70 to 0.90). 'Breastfeeding plus' interventions may have a beneficial effect on reducing the number of women stopping exclusive breastfeeding at 4–6 weeks, but the evidence is very uncertain (RR 0.73, 95% CI 0.57 to 0.95). The evidence suggests that 'breastfeeding plus' support probably results in little to no difference in the number of women stopping any breastfeeding at 4–6 weeks (RR 0.94, 95% CI 0.82 to 1.08, *moderate-certainty evidence*).

We conducted meta-regression to explore substantial heterogeneity for the primary outcomes using the following categories: person providing care, mode of delivery, intensity of support and income status of country. It is possible that moderate levels (defined as four to eight visits) of 'breastfeeding only' support are associated with a more beneficial effect on exclusive breastfeeding at 4–6 weeks and 6 months. 'Breastfeeding only' support may also be more effective in reducing women stopping exclusive breastfeeding at 6 months in LMICs than in HICs. However, no other differential effects were found and thus heterogeneity remains largely unexplained. The meta-regression suggested that there were no differential effects regarding person providing support or mode of delivery; however, power was limited.

Secondary breastfeeding outcomes

Moderate-certainty evidence indicated that 'breastfeeding only' support probably had a beneficial effect on the following: stopping exclusive breastfeeding at 2 months (RR 0.81, 95% CI 0.74 to 0.89), any breastfeeding at 3–4 months (RR 0.87, 95% CI 0.81 to 0.93) and exclusive breastfeeding at 3–4 months (RR 0.81, 95% CI 0.74 to 0.89). Low-certainty evidence suggested that 'breastfeeding only' interventions may have a beneficial effect on the number of women breastfeeding at 9 months (RR 0.87, 95% CI 0.78 to 0.97). However, low certainty evidence suggests that 'breastfeeding only' interventions have little impact on the number of women doing any breastfeeding at either 2 months (RR 0.93, 95% CI 0.77 to 1.11) or 12 months (RR 0.87, 95% CI 0.90 to 1.00).

TABLE 2 Summary of findings: breastfeeding support only compared with usual care

Outcomes	Anticipated absolute effects[a] (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)
	Risk with usual care	Risk with support			
Stopping breastfeeding (any) at 6 months	600 per 1000	**558 per 1000** (534 to 582)	**RR 0.93** (0.89 to 0.97)	14,610 (30 RCTs)	⨁⨁⨁◯ Moderate[b]
Stopping exclusive breastfeeding at 6 months	847 per 1000	**763 per 1000** (746 to 788)	**RR 0.90** (0.88 to 0.93)	16,332 (40 RCTs)	⨁⨁⨁◯ Moderate[b]
Stopping breastfeeding (any) at 4–6 weeks	308 per 1000	**271 per 1000** (244 to 299)	**RR 0.88** (0.79 to 0.97)	11,413 (36 RCTs)	⨁⨁⨁◯ Moderate[b]
Stopping exclusive breastfeeding at 4–6 weeks	518 per 1000	**430 per 1000** (394 to 466)	**RR 0.83** (0.76 to 0.90)	14,544 (42 RCTs)	⨁⨁⨁◯ Moderate[b]

a **The risk in the intervention group** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
b We downgraded one level for serious concerns about inconsistency. Evidence of substantial unexplained heterogeneity.

TABLE 3 Summary of findings: breastfeeding plus compared with usual care

Outcomes	Anticipated absolute effects[a] (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)
	Risk with usual care	Risk with support plus			
Stopping breastfeeding (any) at 6 months	541 per 1000	**508 per 1000** (492 to 524)	**RR 0.94** (0.91 to 0.97)	4879 (11 RCTs)	⨁⨁⨁◯ Moderate[b]
Stopping exclusive breastfeeding at 6 months	685 per 1000	**541 per 1000** (479 to 616)	**RR 0.79** (0.70 to 0.90)	7650 (13 RCTs)	⨁⨁◯◯ Low[b,c]
Stopping breastfeeding (any) at 4–6 weeks	433 per 1000	**407 per 1000** (355 to 467)	**RR 0.94** (0.82 to 1.08)	2325 (6 RCTs)	⨁⨁⨁◯ Moderate[d]
Stopping exclusive breastfeeding at 4–6 weeks	542 per 1000	**396 per 1000** (309 to 515)	**RR 0.73** (0.57 to 0.95)	2402 (6 RCTs)	⨁◯◯◯ Very low[c,e]

a **The risk in the intervention group** (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
b We downgraded one level for serious concerns about risk of bias. Studies at risk of selection bias due to unclear allocation concealment.
c We downgraded one level for serious concerns regarding inconsistency. Evidence of substantial unexplained heterogeneity.
d We downgraded one level for serious concerns about imprecision. Small number of participants. Optimal information size criterion met but 95% CI overlaps the line of no effect and fails to exclude important benefit.
e We downgraded two levels for very serious concerns in risk of bias. Many studies were at risk of selection bias due to unclear allocation concealment. Many studies had high levels of incomplete outcome reporting. Finally, sensitivity analysis excluding a study that could not be adjusted for clustering changed the effect estimate to non-significant.

'Breastfeeding plus' interventions probably had little to no impact on stopping breastfeeding for any of the secondary outcomes: any at 2 months (RR 0.92, 95% CI 0.79 to 1.07, *moderate-certainty evidence*); exclusive at 2 months (RR 0.90, 95% CI 0.78 to 1.03, *very low-certainty evidence*); any at 3–4 months (RR 0.97, 95% CI 0.81 to 1.15, *low-certainty evidence*); exclusive at 3–4 months (RR 0.86, 95% CI 0.75 to 1.00, *low-certainty evidence*); or any at 12 months (RR 0.96, 95% CI 0.91 to 1.00, *moderate-certainty evidence*).

Non-breastfeeding outcomes

There were no consistent findings emerging from the narrative synthesis of the non-breastfeeding outcomes (maternal satisfaction with care, maternal satisfaction with feeding method, infant morbidity and maternal mental health), except for a possible reduction of diarrhoea in intervention infants.

Chapter summary

The update of this Cochrane review on breastfeeding support for healthy term women identified 116 trials, of which 103 contribute data to the analyses. More than 98,816 mother–infant pairs were included. When 'breastfeeding only' support is offered to women, the duration and particularly the exclusivity of breastfeeding is likely to be increased. Support may also be more effective in reducing the number of women stopping breastfeeding at 3–4 months than at later time points. For 'breastfeeding plus' interventions the evidence is less certain.

There does not appear to be a difference in who provides the support (i.e. professional or non-professional) or how it is provided (face to face, telephone, digital technologies or combinations). Indeed, various kinds of support may be needed in different geographical locations to meet the needs of the people within that locality.

Chapter 4 Systematic review of implementation research of effective breastfeeding support interventions for healthy women with healthy term babies

Introduction

The Cochrane review update undertaken in our review 1 confirmed that there is ample evidence to know that breastfeeding women need support to be available and to be provided, and that such support is likely to make a difference. Such an evidence base also suggests that one key research question for the future is to identify how such support can best be provided consistently across countries and settings.

Therefore, there is now a need to improve the evidence base around scaling up issues for breastfeeding support interventions, which will require a greater emphasis on implementation and quality improvement approaches rather than effectiveness studies. To enable further advances in this area, it will be fundamental to identify and synthesise available qualitative and process evaluation data on existing interventions. The overall aim of this review was to conduct a theoretically informed mixed-methods synthesis of process evaluations of breastfeeding support interventions identified as effective in review 1.

Objectives

1. To identify qualitative and quantitative data from process evaluation studies linked to breastfeeding support interventions identified as effective in review 1.
2. To synthesise the views and experiences of those involved in receiving or delivering breastfeeding support interventions identified as effective in review 1.
3. To identify the contextual factors (barriers/facilitators) affecting the implementation of breastfeeding support interventions identified as effective in review 1.

Methods

The protocol for this systematic review is registered on PROSPERO (CRD42021229769).

Search strategy

We systematically searched six electronic databases (MEDLINE, CINAHL Plus, PsycInfo, ASSIA, Scopus and Web of Science). Searches were conducted in March 2022 using combinations of index terms and free-text words relating to 'breastfeeding support' AND 'implementation research' (a sample search strategy for MEDLINE is provided in *Appendix 1*). No restrictions were applied on publication date and publication language. Reference lists of all included studies and relevant systematic reviews were scanned for eligible studies. Supplementary searches were conducted based on the name of interventions identified in Gavine *et al.*,[83] included articles' authors, and forwards and backwards citation checking.

Eligibility criteria

Inclusion criteria

Studies were included if they reported findings of primary research exploring the views and experiences of any participants involved in either delivering or receiving any of the breastfeeding support interventions identified as effective in Gavine *et al.*,[83] including breastfeeding women and babies and their families, service providers, managers, commissioners and policy-makers.

Qualitative and quantitative studies, either standalone or in mixed-methods designs, were included. Studies reported any type of process evaluation outcome relating to the selected interventions, including any subjective participant-reported outcomes and constructs such as attitudes, views, beliefs, perceptions, understandings or experiences.

There were no restrictions on publication date or language of publication.

Exclusion criteria

Articles only reporting on impact evaluation results of breastfeeding support interventions (i.e. effectiveness of interventions) were excluded.

Studies that focused specifically on women or infants with additional care needs were excluded. For mothers this could mean coexisting medical problems (e.g. diabetes, HIV) or pregnancy-related complications (e.g. pre-eclampsia). For infants this could include preterm birth, low birthweight or additional care in a neonatal unit.

Studies relating to interventions taking place in the antenatal period alone were excluded from this review, as were interventions described as solely educational or promotional.

Selection process

Two reviewers independently screened titles, abstracts and relevant full texts against the predetermined eligibility criteria. Any discrepancies were resolved through discussion and consultation with a third reviewer.

Data extraction and quality appraisal

Data extraction was undertaken independently by two reviewers using a piloted data extraction form. Any discrepancies were resolved through discussion and consultation with a third reviewer. The table of characteristics is presented in *Appendix 2*, *Table 13*.

Quality appraisal of included studies was conducted by two reviewers, using a self-developed tool derived from a set of criteria previously used in other National Institute for Health and Care Research (NIHR)-funded work to assess the quality of process evaluations.[89] Studies were not excluded based on the quality/adequacy of the reporting. Instead, the quality of studies was taken into consideration during data synthesis by exploring whether any particular finding or group of findings were dependent, either exclusively or disproportionately, on one or more studies classed as 'low quality' or 'inadequately reported'. Any discrepancies were resolved by discussion and the involvement of a third reviewer where necessary. See *Appendix 2*, *Table 14*.

Data synthesis

We adopted a mixed-methods synthesis approach. We first undertook two preliminary syntheses of quantitative (synthesis 1) and qualitative (synthesis 2) process evaluation studies, and then integrated qualitative and quantitative process evaluation data into a theoretically informed cross-study synthesis (synthesis 3).

For synthesis 1 we used narrative methods[90] to synthesise quantitative findings from included process evaluations. Two reviewers independently assessed the tabulated characteristics of the included quantitative studies and agreed the criteria to organise the included studies. For synthesis 2 we used a data-driven approach to thematic synthesis[91] to synthesise qualitative findings from included process evaluations. This involved three overlapping and interrelated stages: (1) line-by-line coding of findings from primary studies, (2) categorisation of codes into descriptive themes and (3) development of analytical themes to describe or explain previous descriptive themes. To ensure the robustness of the synthesis, various techniques to enhance trustworthiness were undertaken, including audit trail, multiple coding, reviewer triangulation and team discussions. Finally, for synthesis 3, we adopted a theory-driven approach to thematic synthesis[91] to synthesise and bring together quantitative and qualitative findings from included primary studies. This synthesis was informed by the Consolidated Framework for Implementation Research (CFIR),[92] a comprehensive framework that characterises the contextual determinants of implementation and can be used to inform implementation theory development and verification of what works where and why across multiple contexts.

Results

The searches identified 2894 records, which were assessed against the inclusion criteria. Title and abstract screening resulted in 243 records considered eligible or inconclusive. Full-text articles were then retrieved and assessed for eligibility. Two records could not be retrieved. Of the 241 records screened at full text, 225 were excluded. The main reason for exclusion was studies not being linked to an intervention identified as effective in review 1 (*n* = 84), followed by standalone studies that were not linked to any intervention (*n* = 51) and studies not involving implementation research and/or process evaluation data (e.g. pre-implementation or intervention development studies) from eligible interventions (*n* = 50). Other reasons for exclusion were studies linked to either interventions (*n* = 26) or populations (*n* = 6) not eligible for inclusion in review 1, and systematic reviews (*n* = 4) and other publication types not reporting primary research findings (*n* = 4). The remaining 16 studies were included in the final synthesis (*Figure 3*). The 16 studies are linked to 10 RCTs of effective interventions from review 1.

Summary of included studies

A summary of key characteristics of the included studies is presented in *Appendix 2*, *Table 13*.

Twelve studies contributed qualitative data to the synthesis, comprising eight qualitative[93–100] and four mixed-methods[101–104] process evaluation studies; and eight studies contributed quantitative data to the final synthesis, comprising four quantitative[105–108] and four mixed-methods studies.[101–104]

Studies reported data from ten countries: nine from HICs (five in the USA, two in Australia and one each in Canada and the UK); and seven from LMICs (four in Uganda, two in South Africa and one in Pakistan). All of the studies from Uganda and South Africa were evaluations of aspects of the PROMISE-EBF RCTs.[109]

Study settings included rural and urban areas and hospital and community facilities. In eight of the studies in HICs, the target populations were low-income or disadvantaged populations, or those living in areas with low breastfeeding rates.

Study samples ranged from 26 to 130 mothers, 12 to 254 peer counsellors, 13 to 28 healthcare staff and 2 to 409 other stakeholders, including supervisors, programme managers and co-ordinators, and unspecified key informants. Other forms of data included observations, diaries and daily activity logs.

Process evaluations included in this review were linked to effective interventions identified in review 1 (for details, see *Appendix 2*, *Table 13*).

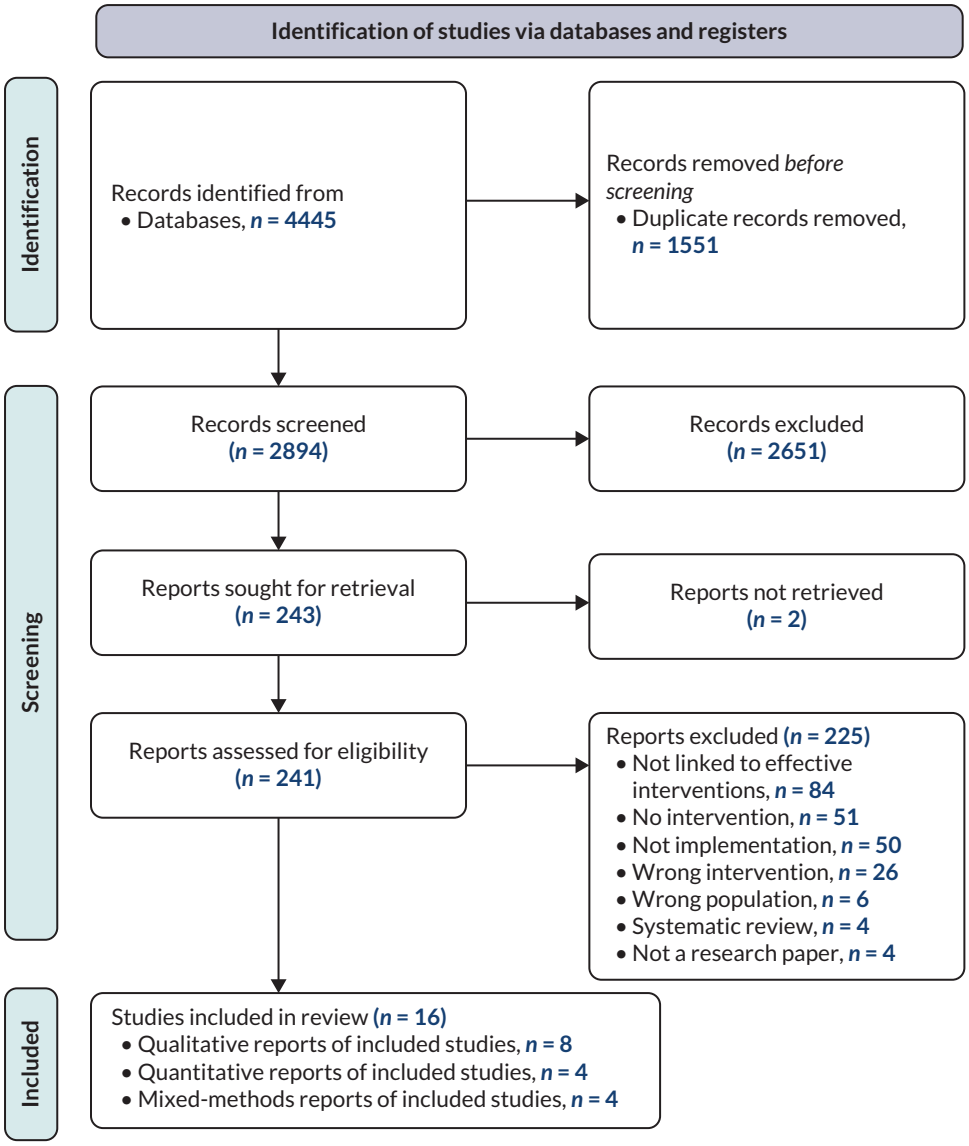

FIGURE 3 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.

The descriptions of linked interventions were coded against a taxonomy of behaviour change techniques. The most commonly identified behaviour change techniques related to social support, goals and planning, and feedback and monitoring. A summary of the behaviour change techniques identified across all the linked interventions is provided in *Appendix 2*, *Table 15*.

Quality appraisal

The quality of the 16 process evaluations was mixed (see *Appendix 2*, *Table 14*). Seven studies were judged to have made a fairly thorough attempt to increase rigour and minimise bias in sampling, data collection and analysis.[93,96,97,100,101,103,107] A further six studies were assessed to have taken at least a few steps to increase rigour of sampling, data collection and analysis.[94,98,99,102,104,105] For the remaining three studies, judgements for at least one element of sampling, data collection or data analysis were hindered by poor reporting.[95,106,108] All studies' findings were judged to be at least fairly well supported by the data. The findings of three studies were judged to have limited breadth and/or depth.[93,106,108] In Andaya *et al.*,[93] the evaluation was based on exit interviews lasting 8–12 minutes. Chapman *et al.*[106] report only coverage of the intervention. Ridgeway *et al.*[108] do not report responses to open-ended questions in their survey. Seven studies were judged not to have privileged the perspectives of breastfeeding

women.[94,97,98,102,104,106,108] Two studies were judged to have low reliability of findings[94,95] and one study was judged to have low usefulness.[94,95]

Stakeholders' perceptions and experiences

Stages 1 and 2 of our mixed-methods synthesis resulted in the categorisation of primary quantitative and qualitative data from included studies into 86 descriptive themes. Building on these findings, further analytical work and team discussion was undertaken, and the initial descriptive themes were grouped around a resulting set of 18 factors affecting the implementation of effective interventions, which in turn informed our preliminary, data-driven synthesis conclusions. These revolved around the following three analytical themes:

- that qualitative/quantitative monitoring data and feedback are provided for women and/or professionals to reflect on and evaluate the progress, quality and experience of implementing the new breastfeeding support intervention
- that breastfeeding support needs of women/families served by the implementing organisation (including any barriers to/facilitators of meeting those needs) are known
- that individuals involved in the new breastfeeding support intervention are appropriately trained, have confidence in their capabilities, and are able to execute the courses of action required to achieve the desired implementation/intervention goals.

For the final stage of our thematic synthesis, we mapped our descriptive and analytical themes against the domains of the CFIR. Our three analytical themes and subthemes aligned across five subdomains of the *implementation process* domain (assessing needs, assessing context, tailoring strategies, engaging, and reflecting and evaluating) of the CFIR framework.

Our final three overarching, theoretically informed analytical themes are described below. *Table 4* shows the distribution of primary studies underpinning each analytical theme and their mapping against the relevant CFIR subdomains.

Assessing the needs of those delivering and receiving breastfeeding support interventions

Included studies identified several implementation challenges relating to the needs, preferences and priorities of those delivering and receiving breastfeeding support interventions. Nine studies reported on issues from the perspective of intervention deliverers.

Some reported having to deal with feelings of frustration when running breastfeeding support services with low attendance rates.[102] This was a particular challenge for those running services located in small or rural areas. For those juggling a breastfeeding support role with healthcare provider roles, the pressure of the competing demands in the context of low attendance rates could make them feel like their time might have been better spent on other activities.[102]

One key strategy reported to both identify and address the needs of breastfeeding support providers was through training.[94–96,98,103,105,107] Studies largely reported that intervention deliverers felt training prepared them well, in terms of both counselling skills and technical competence (e.g. being able to show how to breastfeed correctly). All of this was perceived as key to ensuring consistency in intervention delivery.

Other issues that could be addressed through training were to do with the practical expectations of undertaking the breastfeeding supporter role. Uncertainties about safety, transport and reimbursement while delivering support were among the most reported needs for those delivering community-based interventions,[94,95] as well as around more complex issues, such as managing difficult scenarios or the interplay of cultural beliefs and breastfeeding practice. The last was particularly relevant to lay breastfeeding supporters delivering interventions at community level. They noted the importance of

TABLE 4 Included studies mapped against relevant subdomains of the CFIR

	Implementation process (consolidated framework for implementation research) mapped sub-domains						
	5B – assessing needs					5H – reflecting and evaluating	
	1 – innovation deliverers	2 – innovation recipients	5C – assessing context	5E – tailoring strategies	5F – engaging	1 – implementation	2 – innovation
Included studies (n = 16) (first author and year)	Theme 1: assessing the needs of those delivering and receiving breastfeeding support interventions		Theme 2: assessing the context and optimising delivery of and engagement with breastfeeding support interventions			Theme 3: reflecting and evaluating the success of implementing and providing breastfeeding support	
Ahmed 2012[101]		•				•	•
Andaya 2012[93]				•			•
Bronner 2000[105]	•		•		•	•	
Chapman 2004[106]						•	
Cramer 2017[102]	•		•		•		•
Daniels 2010[94]	•						
Dennis 2002[107]	•	•				•	•
Hoddinott 2012[103]	•	•			•	•	•
Nankunda 2006[95]	•		•		•	•	
Nankunda 2010[96]	•	•				•	
Nankunda 2010[104]	•				•	•	
Nkonki 2010[97]	•					•	
Rahman 2011[98]	•		•			•	
Ridgway 2016[108]				•			•
Rujumba 2020[99]		•				•	
Teich 2014[100]				•			

acknowledging that trainees themselves belong to a range of communities that might be systematically exposed to certain issues/inequities more than others (e.g. rural isolation, HIV prevalence in the community) and/or might hold cultural beliefs about breastfeeding or breastfeeding-related practices that could act as barriers. These should be identified and addressed in a culturally sensitive manner and without antagonising the communities, enabling lay providers to appropriately and inclusively support breastfeeding women from a range of communities.[94,95,97]

Those in implementation leadership roles also emphasised the importance of effective management and supervision. This was reported as a key facilitator of some interventions,[94,97] particularly to ensure that certain needs of intervention deliverers continue to be addressed beyond the provision of formal training. For example, for those engaged in interventions relying on peer, lay and/or volunteer

supporters, there was an important need to provide them with ongoing emotional support, including mentoring and motivation.

Overall, the breastfeeding supporters felt that their role was important, satisfying and rewarding,[15] with implications that were perceived to go beyond the specific breastfeeding support encounters to act as triggers of the wider support network of the breastfeeding women.[95,96]

The needs, preferences and priorities of recipients of breastfeeding support interventions were echoed in five studies.

Breastfeeding women perceived the provision of support as positive, important and needed.[99,107] Key to this was being offered the opportunity to ask questions and being allowed to spend enough time to address any issues.[103,104] Also important was accessing support flexibly as needed, rather than having to fit support around fixed working hours or at times that might not be convenient (particularly if receiving support visits at home or after starting paid work after maternity leave).[101,103,104]

Assessing the context and optimising delivery of and engagement with breastfeeding support interventions

Some studies reported a range of contextual factors affecting the implementation and delivery of breastfeeding support interventions. These included identification of appropriate settings and accessible, available spaces to deliver breastfeeding support;[95,102] consideration of environmental factors that are considered breastfeeding promoting (and avoidance of those that are not) in the intervention delivery settings (e.g. use of breastfeeding promotion leaflets, posters and videos);[105] and availability of and alignment with local policies and procedures, as well as with existing practices, in maternity care.[98,105] Studies also reported examples of tailoring implementation strategies to address barriers, leverage facilitators and optimise how breastfeeding support interventions fit the context. These included strategies to promote and encourage engagement, such as ensuring embeddedness within the community,[95,96] addressing challenges to recruit breastfeeding supporters,[102] favouring lay language;[103] teamwork and positive interactions with other breastfeeding supporters and healthcare professionals;[96,105] responsiveness of support content and language to address known barriers and common issues;[100,103,106,108] and continuity/accessibility of interventions across the continuum of care.[93,103]

Reflecting and evaluating the success of implementing and providing breastfeeding support

Included studies reported a broad range of reflective and evaluative accounts about the success of implementation processes and about how impactful breastfeeding support interventions were perceived by women.

Reports about the success of implementation focused on issues relating to key implementation outcomes such as satisfaction,[103,104,107] fidelity,[103] convenience[101,103,104] or usefulness.[101,104,107] Other studies reported on the key drivers that enabled successful engagement between mothers and breastfeeding supporters,[97,104,107] including elements of responsiveness/tailoring and content areas addressed in support encounters.[95,97,104,106,108] Some studies reported data on the views and experiences of enacting the role of breastfeeding supporter[95,96,98,105,107] and breastfeeding supporter's supervisor/lead,[97,107] all of which documented positive perceptions by those undertaking and/or interacting with those roles. Other studies looked at factors affecting the scale-up of breastfeeding support interventions, including key barriers (e.g. stigma around exclusive breastfeeding, economic barriers and limited resources, health facilities, lack of supportive policies, low male involvement, negative sociocultural beliefs) and facilitators (e.g. promotion at health system level, engagement of professional associations and active collaborations with existing groups, the media and appropriate role models).[98,99]

Some studies included reports of perceived meaningfulness and impact of breastfeeding support interventions from women's perspectives, which can be considered reflective accounts that add to the existing body of evidence about the success of breastfeeding support interventions. Women perceived breastfeeding support interventions as beneficial to women, babies and the wider community;[102] and helpful for improving breastfeeding knowledge,[93] ensuring the early establishment of breastfeeding[93] and enabling women to recognise feeding patterns and problems.[101] Breastfeeding supporters were perceived by women as allies who bolstered their confidence in their decision to breastfeed, particularly for those who were faced with a lack of encouragement from family or hospital staff.[93]

The provision of practical information about breastfeeding mechanics and hands-on support were perceived as useful and enabled women to feel reassured and encouraged to continue breastfeeding.[93] The element of responsiveness in terms of support content areas afforded by breastfeeding support interventions helped make interventions meaningful for women in the context of their specific breastfeeding support encounters.[95,97,104,106,108] The most commonly reported issues addressed were reassurance, general breastfeeding information, supply and demand, breastfeeding positioning and attachment, feed frequency, normal infant behaviour, expressing and breast pump use, nipple pain/damage issues and not having enough milk. More interactive intervention components (e.g. monitoring systems, telephone-based support) were appreciated and seen as useful but perceived as a 'mixed fit' for breastfeeding support. Women saw these modes of support as an addition to rather than a replacement for face-to-face support.[101,103]

Chapter summary

This review comprised 16 studies linked to 10 interventions identified as effective in review 1, which reported the views and experiences of those delivering or receiving breastfeeding support. The quality of the included studies was mixed, but all study findings were judged to be at least fairly well supported by the data.

The synthesis resulted in three overarching themes, theoretically informed by the CFIR: (1) assessing the needs of those delivering and receiving breastfeeding support interventions; (2) assessing the context and optimising delivery and engagement with breastfeeding support interventions; and (3) reflecting and evaluating the success of implementing and providing breastfeeding support.

Included studies identified several implementation challenges relating to the needs, preferences and priorities of those delivering and receiving breastfeeding support interventions. Breastfeeding supporter training was a commonly reported implementation strategy, which also enabled implementation teams to identify and address breastfeeding supporters' needs. Included studies reported a range of contextual factors (e.g. alignment with local policies) affecting the implementation and delivery of breastfeeding support interventions as well as a range of tailoring strategies (e.g. community involvement, use of lay language, responsive support content/information) to address contextual factors. Reports about implementation success focused on issues relating to key implementation outcomes such as satisfaction, fidelity and usefulness.

Chapter 5 Health economic evaluation

Overview

Previous chapters have identified which support interventions were effective in terms of stopping the drop-off of women breastfeeding, and what contextual factors need to be considered when implementing interventions into healthcare settings in the UK. This chapter builds on this evidence by exploring how well breastfeeding support interventions work in relation to how much they cost health services. A systematic review of economic evidence was conducted to appraise and synthesise what was already known about the cost-effectiveness of breastfeeding support interventions for healthy mothers with healthy babies. This was followed by a model-based economic evaluation, which was informed by the systematic reviews of effect and of cost-effectiveness. The health economic component of the evidence syntheses was designed and interpreted with input and advice from the stakeholder engagement groups, workshops and the study steering committee.

Systematic review of economic evidence

The aim of this review of economic evidence was to gain an understanding of whether breastfeeding support interventions for healthy mothers with healthy babies were considered value for money. The overarching review question was: What are the incremental costs and cost-effectiveness of breastfeeding support interventions in comparison with standard care, no intervention, or an alternative intervention for healthy mothers with healthy babies in the UK? The review objectives were to:

1. identify and synthesise the evidence base for incremental costs and cost-effectiveness of breastfeeding support interventions
2. assess the applicability of the evidence to a UK setting
3. identify limitations and uncertainties in the applicable economic evaluations
4. examine the level of consistency between applicable economic evaluations.

Methods

Eligibility criteria

Guidance on searching for economic evidence and conducting reviews of economic evidence was adhered to,[87,110–112] along with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement for reporting systematic reviews.[113] The eligibility criteria for this review mirrored those for the systematic review of evidence of effect, reported in *Chapter 3*, in terms of the population, intervention and comparator. For the population, studies were included if they related to healthy pregnant women considering or intending to breastfeed or breastfeeding healthy babies. Healthy women and babies were considered those who did not require additional medical care. For the intervention criterion, studies were included if they involved contact with professional(s) or volunteer(s) offering support that was supplementary to the standard care offered in that setting. The support could include elements such as reassurance, praise, information and the opportunity to discuss and to respond to the mother's questions. Interventions only provided in the antenatal period were excluded. The review planned to include interventions that were deemed suitable and/or potentially transferable for use in UK settings. Understanding of this was to be gained through stakeholder engagement, with discussion and agreement reached through the focus groups outlined in *Chapter 2*. In relation to the comparator criterion, studies were included if the comparison group received standard care, an alternative intervention or no comparator. In keeping with the systematic review of evidence of effect, it was decided to group studies by whether the intervention was considered a 'breastfeeding only'

intervention or a 'breastfeeding plus' intervention by providing additional broader support targeting a range of health or non-health effects.

The outcomes of interest for the review included the health effects recorded for the systematic review of effect (any and/or exclusive breastfeeding), as well as any outcomes associated with supporting women to breastfeed that were selected and measured in the economic evaluation. These included, but were not limited to, health-related quality of life and healthcare resource use. Economic outcomes of interest were those that were selected, measured and valued, such as incremental costs (cost savings), incremental cost-effectiveness ratios (ICERs), net benefit ratios and quality-adjusted life-years (QALYs). Finally, types of studies included were full economic evaluations (cost-effectiveness, cost–benefit and cost–utility analyses) and partial economic evaluations (cost–consequences analyses, cost analyses, cost descriptions). Economic analyses excluded were non-comparative studies such as cost-of-illness studies, as it was considered that the objectives and results of these study designs would not align with the review question.

Search strategy

A search strategy was developed encompassing three domains: (1) breastfeeding, (2) support and (3) costs/economics, under which relevant index terms and text words were identified and collated. The domain of costs/economics made use of the search filter for economic studies used by the Scottish Intercollegiate Guidelines Network, which was adapted from the search filter designed by the NHS Centre for Reviews and Dissemination at the University of York. Within each domain, search terms were combined with the Boolean operator 'OR' and then across domains with the Boolean operator 'AND'. An example of the list of search terms used for one of the bibliographic database searches can be found in *Appendix 1*. The full search strategies are available from the corresponding author on request.

Five electronic bibliographic databases were searched using all three search domains: MEDLINE via Ovid, EMBASE via Ovid, CINAHL via EBSCO*host*, HMIC via Ovid and MIDIRS via Ovid. Electronic databases for economic literature were searched with a modified search syntax without the need for the search filter for economic studies: American Economic Association's electronic bibliography (EconLit) via EBSCO*host*, NHS Economic Evaluation Database (NHS EED), Paediatric Economic Database Evaluation (PEDE), IDEAS economics database via RePEc and EconPapers via RePEc. The stakeholder working group provided additional advice on relevant sources to facilitate the search. A modified search syntax relating to all three domains was developed and used with the following search engines: ClinicalTrials.gov, WHO International Clinical Trials Registry Platform; the Virginia Henderson International Nursing Library (VHL); GreyNet International; OISter and Google Scholar. For this last search, it was decided to extract the first 500 records from the return, as search results were presented by relevance and this number was deemed sensitive to identifying eligible records. No language or date restrictions were applied other than those inherent in each database; for example, NHS EED contains economic evaluations of health and social care interventions published between 1994 and the end of 2014.

The search was last updated on 2 February 2022. Reference lists of systematic reviews identified during the search and reference lists of eligible studies were consulted to identify any relevant studies missed from the database searches. In addition, eligible studies were forward searched using the 'cited by' tab in Google Scholar. This process was completed in July 2022.

Selection process

Returned records from database searches were transferred into the reference management software EndNote version 20.3 (Clarivate Analytics, Philadelphia, PA, USA) and duplicate records were removed. All unfiled references were then transferred into Covidence to be screened for eligibility for inclusion. Two reviewers independently screened titles and abstracts against the inclusion criteria. All potentially relevant records were brought forward for the full-text sift. During the full-text sift, two reviewers independently read all full papers and reports to assess for eligibility. Any conflicts were discussed, and consensus was reached. Any unresolved conflicts were discussed with the broader project team for final

consensus to be reached. Reasons for exclusion at this stage were recorded. A PRISMA flow diagram was completed to illustrate the selection process.[113]

Data extraction and quality assessment

All studies eligible for inclusion were progressed to data extraction and quality assessment. Two review authors independently extracted and recorded data using a piloted data extraction form in Covidence. The data extraction form for Cochrane reviews was used as a starting point, allowing for relevant data to be extracted from trial-based studies, and modified to include data related specifically to the economic evaluation. These items extracted details on the type of economic evaluation, perspective taken, currency, price year, year of conversion, time horizon, discount rate, data sources, model assumptions, measurement of uncertainty, consideration of heterogeneity, sensitivity analyses, base-case results in terms of incremental costs, cost-effectiveness and/or net-benefit estimates, where available. Data were summarised in tabular form for each included study.

Quality assessment of the economic evaluations was conducted using the checklist provided by the National Institute for Health and Care Excellence (NICE),[111] which is separated into two sections. Section 1 assesses the applicability of each included study to the review question. Those judged directly or partially applicable progress to section 2, which assesses the limitations of the economic evaluation. The checklist, which was partly informed by the Evers checklist[114] and the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist for reporting economic evaluations,[115] is used to review economic evaluations and incorporate findings into the development of NICE guidelines. For section 1, economic evaluations were reviewed independently by two authors and rated as directly applicable, partially applicable or not applicable. Disagreements were resolved by discussion until consensus was reached. Those studies judged to be not applicable to the review question did not progress to section 2 of the checklist for quality assessment. For those judged to be directly or partially applicable, section 2 was completed, again independently by two authors. Section 2 allowed for an overall assessment of the methodological quality of the studies, judging them to have minor limitations, potentially serious limitations or very serious limitations. The classification depended on whether the studies met the 11 quality criteria. Studies classified as having very serious limitations had failed to meet one or more quality criteria that would be highly likely to change the conclusions about cost-effectiveness; those with potentially serious limitations failed to meet one or more criteria that could change the conclusions about cost-effectiveness; and those with minor limitations failed to meet one or more criteria, but this would be unlikely to change the conclusions about cost-effectiveness. Quality assessments for each section were summarised separately in tabular form.

Synthesis methods

Economic evidence profiles were created for those studies deemed directly or partially applicable, with limitations and uncertainty summarised for each study, along with incremental costs, incremental effects and ICERs. In terms of the estimates of costs extracted from individual studies, these were adjusted to GBP 2022 prices using the Campbell and Cochrane Economics Method Group – EPPI-Centre Cost Converter web-based tool, which was created by the Campbell and Cochrane Economics Methods Group and is available at https://eppi.ioe.ac.uk/costconversion/. A narrative synthesis summarised the characteristics and results of the applicable economic evaluations grouped by the level of support provided by the interventions (breastfeeding only or breastfeeding plus), in keeping with the systematic review of effect. Inconsistency between results of economic evaluations were considered, with the potential impact of including methodologically weak studies explored as part of the narrative synthesis. If results were available for subgroups of women who were considered socially disadvantaged, inconsistencies between results were also considered.

This review of economic evidence was not registered; however, the review protocol can be accessed via the repository held by the Queen's University Belfast Research Portal (https://pure.qub.ac.uk/).

Results

Study selection

Following engagement with stakeholders, as reported in *Chapter 2*, agreement was reached that all breastfeeding support interventions identified as effective were deemed suitable and transferable to a UK setting. Justification for this was based on the consideration that if an intervention was effective and resources were available, then implementation should be supported to adapt services to deliver the intervention. For this review of economic evidence, consideration also needed to be given to whether the system and context of the setting were similar to those of the UK. Subsequently, while no consideration was given to country setting for inclusion, only those studies conducted in Organisation for Economic Cooperation and Development (OECD) settings were assessed for applicability, and only those judged to be directly or partially applicable were assessed for limitations.[111]

Figure 4 presents the PRISMA flow diagram for the study selection process. Following the removal of duplicate records, 5699 records were screened at the title and abstract stage. Of these, 5491 were excluded and the full text of 208 records was sought. Nine records could not be retrieved: three were ongoing studies still in the recruitment phase of the aligned RCT, three had no relevant data available and three were awaiting classification with no response from the corresponding authors. Of the 199 records screened for eligibility, 162 were excluded. The main reason for exclusion was the wrong design (*n* = 116), as on full-text review many studies did not report an economic evaluation. Further reasons for exclusion were the wrong intervention (*n* = 28), wrong population (*n* = 15) and wrong outcomes (*n* = 1). The systematic search, identification and screening process resulted in 39 studies eligible for inclusion.

Study characteristics

Of the 39 studies, 7 were conducted in a UK setting,[47,116–120,154] and 14 were conducted in OECD settings, with 7 in the USA,[121–127] 5 across Australia and/or New Zealand,[128–132] and 1 each in Canada[133] and Ireland.[134] The remaining 18 studies were conducted in non-OECD settings, with 10 conducted in sub-Saharan Africa,[135–144] 3 in Asia/South East Asia,[145–147] 3 in Latin America,[148–150] and 2 across multiple countries with high adult and child mortality or undernutrition.[151,152]

Studies that assessed 'breastfeeding only' support interventions (*n* = 21) were shorter in duration, lasting from a minimum of 7 days[133] to a maximum of 10 weeks postpartum,[136] and were delivered by professionals,[47,117,133,134,147,148,150] lay providers[120,124,136,137,142,145,152] or both.[118,119,121,123,126,135]

'Breastfeeding plus' support interventions were assessed in 18 of the 39 evaluations, with primary aims being obesity prevention,[128–131] nutrition improvement,[138,139,151] and maternal and infant care and/or support.[116,120,125,141,144,153] Four studies conducted economic evaluations related to baby-friendly hospital initiative (BFHI) accreditation or Ten Steps to Successful Breastfeeding.[122,132,146,149] The duration of 'breastfeeding plus' interventions ranged from a short time frame with hospitalisation for labour and delivery[122,141] to a longer time frame from pregnancy to infant age of 2 years.[143,154]

A range of methods were used for the economic evaluations. Seventeen studies were partial economic evaluations with a cost analysis comparing two or more alternatives[117,120,122–124,126,128,133,153] or a cost/cost-outcome description with one alternative.[47,121,137,139,142,144,145] Full economic evaluations were reported in the remaining 23 studies, with 10 studies reporting a cost-effectiveness analysis,[118,129,131,135,140,143,147,149–151] 6 studies reporting a cost–benefit analysis, 5 studies reporting a cost-effectiveness and a cost–utility analysis[125,127,132,134,138,146] and 2 studies reporting a cost–utility analysis alone.[119,152] Eighteen of the studies were trial-based economic evaluations, with 13 of these aligned with RCTs[116–118,123,126,128–130,133,136,138,142,155] reported in the Cochrane review.

Applicability

At this stage of the review process, studies conducted in OECD settings progressed to quality assessment. An evidence table of 21 economic evaluations identified for inclusion that were conducted

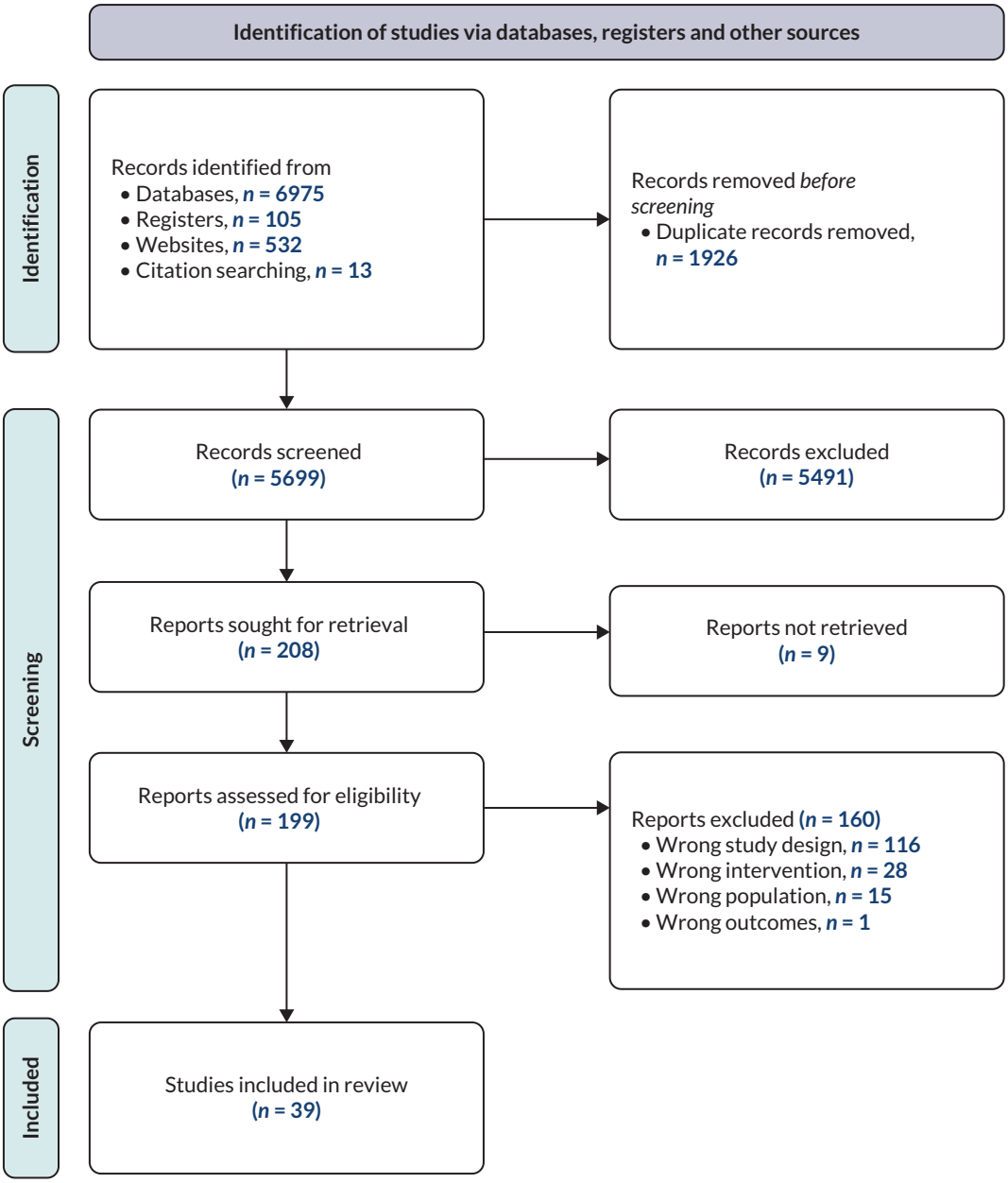

FIGURE 4 The PRISMA flow diagram for review of economic evidence for breastfeeding support interventions for healthy mothers with healthy babies.

in OECD settings is presented in *Appendix 3*, *Table 16*. Each evaluation is described in terms of the setting, intervention, comparator and participant characteristics. Detailed methods of economic analysis are provided, along with a summary of results and the judgment of applicability to the review question.

In terms of the applicability criteria assessed, all 21 studies fulfilled or partially fulfilled the criteria for the study population. Reasons for a partial judgment for the population stemmed from eligibility for participation that did not specify inclusion/exclusion criteria based on the health status of the mother and infant. All interventions were judged to be relevant to the review question, providing either 'breastfeeding only'[47,103,117–119,121,123,124,126,127,133,134] or 'breastfeeding plus' support.[116,120,122,125,128–132,153]

Twelve studies were judged not applicable. The use of a payer perspective taken for the costing of the intervention and/or healthcare resource use in an organisational setting was considered too diverse from a UK provider perspective in six of the studies.[121–125,127] In addition, studies that only provided costs

for one alternative or a cost comparison were deemed not applicable.[47,117,121,123,127,128,132,134,153] Without data on incremental cost or incremental cost-effectiveness comparing two alternatives, the studies failed to provide enough relevant information for the review question. Failing to meet these criteria for applicability would likely change the conclusions about cost-effectiveness or give rise to no meaningful conclusions; thus, these studies were excluded from further consideration.

Nine of the 21 studies were judged applicable. Two studies were deemed directly applicable,[116,119] as they fulfilled all the criteria in terms of the population, intervention, provider perspective for costs and outcomes recorded and reported incremental costs or ICERs with relevant discounting of costs and outcomes where the time horizon was beyond 1 year. The remaining studies were judged to be partially applicable. Either the setting and system where the study was conducted was not the UK[126,130,131,133,154] or the limited time horizon and/or scope for the economic evaluation indicated that not all relevant costs and outcomes had been accounted for.[118,126,133,155]

Evidence of cost-effectiveness from applicable studies

Tables 5 and *6* present the economic evidence profiles for applicable studies that evaluated 'breastfeeding only' support[118,119,126,133] and 'breastfeeding plus' support.[116,130,131,154,155] Base-case results for incremental costs, incremental effects and incremental cost-effectiveness are provided. Costs have been converted and uplifted to 2022 GBP for ease of comparison. Two of the 'breastfeeding only' support studies[126,133] provided healthcare costs and outcomes of effect on breastfeeding separately and did not evaluate in terms of incremental costs per additional woman breastfeeding. For illustrative purposes, we estimated ICERs from the events data on breastfeeding (any and exclusive) for these studies.

The evidence of cost-effectiveness for 'breastfeeding only' interventions in terms of incremental cost per QALY gained comes from one well-conducted model-based cost–utility analysis by Mavranezouli *et al.*[119] At a UK willingness-to-pay (WTP) threshold of £20,000–30,000 per QALY gained, the modelled intervention (+ standard care) was not considered cost-effective in comparison with standard care alone. Three evaluations[118,126,133] have estimates of the cost per additional woman exclusively breastfeeding, which ranged from £67 at 5–12 days to £112 at 8 weeks and £2446 at 6 months postpartum. For the cost per additional woman breastfeeding (any), ICERs ranged from £108 at 8 weeks to £4226 at 6 months postpartum, the latter due in large part to a lower effect. However, without understanding of the threshold for health providers' WTP for an additional woman breastfeeding, exclusively or any, it is unclear whether 'breastfeeding only' support is cost-effective.

The evidence of cost-effectiveness of 'breastfeeding plus' interventions in terms of incremental cost per QALY gained comes from two evaluations: one trial-based without extrapolation beyond study time frame of infant aged 1 year[116] and a second trial- and model-based cost–utility analysis up to child aged 15 years.[130] At a UK WTP threshold of £20,000–30,000 per QALY gained, both interventions (+ standard care) were not considered cost-effective in comparison with standard care alone. None of the studies assessing 'breastfeeding plus' interventions estimated the incremental cost per additional woman breastfeeding. Additional ICERs related to the cost per unit BMI averted for interventions that had a broad aim of obesity prevention in children. One study[154] provided an Australian WTP threshold of AU$500 (equivalent to £236 at 2012 prices), suggesting that these interventions are cost-effective.

Appraisal of limitations and uncertainty in the results

Methodological limitations were judged as minor,[119] potentially serious[116,129–131,155] or very serious.[118,126] The last set reflects that the studies were conducted to assess the effect of an intervention with a relatively short duration to support mothers to continue to breastfeed, with the alongside economic evaluation limited to the time horizon of the trial. Few health effects were measured and valued in the analysis, such as the costs of hospitalisations for infant morbidity, which would likely change the conclusions about cost-effectiveness. The time frames were short and reflect the duration of the intervention and the time horizon for the economic evaluation. Mavrnezouli *et al.*[119] was the only

TABLE 5 Economic evidence profiles for applicable studies in the systematic review of economic evidence of breastfeeding support only interventions for healthy mothers with healthy babies

Study ID	Applicability	Limitations	Incremental			Uncertainty
			Cost (£)[a]	Effect	ICER (£/effect)[a]	
Hoddinott *et al.*, 2012[118]	**Partially applicable** Provider perspective, cost per unit BMI avoided reported, within-trial time horizon from discharge following birth up to infant age 8 weeks	**Very serious limitations** Limited time horizon of 8 weeks; limited costs and outcomes recorded; no sensitivity analyses conducted	24.87; 24.87	0.23; 0.22	107.52 per additional woman breastfeeding; 112.47 per additional woman exclusively breastfeeding	Measures of uncertainty not reported. Alternative intervention costing scenarios suggest costs would be sensitive to varying staff requirements and period of coverage
Mavranezouli *et al.*, 2022[119]	**Directly applicable** UK setting, provider perspective, cost per QALY gained reported, time horizon from birth up to 1 year or lifetime, depending on condition	**Minor limitations** Economic model undertaken over a long time horizon with deterministic and probabilistic sensitivity analysis. May be limited by the quality of the data from sources for model parameters	69.94	0.001	56,074.98 per QALY gained	The value of the ICERs held with the sensitivity analysis. The two-way sensitivity analysis suggested that the cost-effectiveness of the intervention improved as its effectiveness increased and intervention cost decreased
Pugh *et al.*, 2002[126]	**Partially applicable** OECD setting, provider and family perspective with costs reported separately, within-trial time horizon from birth to 6 months, incremental costs reported	**Very serious limitations** Limited time horizon; intervention costs only from provider perspective with health service use not valued; study reported costs and outcomes separately; no sensitivity analyses conducted	332.06; 332.06	0.136; 0.08	2446.22 per additional woman exclusively breastfeeding at 6 months;[b] 4226.21 per additional woman breastfeeding (any) at 6 months[b]	Measure of uncertainty (standard error) reported around incremental costs. Alternative scenarios suggest incremental costs would be sensitive to change in method of valuing staff time ICER estimated herein without addressing uncertainty
Stevens *et al.*, 2006[133]	**Partially applicable** OECD setting, provider and family perspective with costs reported separately, within-trial time horizon from birth to 5–12 days, incremental costs reported	**Potentially serious limitations** Limited time horizon; study reported costs and outcomes separately; no sensitivity analyses conducted	14.55	0.216	67.36 per additional woman exclusively breastfeeding at 5–12 days[b]	Incremental costs were not statistically significant ICER estimated herein without addressing uncertainty

a Costs converted and uplifted to 2022 GBP.
b ICER estimated using trial-based events data.

TABLE 6 Economic evidence profiles for applicable studies in the systematic review of economic evidence of breastfeeding support plus interventions for healthy mothers with healthy babies

Study ID	Applicability	Limitations	Incremental (bootstrapped 95% CI)			Uncertainty
			Cost (£)[a]	Effect	ICER (£/effect)[b]	
Barnes *et al.*, 2017[116]	**Directly applicable** UK setting, provider perspective, cost per QALY gained reported, time horizon from pregnancy up to infant aged 1 year	**Potentially serious limitations** Data not extrapolated beyond study context; broader outcomes not considered which likely would affect cost-effectiveness estimates	2377.38 (−967.25 to 5723.16)	−0.01 (−0.05 to 0.03)	−283,960.75 per QALY gained	The value of the ICERs held with the sensitivity analysis. The probability of group FNP + usual care being more cost-effective than usual care alone at a WTP threshold of £20,000 per QALY gained ranged from 0% to 3%
Hayes *et al.*, 2014[129]	**Partially applicable** OECD setting, provider perspective, cost per unit BMI avoided reported, within-trial time horizon from birth to infant age 2 years	**Potentially serious limitations** Trial-based economic evaluation with a limited time horizon of 2 years, retrospective costing used, no sensitivity analyses conducted	825.95 (487.34 to 1189.91); 825.95 (487.34 to 1189.91)	0.33 (−0.043 to 0.662); 0.23 (0.026 to 0.475)	2383.20 per unit BMI avoided; 355.51 per 0.1-BMI *z*-score reduction	In the scenario analysis, the probability of Healthy Beginnings + usual care being more cost-effective than usual care alone at a WTP threshold of $500 per 0.1-BMI z-score reduction was 66%, compared with the base-case 30%
Morrell *et al.*, 2002[155]	**Partially applicable** UK setting, provider perspective, intervention costs reported only, time horizon limited to within-trial (birth to infant age 6 months)	**Potentially serious limitations** Cost analysis with intervention activities measured and valued only; limited time horizon of 6 months; limited sensitivity analysis	287.16 (127.98 to 437.96)			The incremental cost was largely driven by the intervention cost. The sensitivity analysis to explore uncertainty around the cost of the developing service estimated that a reduction in postnatal support workers time spent on home visits would result in a reduction in intervention costs, but this reduction may adversely impact on future health services resource use
Tan *et al.*, 2020[130]	**Partially applicable** OECD setting, provider perspective, cost per QALY gained reported, modelling was undertaken over a 15-year time horizon	**Potentially serious limitations** QALY estimates based on children's weight status; important outcomes not considered, for example mother's health-related quality of life; healthcare costs from birth to 5 years omitted, with authors' assumption that they are unlikely to affect cost-effectiveness results. These are likely to change the conclusions about cost-effectiveness	297.17 (265.78 to 330.65); 297.17 (265.78 to 330.65); 314.43 (305.02 to 324.90)	0.006 (−0.007 to 0.017); −0.11 (−0.38 to 0.16); −0.09 (−0.28 to 0.11)	49,528.15 per QALY gained (age 15 years); 2701.72 per BMI avoided (age 15 years); 3493.81 per BMI avoided (age 5 years)	The ICER for the cost per QALY gained was not considered cost-effective for the combination intervention, which included a breastfeeding advice component. Subsequently, sensitivity analyses were not conducted to measure uncertainty. The combination intervention was more cost-effective over a 15-year than a 5-year time horizon in terms of BMI unit avoided, due in large part to the projected savings in healthcare costs

TABLE 6 Economic evidence profiles for applicable studies in the systematic review of economic evidence of breastfeeding support plus interventions for healthy mothers with healthy babies (*continued*)

Study ID	Applicability	Limitations	Incremental (bootstrapped 95% CI)			Uncertainty
			Cost (£)[a]	Effect	ICER (£/effect)[b]	
Wen *et al.*, 2017[131]	**Partially applicable** OECD setting, provider perspective, incremental cost per unit BMI avoided reported, time horizon limited to within-trial (birth to infant age 2 years)	**Potentially serious limitations** The study did not assess cost-effectiveness with the cost per QALY gained and conducted a within-trial economic evaluation that did not take into account breastfeeding outcomes or longer-term costs and outcomes	Telephone 266.81 (207.28 to 339.60); SMS 90.37 (53.12 to 134.34)	Telephone −0.05 (−0.35 to 0.23); SMS −0.03 (−0.03 to 0.25)	Telephone 5579.69 per unit BMI avoided; SMS 2696.56 per unit BMI avoided	The value of the ICERs held with the sensitivity analysis. The sensitivity analysis suggested that taking a wider perspective with the inclusion of productivity losses increased the value of the ICER, but the ICER for SMS support remained more favourable than for telephone support when compared with usual care alone Unclear whether either intervention is cost-effective without understanding of the threshold for health providers' WTP for the prevention of BMI gain

FNP, family nurse partnership; WTP, willingness to pay.
a Costs converted and uplifted to 2022 GBP.
b ICER estimated using events data.

evaluation to model the costs and outcomes over the lifetime. While the model fell back on not having trial-based individual participant data for costing the intervention arms and using estimating baseline probabilities for breastfeeding sourced from England alone, the model parameters were comprehensive, with a wide range of conditions accounted for. The authors note some caution in the sources of model parameters; although priority was given to sourcing data from high-quality systematic reviews and meta-analyses or meta-regressions, the quality of the included studies in these reviews suggested a moderate to high level of risk of bias. Those studies judged to have potentially serious limitations tested the effect of 'breastfeeding plus' support. Four of these studies took a within-trial approach, not assessing costs and outcomes beyond the follow-up period.[116,129,131,155] Tan *et al.*[130] modelled intervention effect up to child aged 15 years; however, QALY estimates were based on the children's weight status and the authors did not include healthcare resource use from birth to 5 years with the assumption that differences across groups were unlikely to affect conclusions about cost-effectiveness.

In terms of measures of uncertainty, where sensitivity analysis was reported the value of the ICERs held.[116,119,131] The remaining studies either did not handle uncertainty[130,133] or made allowance for methodological uncertainty with scenario analyses from the base case.[118,126,129,155] These analyses suggested that incremental costs and ICERs were sensitive to change in alternative intervention costing scenarios, for example changing the costing method for staff time or the grade of staff delivering the service.

Consistency between studies

For 'breastfeeding only' support, there appeared consistency in the estimated ICERs for cost per additional woman breastfeeding (any or exclusive); however, without evidence of UK WTP thresholds for this outcome, it is unclear if the intervention would be considered cost-effective by health providers. Only one 'breastfeeding' support evaluation estimated the cost per QALY, which indicated an intervention that was unlikely to be cost-effective when compared with usual care.

There was less consistency between studies assessing 'breastfeeding plus' interventions. Studies that reported cost per QALY concluded that the interventions were not cost-effective. However, Barnes *et al.*[116] reported a negative ICER, as the intervention was more costly and less effective than the control, while Tan *et al.*[130] reported a positive ICER that exceeded the threshold value, similar to findings by Mavranezouli *et al.*[119] None of the studies in this category reported cost per additional woman breastfeeding as an outcome. This is as expected as most of the studies were obesity prevention interventions with a primary outcome of reducing BMI in children. The beneficial effect of breastfeeding (any or exclusive) for up to 6 months against obesity is recognised,[156] hence the support for breastfeeding in these broader interventions.[130,131,154] There was less consistency between studies assessing 'breastfeeding plus' interventions.

Chapter summary

Thirty-nine studies were identified that conducted a partial or full economic evaluation of a breastfeeding support intervention for healthy women compared with a control. Nine of these studies were judged to be applicable or partially applicable to the UK setting. Of these, four assessed the cost-effectiveness of 'breastfeeding only' support and five assessed the cost-effectiveness of 'breastfeeding plus' support.

For 'breastfeeding only' support, there was limited evidence that interventions were cost-effective. One model-based cost–utility analysis estimated that a hypothetical intervention providing six contacts with a health professional or lay person, starting in the antenatal period and continuing in the early postnatal period, was considered unlikely to be cost-effective in terms of cost per QALY gained (£56,075 per QALY gained). There was limited evidence for the incremental cost per additional woman breastfeeding (any or exclusive), with estimates from cost-effectiveness analyses ranging from £67 at 5–12 days to

£2446 at 6 months postpartum. Without WTP thresholds, whether the interventions are cost-effective is unclear. Evidence for breastfeeding plus support was reported in two studies that modelled cost-effectiveness in terms of cost per QALY gained. Both studies identified the interventions as not value for money.

We judged that there was uncertainty in the findings of cost-effectiveness due to the limited number of studies and the lack of good-quality evidence. Limitations of the evaluations centred on a short time horizon, with seven out of nine studies not extrapolating beyond the time frame of the underlying effectiveness study, and a limit to the scope of costs and benefits measured. Five of the nine studies costed the intervention only and did not record the health service resource use of the mother or infant. These limitations suggest uncertainty in the findings. There appeared to be consistency between studies evaluating 'breastfeeding only' support in terms of cost per additional woman breastfeeding (any or exclusive). There was less consistency observed between studies assessing 'breastfeeding plus' interventions. These inconsistencies may be due to the different time horizons, differing scope of costs and benefits measured and valued and different outcomes of cost-effectiveness estimated, which make comparison difficult.

Chapter 6 Systematic review of interventions to support women with long-term conditions to breastfeed

Introduction

Women with LTCs face additional challenges in breastfeeding. The Cochrane review on breastfeeding support for healthy women with healthy term babies by its nature excludes women with LTCs. By receiving additional study funding, we were able to conduct an additional piece of work that looked at the effectiveness of breastfeeding support for women with LTCs.

Aim and objectives

The aim of this systematic review was to identify the effectiveness of breastfeeding support interventions in women with LTCs.

The objectives were to:

1. identify breastfeeding support interventions that have been designed for women with LTCs
2. describe the characteristics of breastfeeding support interventions –
    a. provider
    b. intensity of support
    c. type of support (e.g. face to face, telephone, digital technologies, group or individual support, proactive or reactive)
    d. additional intervention components (i.e. wider child and maternal healthcare)
    e. timing of support (antenatal, postnatal)

3. determine the effectiveness of breastfeeding support interventions for women with LTCs.

Methods

This systematic review followed the methods for systematic reviews of interventions outlined in the Cochrane Handbook.[87] The protocol is registered on PROSPERO (CRD42022337239).

Eligibility criteria

Inclusion criteria

Types of studies
We included individually randomised and cluster-randomised controlled trials.

We excluded the following types of study designs: non-RCTs, quasi-experimental studies, one-group before-and-after studies, cohort studies, case–control studies, case reports and qualitative studies.

Participants
Studies were included if they included women with a long-term physical or mental health condition who were in one of the following groups: pregnant women, mothers who may initiate breastfeeding,

and mothers who are breastfeeding. The LTCs included were based on the list developed as part of the MuM-PreDiCT study.[59]

We also included women with gestational diabetes mellitus (GDM) as this group has a 10-fold increased risk of developing type 2 diabetes mellitus.[55] Moreover, women with GDM are less likely to breastfeed exclusively and face similar challenges to women with type 1 and type 2 diabetes, such as delays in lactogenesis, neonatal hyperglycaemia and increased rates of caesarean section.[157,158]

Studies were also included if the intervention involved fathers and/or other caregivers in addition to mothers with a LTC.

Studies with mothers whose infants required additional care were also included.

We excluded studies that included only women without LTCs. However, we did include studies that included healthy women and women with LTCs, if the data on women with LTCs were reported separately.

Intervention

To be eligible for inclusion, breastfeeding support interventions had to be two-way between the supporter and the participant. They could include discussing the practical management of breastfeeding (e.g. attachment of the baby, identifying baby's cues, issues around delayed lactogenesis, separation of mother and infant), symptom management and/or the use of medications when breastfeeding. They could include elements such as reassurance, praise, information and the opportunity to discuss and to respond to the mother's questions.

We included interventions that were delivered by healthcare professionals and/or peers. Interventions could be delivered antenatally, postnatally or both. Interventions could be delivered in the community or in hospital. Finally, we included interventions that used any mode of delivery (e.g. face to face, telephone, digital technologies, SMS).

We did not include interventions that were purely educational and one-way (i.e. information from a provider with no opportunity for the women to respond).

Comparator

The comparator could be standard care or no breastfeeding support.

Types of outcome measures

We did not exclude studies based on their outcome measures. Our primary outcomes were:

1. number of women who stop any breastfeeding at 4–8 weeks
2. number of women who stop exclusive breastfeeding at 4–8 weeks
3. number of women who stop any breastfeeding at 6 months
4. number of women who stop exclusive breastfeeding at 6 months.

Additional outcomes were:

1. number of women who stop any breastfeeding at 3–4 months
2. number of women who stop exclusive breastfeeding at 3–4 months
3. breastfeeding initiation
4. maternal satisfaction with care
5. maternal satisfaction with feeding method
6. perinatal mental health indicators
7. infant and child morbidity and mortality including neonatal intensive care unit admissions.

Studies that did not measure any of the primary or additional outcomes were included in the review but did not contribute data.

Exclusion criteria

Types of studies

We excluded the following types of study designs: non-RCTs, quasi-experimental studies, one-group before-and-after studies, cohort studies, case–control studies, case reports and qualitative studies.

Participants

We excluded studies that included only women without LTCs (i.e. those that included general populations of healthy women). However, we did include studies that included healthy women and women with LTCs, if the data on women with LTCs were reported separately.

Intervention

We excluded interventions that were purely educational or health promotion and one-way (i.e. information from a provider with no opportunity for the women to respond).

Additional limitations

We did not exclude studies based on date of publication.

Abstracts were eligible for inclusion if they provided sufficient information to extract data. If they did not provide sufficient information, we contacted authors to try to obtain further information.

Studies published in either peer-reviewed journals or the grey literature were eligible for inclusion.

Due to resource constraints, only studies published in English were included.

Searches

Electronic databases

We searched the following databases in August 2022: MEDLINE (via Ovid), CINAHL (via EBSCO*host*), MIDIRS (via Ovid), the Cochrane Central Register of Controlled Trials (CENTRAL), PsycInfo (via Ovid) and EMBASE (via Ovid). Searches were based on the following four strings:

- breastfeeding terms
- support terms
- LTC terms based on the list developed as part of the MuM-PreDiCT study[59]
- RCT terms.

No limits were placed on language, date or publication type. An example MEDLINE search strategy is available in *Appendix 1*.

Additional searches

We searched the reference lists of included studies and systematic reviews identified in the search.

We also searched the list of excluded studies in the Cochrane review on breastfeeding support for healthy women with healthy term babies.[83]

We also searched for grey literature through a targeted website search of relevant third-sector organisations.

Study selection

We imported all records identified via electronic databases into Covidence, a web-based collaboration software platform that streamlines the production of systematic and other literature reviews.[84] The title and abstract of each record were double-screened by two reviewers (AG, LH, SS, AMcF, FL, PB or FXV). If the two reviewers disagreed, consensus was reached via discussion by AG and LH. The same process was followed for full-text screening. The results of this selection process are shown in a PRISMA flow chart (see *Figure 5*).

Data extraction and management

We used Covidence to manage information on study characteristics extracted from the study. Two review team members completed the data extraction template separately (AG, AMcF, FXV, PB, SC, SS). AG addressed any conflicts.

We used the template in Covidence to extract data on the following:

- study details – methods (e.g. cluster or individually randomised trial), funder, conflicts of interest, dates of study, additional linked papers
- participants – number of participants, description of their LTC, context and baseline characteristics (age, parity, ethnicity, education level, socioeconomic status, details of condition, delivery method)

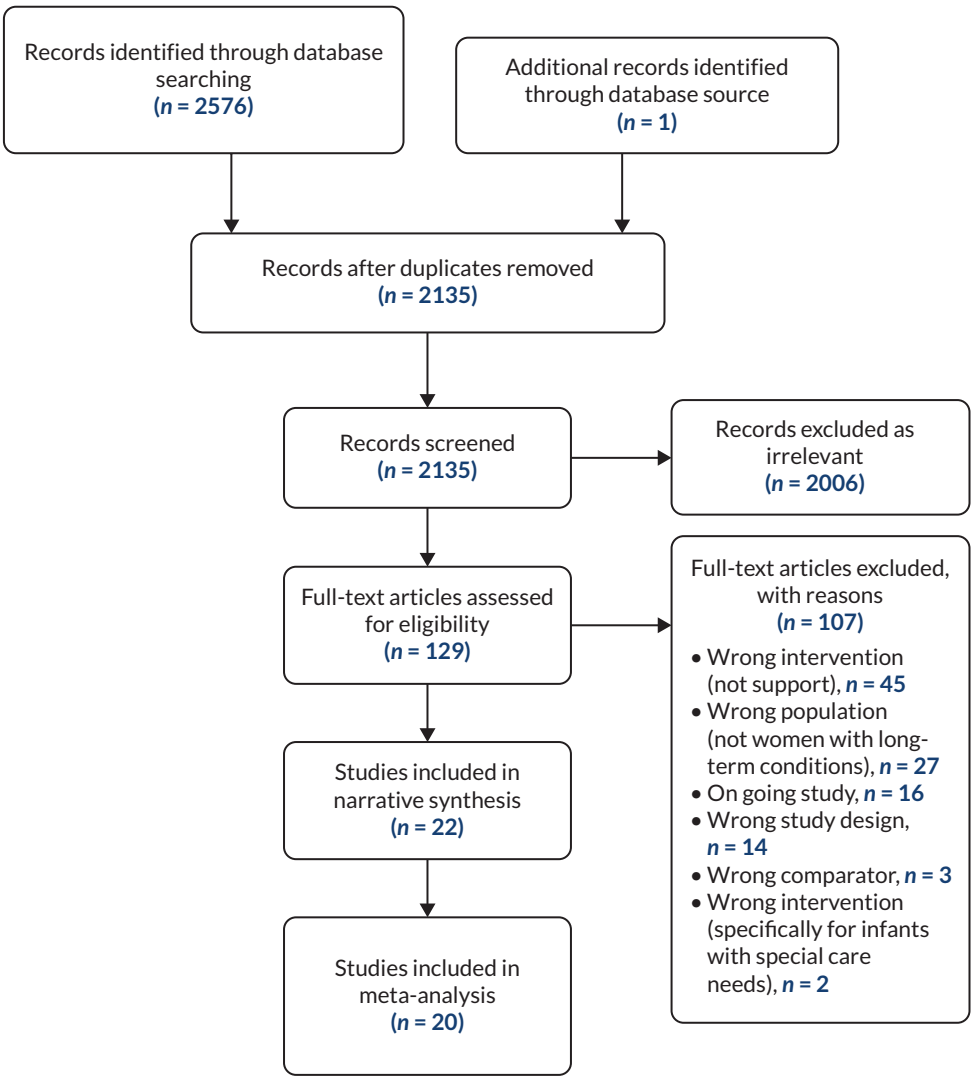

FIGURE 5 The PRISMA flow diagram illustrating study selection.

- intervention – details of person providing support, delivery method (e.g. face to face, telephone, digital), number of contacts, timing of support (e.g. antenatal, postnatal), description of intervention, theoretical basis.

AG extracted study outcome data into a Microsoft Excel® (Microsoft Corporation, Redmond, WA, USA) spreadsheet and they were checked by a second reviewer (LH, SS). For the primary outcomes we extracted data on the number of women randomised to each group and the number of women who had stopped breastfeeding at each time point. Due to the high levels of heterogeneity in additional outcomes, we did not plan to do a meta-analysis with these data, and the findings of the individual study were extracted to a spreadsheet.

When study information was not available, we contacted study authors for further details.

Risk-of-bias assessment

We assessed risk of bias using the Cochrane Risk of Bias Tool 1 in Covidence.[159] Two review members conducted this independently (AG, AMcF, FXV, PB, SC, SS) and conflicts were addressed by AG.

Measures of treatment effect

All data for the main outcomes were dichotomous, and we presented the results as summary risk ratios with 95% CIs.

Unit of analysis issues

Cluster-randomised trials

Sample sizes were adjusted using the methods described in the Cochrane Handbook, incorporating an estimate of the intracluster correlation coefficient derived from the trial.[87] For one study there were insufficient data to calculate this adjustment, so we conducted sensitivity analyses to investigate the impact of including this study.[160]

Trials with multiple arms

To avoid 'double counting' in studies involving one control group and two different intervention groups, we split the control group number of events and participants in half so that we could include two independent comparisons.[87]

Dealing with missing data

Analyses were carried out, as far as possible, on an intention-to-treat basis (i.e. all participants randomised to each group were included in the analyses). We used one of the approaches in the Cochrane Handbook to deal with missing data,[87] whereby all participants randomised were included as the denominator. For missing participants, we imputed an assumed worst-case outcome (i.e. not breastfeeding). Sensitivity analyses were conducted to investigate the effect of excluding studies with high levels of attrition.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the tau-squared, *I*-squared and chi-squared statistics. We regarded heterogeneity as substantial if I^2 was > 30% and either τ^2 was > zero or there was a low *p*-value (< 0.10) in the chi-squared test for heterogeneity. The findings of this were interpreted in conjunction with a consideration of clinical heterogeneity (i.e. type of LTC, context, nature of support).

Assessment of reporting biases

For all outcomes where there were at least 10 studies, we generated funnel plots. We examined plots visually to assess if there was asymmetry that might suggest different treatment effects in smaller studies, which may suggest publication bias.[161] If there was funnel plot asymmetry in the presence of

high levels of heterogeneity, we compared the findings of our random-effects model with those of a fixed-effect model.[162] If the random-effects model showed a more beneficial effect, we considered this suggestive of the intervention being more effective in smaller studies. If it did not show a beneficial effect, we considered that asymmetry may be a result of high levels of heterogeneity.

Data synthesis

Statistical analysis of the main outcomes was performed using Review Manager 5.4 (The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark).[163] As we anticipated some heterogeneity between studies in terms of the interventions and populations, we used a random-effects model. The appropriateness of combining different LTCs was considered in consultation with the study steering committee. It was agreed that this could be considered appropriate for the breastfeeding outcomes. The rationale for this is as follows. First, breastfeeding support was similar across the interventions, the exception being some of the support for women with HIV. This is because there is a risk of transmission of HIV to the child if breastfeeding is not exclusive, and mixed feeding must be avoided.[164] We explored the impact of this further via sensitivity analysis (see *Sensitivity analysis*). Second, there is multimorbidity between the conditions. For instance, antenatal depression has been reported to be associated with obesity,[165] and obesity is a risk factor for GDM.[166] Finally, the prevalence of some of the LTCs is higher in areas of high socioeconomic deprivation,[58] which may increase the similarity of the external factors influencing breastfeeding rates in the studies.

The results were presented as the average treatment effect with 95% CIs, and the estimates of τ^2 and I^2.

Subgroup analysis and investigation of heterogeneity

Due to the small numbers of studies for each outcome, we considered that subgroup analysis or meta-regression would not be meaningful. However, post hoc we considered that the studies with women with HIV were considerably different from studies with women with non-communicable diseases. This is because there is a risk of transmission of HIV to the child if breastfeeding is not exclusive, and mixed feeding must be avoided.[164] We therefore conducted a sensitivity analysis to assess whether or not the studies with women with HIV had biased the overall findings.

Sensitivity analysis

In addition to the sensitivity analysis that separated studies with women with HIV from studies with women with non-communicable diseases, we performed sensitivity analyses based on risk of bias. We first removed studies rated as being at high or unclear risk of bias for allocation concealment. We then removed studies rated as being at high or unclear risk of incomplete outcome data to assess the impact of attrition on our findings. As we had several cluster-randomised studies for which we could not calculate a design effect, we also conducted a sensitivity analysis to assess the impact of these studies on our findings.

Summary of findings

We assessed the certainty of the evidence using the GRADE approach for all main outcomes.[85] This approach considers study limitations, consistency of effect, imprecision, indirectness and publication bias. Evidence can be downgraded by one or more levels for issues in these domains. The findings of this process are reported in a summary of findings table (see *Effects of interventions*).

Results

Description of studies

Results of the search

The database search identified 2134 unique records, and we identified one study from the list of excluded studies in the Cochrane review on breastfeeding support for healthy women with term

babies. We excluded 2006 of these based on title and abstract. We then reviewed 129 full texts, and, of these, 107 were excluded for the following reasons: not a breastfeeding support intervention (i.e. solely educational or health promotion and involved one-way contact with women, or no breastfeeding content), *n* = 45; not women with LTCs, *n* = 27; ongoing study, *n* = 16; wrong study design, *n* = 14; wrong comparator, *n* = 3; and intervention specifically targeted at infants in neonatal units, *n* = 2 (*Figure 5*). We searched MEDLINE and Google for results of any ongoing studies identified in our database search that we could not link to a study in Covidence. In total, 22 studies were included in the review. Several studies linked to additional references in Covidence (e.g. protocol papers, additional findings). For ease of reading, we have referred to just the main paper for each study within the text. We have included additional references in the table of characteristics (see *Appendix 4*, *Table 17*).

Included studies

Of the 22 studies included, 18 contributed data to the review. Four studies did not contribute data. First, Lewkowitz *et al.*[166] did not measure any of the breastfeeding outcomes included in the meta-analyses. Second, Fan *et al.*[167] did not provide the number of women with each condition randomised to each group. Third, Ijumba *et al.*[168] did not provide the raw data in a way that could be used in a meta-analysis. Finally, Martin *et al.*[169] did not report breastfeeding rates by intervention group. Thus, at least 5048 mother–infant pairs were included in the meta-analysis. Three studies provided only partial outcome data, as only some of the relevant outcomes were reported in a way that could be used in a meta-analysis.[170–172]

A summary of the included studies is presented in *Appendix 4*, *Table 17*.

One study reported on two separate interventions: BIBS 1 and BIBS 2.[173] BIBS 1 investigated the effectiveness of breastfeeding support from a lactation counsellor and we therefore included it. However, BIBS 2 compared the effectiveness of electric and manual breast pumps, which does not meet our eligibility criteria, and we have therefore not included it.

The majority of studies were conducted in the following HICs: the USA (*n* = 8),[160,166,172–177] Australia (*n* = 3),[167,169,178] Denmark (*n* = 1),[179] Ireland (*n* = 1)[180] and the UK (*n* = 1).[181] A further five studies were conducted in the following upper-middle-income countries: South Africa (*n* = 3),[168,182,183] China (*n* = 1)[184] and Colombia (*n* = 1).[185] Two studies were conducted in lower-middle-income countries: Kenya (*n* = 1)[186] and India (*n* = 1).[187] Only one study in a lower-income country was identified: Uganda (*n* = 1).[171]

Methods used in trials

Most studies were individually randomised two-arm trials (=14). Six studies used cluster-randomised designs to compare two interventions.[160,168,182,183,186,187] We were unable to adjust for clustering in one of these studies.[160]

Two studies were three-arm studies. For one study we included both interventions.[171] For the other study we included one intervention arm and used the other intervention as the control arm, as it did not contain breastfeeding content and women in the intervention group also received it in addition to their breastfeeding support.[169] We therefore included 23 interventions in the review.

Participants

Long-term conditions

Nineteen of the studies specifically included women with a LTC. However, three studies included both women with and women without a specific LTC and reported findings for these separately. First, two cluster-RCTs included women with and without HIV and analysed these data separately;[168,186] however, data from one of these studies were not presented in a way that allowed us to include them in the meta-analysis.[168] Another study analysed breastfeeding rates separately in women with obesity or

depression.[167] However, as the denominators were not reported in this conference abstract, we could not include the study in our meta-analysis.

The most common condition was overweight and obesity, with nine interventions focused on this.[166,169,172–174,176,179,180,185] The BMI score required for inclusion ranged from 25 to 30 kg/m^2. A further three studies focused on GDM.[160,175,184] With the exception of one,[185] these studies were conducted in HICs.

Substance misuse was the focus of two studies.[178,181] Only one study specifically included breastfeeding support for women with depression.[177]

In LMICs, HIV was the most common condition, with five studies focused on this.[168,171,182,183,187] All women included in these studies received treatment with antiretrovirals.

Socioeconomic status

Four of the studies aimed at women with overweight or obesity were specifically targeted at low-income women.[166,172,174,176]

A further five studies mainly included women who experienced higher levels of socioeconomic deprivation than the national average.[160,169,171,173,178]

Parity

Of the 13 studies that reported parity, all included primiparous and multiparous women. No study had an exclusion criterion relating to parity. Rates of primiparity ranged from 15% to 57%.

Mode of birth

Of the nine studies that reported mode of birth, eight reported that most women had a vaginal delivery;[166,172–174,178,179,181,182] however, rates of caesarean section ranged from 25% to 45%. Only one study reported that more women gave birth via caesarean section.[184]

Interventions

Interventions varied in how much content was directed at breastfeeding support. Breastfeeding support was the sole focus of six interventions for women with overweight/obesity.[167,173,174,180,184,185]

Other studies provided additional components to help with the LTC of interest. All the interventions aimed specifically at HIV-positive women included other aspects of prevention of mother-to-child transmission.[171,182,183,186,187] Four studies that focused on either women with GDM or those who were overweight or obese also provided weight loss support (e.g. diet and exercise).[160,169,175,176] Finally, one study of women with depression also provided cognitive–behavioural therapy for management of depression.

Several other studies included additional components to support the following: maternal well-being;[176–178] aspects of infant well-being such as growth and immunisations;[172,178,179,181,182] and wider parenting skills such as sleep and activities.[166,172,176]

Provider

Half of the included studies used an intervention that was provided either exclusively or in part by a lactation consultant[160,167,169,172,173,175,177,179,180,184] or certified breastfeeding consultant.[185] Only a few studies involved support from other healthcare professionals, including midwives,[178,180] nurses[173] and maternity support workers.[181] Two studies of obese women also included dietitian support.[169,175]

Ten studies included some form of non-healthcare professional support, which may or may not have been combined with professional support. This mainly took the form of support from trained community

members.[166,168,172,174,183,186,187] In two studies it involved online peer support from other breastfeeding mothers with GDM or obesity.[176,184] In another study it involved a family member or friend being nominated as supporter.[171] These studies tended to be conducted in LMICs or areas of socioeconomic deprivation in HICs.[176,184]

Several studies also involved a combination of healthcare professional and non-healthcare professional support and the professional's role tended to focus on training or facilitating sessions.[172,176,182]

Mode of delivery

Most studies included at least some face-to-face support. Ten studies only used face-to-face support.[168,169,171,172,178,181–183,186,187] Five studies used a combination of face-to-face and telephone support.[160,170,173–175] Often the calls were used to provide reactive additional support for women with difficulties.

Three studies used a combination of digital, telephone and face-to-face support. In two studies the digital element took the form of online support groups.[167,176] One study was conducted during the COVID-19 pandemic and so face-to-face group clinics were replaced with video calls (or individual face-to-face appointments).

Only two studies used the telephone as the sole delivery mode.[167,179] One study only used a digital approach, which included online lessons, video calls and messaging.[177]

Timing of delivery

Most interventions were delivered in both the antenatal and the postnatal periods.[160,168,169,172–177,180,182–187] Five studies were postnatal only[167,171,178,179,181] and one study was antenatal only.[166]

Number of contacts

We tried to group intervention intensity as low intensity (three or fewer contacts), moderate intensity (four to eight contacts) or high intensity (nine or more contacts).

Intensity levels

Just over half of the interventions were judged to be of moderate intensity.[167–169,171–173,178,181–185] However, a number of these interventions also offered reactive support as required so the number of contacts may have been greater. Conversely, we judged eight of the interventions to be high intensity.[160,174–177,179,180,186] This may be an overestimation, as for some breastfeeding was not the sole focus or it depended on women engaging with digital content such as support groups. No studies were low intensity and two did not specify.[166,187]

Control group care

Most studies compared the intervention with standard care.[167,171–175,179–181,183–187] However, there are considerable differences in what constituted standard care between the studies, for example the provision of lactation consultants or peer supporters or care in a baby-friendly hospital (see *Appendix 4*).

In four studies the comparator was a non-breastfeeding intervention designed to promote other aspects of infant or maternal health such as weight loss or maternal mental health.[168,170,176,177]

Finally, two studies compared the breastfeeding support intervention with limited breastfeeding support.[166,178]

Risk of bias in included studies

See *Appendix 5*, *Table 18*, for a summary of our risk-of-bias assessments.

Random sequence generation (selection bias)

Most studies were rated as being low risk for this domain (*n* = 18). Four studies did not provide sufficient information.[167,173,178,183]

Allocation concealment (selection bias)

We judged only eight studies as being at low risk of allocation concealment.[169,172,176,178–180,184,185] One study was judged to be high risk.[181] No other studies provided sufficient information, so we judged them as unclear.

Blinding of personnel and participants (performance bias)

Owing to the nature of the intervention, it was not possible to blind participants and/or personnel, so we judged all studies as being at high risk of bias.

Blinding of outcome assessment (detection bias)

As all breastfeeding data were all self-reported by mothers, we judged 21 of the studies as being at high risk of bias in this domain. We judged one cluster-RCT to be at unclear risk of bias as it would potentially have been possible to blind the women in a cluster to allocation, but it is not clear if it was the unblinded service providers who collected the data.[187]

Incomplete outcome data (attrition bias)

Half of studies were judged as being at high risk of attrition bias, which we defined as loss to follow-up of > 20%.[160,169,172,174,177,180–183,185,187] Nine studies were judged as having a low risk of bias in this domain.[166,168,171,173,175,176,179,184,186] Finally, two studies were judged to be at unclear risk of bias. One study had higher attrition in the control group (12%) than in the intervention group (4%) and no details were provided.[178] A second, Fan *et al.*,[167] provided insufficient information to make a judgement.

Selective outcome reporting (reporting bias)

We judged most studies (*n* = 15) as being at unclear risk of bias for this domain. The primary reason was that studies did not have a published protocol for us to assess this. The remaining seven studies were judged as being at high risk of bias for the following reasons: not reporting outcomes detailed in protocol or methods;[160,172,182] not fully reporting outcomes;[174] not stating when breastfeeding would be measured;[175] and adding in breastfeeding outcomes post hoc.[166,179]

Other biases

We judged only two studies to be at low risk of bias in this domain.[166,175] Eleven studies were judged as being at high risk of bias for one or more of the following reasons: insufficient information to adjust for clustering;[160] baseline imbalance;[172,173,176,182,183] industry funding/support;[173,176,182] financial conflicts of interest;[187] loss of clusters;[182] issues with intervention implementation;[173] and reporting errors.[172] For the remaining nine studies there was insufficient information to judge this domain.

Effects of interventions

Table 7 presents the summary of findings for the primary outcomes. The forest plots for all primary and additional breastfeeding outcomes are presented in *Appendix 6*, *Figures 9–15*. We have also included tables with the data from the sensitivity analyses (see *Tables 19–24*) and the funnel plots for studies with at least 10 studies in *Appendix 6*, *Figures 16 and 17*.

Primary outcomes

Stopping any breastfeeding at 4–8 weeks

Ten studies with 1385 participants measured stopping any breastfeeding at 4–8 weeks.[160,172,173,175,177–181,184] Breastfeeding support interventions probably have little to no impact on the number of women stopping any breastfeeding at 4–8 weeks (RR 0.90, 95% CI 0.77 to 1.06; *moderate-certainty evidence*). There was no evidence of any significant statistical heterogeneity ($\tau^2 = 0.01$, $I^2 = 16\%$, $\chi^2 = 10.71$, $p = 0.30$). See *Appendix 5*, *Figure 9*.

TABLE 7 Summary of findings: breastfeeding support compared with usual care for women with LTCs

Outcomes	Anticipated absolute effects[a] (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty of the evidence (GRADE)
	Risk with usual care	Risk with breastfeeding support			
Not any breastfeeding at 4–8 weeks	339 per 1000	**305 per 1000** (261 to 359)	**RR 0.90** (0.77 to 1.06)	1385 (10 RCTs)	⨁⨁⨁◯ Moderate[b]
Not exclusive breastfeeding at 4–8 weeks	686 per 1000	**631 per 1000** (570 to 707)	**RR 0.92** (0.83 to 1.03)	2165 (10 RCTs)	⨁⨁◯◯ Low[b,c]
Not any breastfeeding at 6 months	513 per 1000	**425 per 1000** (343 to 518)	**RR 0.83** (0.67 to 1.01)	1018 (6 RCTs)	⨁⨁⨁◯ Moderate[b]
Not exclusive breastfeeding at 6 months	820 per 1000	**779 per 1000** (730 to 820)	**RR 0.95** (0.89 to 1.00)	3206 (12 RCTs)	⨁⨁⨁◯ Moderate[c]

a The **corresponding risk** (and its 95% CI) is based on the assumed risk in the intervention group and the **relative effect** of the intervention (and its 95% CI).
b We downgraded one level for serious concerns in imprecision. Small number of participants and 95% CI overlap the line of no effect and fail to exclude important benefit.
c We downgraded one level for serious concerns about substantial and unexplained heterogeneity.

A sensitivity analysis using only studies assessed as having low risk of bias for allocation concealment found very similar effect estimates. A sensitivity analysis excluding studies rating as being at low risk of attrition bias changed the direction of the findings; however, the 95% CI widened and still crossed the line of no effect (RR 1.02, 95% CI 0.62 to 1.67). Similarly, a sensitivity analysis excluding studies with cluster-RCTs, for which we could not calculate a design effect, found similar effect estimates to the main analysis. No studies in this analysis included interventions for women with HIV. See *Appendix 5*, *Table 19*.

An assessment of publication bias via funnel plot inspection suggested possible asymmetry; however, given the small number of studies, we would interpret this with caution. See *Appendix 5*, *Figure 15*.

Stopping exclusive breastfeeding at 4–8 weeks

Ten studies with 2165 participants measured stopping exclusive breastfeeding at 4–8 weeks.[160,172–174,177,179,180,184,186,187] Breastfeeding support interventions probably have little to no impact on the number of women stopping exclusive breastfeeding at 4–8 weeks (RR 0.92, 95% CI 0.83 to 1.03; *low-certainty evidence*). There was evidence of substantial statistical heterogeneity ($\tau^2 = 0.01$, $I^2 = 53\%$, $\chi^2 = 19.32$, $p = 0.02$). See *Appendix 5*, *Figure 10*.

A sensitivity analysis using only studies assessed as having low risk of bias for allocation concealment and low risk of attrition bias found similar effect estimates; however, the 95% CI widened. Similarly, a sensitivity analysis excluding studies with interventions for women with HIV found similar effect estimates. Excluding the cluster-RCT for which we could not calculate a design effect changed the effect estimate and 95% minimally (RR 0.94, 95% CI 0.84 to 1.06). See *Appendix 5*, *Table 20*.

An assessment of publication bias via funnel plot inspection suggested possible asymmetry; however, given the small number of studies and substantial levels of heterogeneity, we would interpret this with caution. See *Appendix 5*, *Figure 16*.

Stopping any breastfeeding at 6 months

Five studies reporting on six interventions in studies with 1018 participants measured stopping any breastfeeding at 6 months.[171,175,178,180,184] Breastfeeding support interventions probably have no impact on the number of women stopping any breastfeeding at 6 months (RR 0.83, 95% CI 0.67 to 1.01; *moderate-certainty evidence*). There was no evidence of any significant statistical heterogeneity ($\tau^2 = 0.00$, $I^2 = 0\%$, $\chi^2 = 1.21$, $p = 0.98$). See *Appendix 5*, *Figure 11*.

Sensitivity analyses using only studies assessed as having low risk of bias for allocation concealment and for attrition widened the 95% CI. A sensitivity analysis excluding interventions for women with HIV found very similar effect estimates and 95% CIs. There were no cluster-RCTs for which we could not calculate a design effect. See *Appendix 5*, *Table 21*.

An assessment of publication bias via funnel plot inspection was not possible because of the small number of studies.

Stopping exclusive breastfeeding at 6 months

Eleven studies[171,174,176,178–180,182–184,186,187] reporting on 12 interventions in studies with 3206 participants measured stopping exclusive breastfeeding at 6 months. Breastfeeding support interventions probably have little to no impact on the number of women stopping exclusive breastfeeding at 6 months (RR 0.95, 95% CI 0.89 to 1.00; *moderate-certainty evidence*). There was evidence of substantial statistical heterogeneity ($\tau^2 = 0.01$, $I^2 = 84\%$, $\chi^2 = 67.87$, $p < 0.00001$). See *Appendix 5*, *Figure 12*.

Sensitivity analyses using only studies assessed as having low risk of bias for allocation concealment and for attrition both widened the 95% CI. Sensitivity analyses excluding interventions for women with HIV found very similar effect estimates and 95% CIs. There were no cluster-RCTs for which we could not calculate a design effect. See *Appendix 5*, *Table 22*.

An assessment of publication bias via funnel plot inspection suggested possible asymmetry; however, given the small number of studies and high levels of statistical heterogeneity, we would interpret this with caution. See *Appendix 5*, *Figure 17*.

Additional outcomes

We have divided the additional outcomes into breastfeeding and non-breastfeeding outcomes. The additional breastfeeding outcomes were analysed via meta-analysis, and the forest plots are available in *Appendix 6*. There was considerable heterogeneity in the non-breastfeeding additional outcomes and how they were measured. Meta-analysis was therefore not appropriate, so a narrative summary is provided instead.

Additional outcomes: breastfeeding

Not initiating breastfeeding

Eight studies[166,169,173,176–180] with 903 participants measured not initiating any breastfeeding. However, studies varied considerably in their definition of breastfeeding initiation (e.g. within 1 hour, within 24 hours, before discharge, or ever). In addition, some interventions did not commence until breastfeeding had been initiated. This led to some studies having higher rates of breastfeeding at 4–8 weeks than at initiation, which was nonsensical. A post hoc decision was therefore made to exclude this outcome from the review.

Stopping any breastfeeding at 3–4 months

Four studies[173,177,180,184] with 522 participants measured stopping any breastfeeding at 3–4 months. Breastfeeding support interventions probably have little to no impact on the number of women stopping any breastfeeding at 3–4 months (RR 0.86, 95% CI 0.53 to 1.38; *low-certainty evidence*). There was evidence of substantial statistical heterogeneity ($\tau^2 = 0.14$, $I^2 = 68\%$, $\chi^2 = 9.29$, $p = 0.03$). See *Appendix 5*, *Figure 13*.

A sensitivity analysis using only studies assessed as having low risk of bias for allocation concealment and low risk of attrition bias found similar effect estimates; however, the 95% CI widened. No studies in this analysis included interventions for women with HIV or cluster-RCTs for which we could not calculate a design effect. See *Appendix 5*, *Table 23*.

An assessment of publication bias via funnel plot inspection was not possible because of the small number of studies.

Stopping exclusive breastfeeding at 3–4 months

Five studies[171,175,178,180,184] with six interventions and 785 participants measured stopping exclusive breastfeeding at 3–4 months. Breastfeeding support interventions may have a beneficial effect on the number of women exclusively breastfeeding at 3–4 months (RR 0.77, 95% CI 0.59 to 1.00; *low-certainty evidence*). There was evidence of substantial statistical heterogeneity ($\tau^2 = 0.06$, $I^2 = 76\%$, $\chi^2 = 20.89$, $p = 0.0009$). See *Appendix 5*, *Figure 14*.

A sensitivity analysis using only studies assessed as having a low risk of bias for allocation concealment widened the 95% CI (RR 0.70, 95% CI 0.48 to 1.02). Removal of the one study with HIV-positive women widened the 95% CI marginally (RR 0.77, 95% 0.59 to 1.01). Conversely, removal of studies at low risk of attrition bias showed a more beneficial effect estimate and narrower 95% CI (RR 0.60, 95% CI 0.46 to 0.80). There were no studies for which a design effect could not be calculated. See *Appendix 5*, *Table 24*.

An assessment of publication bias via funnel plot inspection was not possible because of the small number of studies.

Additional outcomes: non-breastfeeding

Fifteen of the included studies non-breastfeeding outcomes between intervention and control groups. We grouped these into the following categories: infant outcomes (seven studies); maternal physical health (six studies); maternal mental health (four studies); maternal satisfaction with feeding method (one study); and measured maternal satisfaction with care (one study).

Infant outcomes

The most frequently measured outcome was infant growth (six studies). Five studies were focused on overweight/obesity or GDM and the aim was to reduce infant weight at follow-up. No differences between intervention and control groups were found in any of these studies. Three studies used weight-for-length or -age *z*-scores. More specifically, Aldana-Parry *et al.*[184] calculated scores at 4 months and found no difference between intervention and control groups (0.75 ± 1.3 vs. 0.65 ± 1.7; $p = 0.76$). Similarly, Reifsnider *et al.*[172] found no difference in scores at 12 months between intervention and control groups (0.72 ± 1.13 vs. 0.84 ± 1.20, $p = 0.66$). Fiks *et al.*[176] reported there was no difference in weight-for-length *z*-scores (raw data not provided). Carlsen *et al.*[179] measured infant weight at 6 months and found no differences between the intervention and control groups (8169 g ± 963 vs. 8356 g ± 959; $p = 0.18$). Similarly, an additional paper for the study by Steube *et al.*[188] found no difference in infant length, weight, BMI percentile, biceps circumference or triceps skinfolds at any time point.

However, in LMIC settings where low weight is the concern, intervention infants were more likely to have a slightly larger increase in weight-for-age score between 2 and 12 months [odds ratio (OR) 1.08; $p = 0.035$].[183]

Only one study,[178] which was an intervention for women with substance misuse, measured rates of immunisations at 2, 4 and 6 months and found no differences between the groups at any time point ($p = 0.757$, $p = 0.477$, $p = 0.283$).

Only one study measured rates of hospital admissions and childhood infectious diseases. Chapman *et al.*[174] found beneficial effects in terms of infant hospitalisations in the intervention compared with the control in the first 3 months (10% vs. 26%; $p = 0.03$) and 6 months after birth (11% vs. 28%; $p = 0.03$). There were also higher rates of diarrhoea in control infants at 6 months but not at 3 months (details not provided). There was no difference in rates of otitis media or attendance at the emergency department.

One study that examined support for HIV-positive women included infant mortality as an outcome and did not identify any differences between intervention and control groups (aOR 1.6, 95% CI 0.37 to 6.91).[187]

Maternal physical health outcomes

Four studies focused on overweight/obesity or GDM included maternal weight as an outcome and did not identify any differences between intervention and control groups (note that in some studies the comparator included a weight loss component). All studies measured maternal weight using different methods. Aldana-Parry *et al.*[185] compared the mean maternal weight loss between the first week postpartum and 4 months and found no difference between the intervention (1.9 kg ± 4.7 kg) and the control (4.2 kg ± 5.1 kg; $p = 0.07$). Similarly, in the DEBI study,[160,188] there were no differences between intervention and control groups in weight, BMI, and skinfolds at 6 weeks, 4 months, 7 months or 10 months. The intervention group had a slightly smaller waist circumference at 7 months than the control group (104.70 cm vs. 115.60 cm; $p = 0.046$). However, there was no difference at any other time points. A linked paper to Ehrlich *et al.*[189] reported that although women with GDM in the intervention group had higher rates of meeting their postpartum weight loss goals than controls at 6 weeks (20.9% vs. 17.4%; $p = 0.54$), 7 months (38% vs. 23.9%; $p = 0.13$) and 12 months (37.5% vs. 21.4%), none of these reached statistical significance. Martin *et al.*[169] reported no difference in BMI between the intervention and the control group at 3 months (30.6 ± 5.4 vs. 30.7 ± 4.1; *p*-value not reported) or 6 months (31.2 ± 4.4 vs. 30.6 ± 4.3; *p*-value not reported).

Two studies included measures related to blood sugar levels and found no differences between groups. The DEBI study[188] found no differences in fasting insulin and 2-hour glucose at any time points. Similarly, Martin *et al.*[169] found no differences in HBA_{1c}, insulin or glucose levels at any time points.

Two studies included maternal physical activity as an outcome and found no differences between groups. The DEBI study[188] found no difference in levels of physical activity at 6 weeks ($p = 0.92$) or 7 months ($p = 0.91$). Fiks *et al.*[176] also included number of periods of physical activity per week as an outcome measure and found no difference between intervention and control groups at 6 months (2.2 vs. 2.0; $p > 0.05$).

Two studies[188,189] included measures related to diet (percentage of calories from dietary fat) and found a small reduction in the intervention group compared with the control group at 7 months (8.04% vs. 7.47%; $p = 0.002$).[189] This was not significant at 6 weeks (7.44% vs. 8.02%; $p = 0.54$). The DEBI study[188] included 23 variables related to diet, which were measured at 6 weeks, 4 months, 7 months and 10 months. There were differences in only four of these, and all with the exception of water consumption favoured the control group: sweetened beverages at 6 weeks (intervention 79.49% vs. control 53.85%; $p = 0.03$); drinking water at 4 months (intervention 78.57% vs. control 47.83%; $p = 0.76$); fast food (intervention 88% vs. control 52%; $p = 0.01$); and using fat for cooking (intervention 100% vs. control 77.78%; $p = 0.04$).

One study[178] measured maternal substance use using the Opiate Treatment Index and found similar scores in the intervention and control groups for the following: heroin (0.22 vs. 0.04; $p = 0.084$), other opiates (2.0 vs. 0.14; $p = 0.72$), cannabis (2.0 vs. 1.9; $p = 0.56$), amphetamines (0.15 vs. 0.11; $p = 0.99$), benzodiazepines (1.0 vs. 1.5; $p = 0.74$); alcohol (0.21 vs. 0.36; $p = 0.22$) and cigarettes (10 vs. 12; $p = 0.52$). A higher score suggests more use. Findings were similar at 6 months.

Finally, one study[187] that provided support for women with HIV measured maternal mortality and found no difference between the intervention and control groups (aOR 0.58, 95% CI 0.23 to 1.34).

Maternal mental health outcomes

Two studies included depression as an outcome, with mixed findings. First, in a study[183] for HIV-positive women, women in the intervention group had a larger decrease in depressed mood by 12 months than women in the control group (OR 1.08; $p = 0.002$). However, Pezley *et al.*[177] provided cognitive–behavioural therapy for the management of depression and anxiety to both intervention and control groups. Depression scores and anxiety scores remained consistent with baseline in the third trimester and at 6 and 12 weeks postpartum (significance levels not reported).

Two studies included a measure of stress. In a support intervention[176] for women with obesity, parental stress was included as an outcome and scores were similar between intervention and control groups (30.2 vs. 29.6; $p > 0.05$).

The DEBI study[188] for women with GDM included stress management as an outcome and found no difference between the groups at 6 weeks, 4 months, 7 months or 10 months.

Maternal satisfaction with feeding method

Only one study measured the mother's satisfaction with feeding method. In a study with women with obesity, Lewkowitz *et al.*[166] asked participants if they would be likely to breastfeed again were they to have another child, and there was no difference between the intervention and control groups (RR 1.03, 95% CI 0.86 to 1.25).

Maternal satisfaction with feeding method

Only one study measured satisfaction with care. MacVicar *et al.*[181] examined support for women receiving opioid substitution and reported that the intervention group felt more satisfied with the

support received (mean 9.6 vs. 6.8). However, the number of participants was very small (*n* = 11) and significance was not tested.

Strengths and limitations

We followed systematic review methods outlined in the Cochrane Handbook;[87] however, there is the potential that bias was introduced into the review. First, because of resource constraints we were able to include only studies published in English, so there is a risk of language bias. Second, although we attempted to identify all published and unpublished trials on breastfeeding support for women with LTCs, it is possible that not all existing trials were identified. Funnel plot analyses suggested some possible asymmetry; however, interpretation is limited by the small number of studies. Third, we were unable to adjust for clustering in one of the studies; however, a sensitivity analysis from which that study was removed did not change the effect estimate. Fourth, there was considerable variability in how breastfeeding initiation was measured (e.g. within 24 hours vs. ever), so a post hoc decision was made to exclude this outcome from the meta-analysis. Finally, there is heterogeneity between the studies, which may be a result of differences between interventions and population characteristics, in particular the LTCs.

Chapter summary

Twenty-two studies were identified that examined the effectiveness of breastfeeding support for women with single LTCs. Of these, 20 contributed data to the review. No studies were identified that included women specifically with MLTC.

The most common conditions were overweight and obesity, with nine studies focused on this. A further three studies were for women with GDM. Five studies included women with HIV. Two studies were for women with substance misuse problems and only one was for women with anxiety and depression. Interventions varied in terms of whether they only provided breastfeeding support or if they also provided support for the LTC. The majority of studies had an antenatal component.

We performed meta-analysis for all the primary and additional breastfeeding outcomes. There was little to no difference between intervention and controls for any of these. We judged these outcomes to be low and moderate certainty. When we used a sensitivity analysis to exclude interventions for women with HIV, there was no meaningful change in the effect estimates. We considered the overall risk of bias in the included trials to be mixed. Sensitivity analyses excluding studies rated as being at high or unclear risk of bias for allocation concealment and attrition also did not alter the effect estimates.

Fifteen studies measured secondary non-breastfeeding outcomes, which included infant weight, infant health, maternal weight and health behaviours, satisfaction with care and satisfaction with feeding method. Because of the heterogeneity in outcomes, meta-analysis was not possible and so results were reported narratively. There was little evidence of any beneficial intervention effect on any of the secondary outcomes measured.

To conclude, this review identified that the breastfeeding support interventions for women with LTCs probably had little to no effect on breastfeeding outcomes. There is, therefore, a need for further research to develop breastfeeding support interventions for women with LTCs.

Chapter 7 Systematic review of views and experiences of breastfeeding support for women with long-term conditions

Introduction

As part of our additional funding for MLTC, we sought to complement the evidence on effectiveness from review 4 (see *Chapter 6*) by undertaking a mixed-methods review looking at what is known about the views and experiences of breastfeeding support in women with LTCs.

Objectives

1. To identify and synthesise the views and experiences of those involved in delivering and receiving breastfeeding support for women with LTCs.
2. To identify the contextual factors (barriers/facilitators) affecting the implementation of breastfeeding support for women with LTCs.

Methods

The protocol for this systematic review is registered on PROSPERO (CRD42022374509).

Search strategy

A comprehensive search strategy was developed employing combinations of search filters, free-text words and index terms relating to breastfeeding support and LTCs. Terms relating to LTCs were derived from the list of LTCs published in the MuM-PreDiCT study.[59] We included permutations and variations of search terms, and no limits were placed on date or language.

The following bibliographic databases were searched for primary studies in October 2022: MEDLINE, EMBASE, CINAHL, PsycInfo and MIDIRS. Citations and references in all included papers and any relevant reviews identified were screened for eligible primary studies. This review was conducted in parallel with a systematic review that aimed to identify the effectiveness of breastfeeding support interventions for women with LTCs (see *Chapter 6*). Therefore, we conducted additional searches to identify any papers related to the interventions included in that review. We also searched reference lists of included studies and searched websites of organisations related to key conditions (e.g. Diabetes UK, Crohn's and Colitis UK, Epilepsy Action).

Eligibility criteria

Inclusion criteria

Studies were included if they reported qualitative and/or quantitative findings of primary research exploring the views and experiences of breastfeeding support for women with LTCs, including breastfeeding women and babies and their families, service providers, managers, commissioners and policy-makers.

Qualitative and quantitative studies, either standalone or in mixed-methods designs, were included.

Long-term conditions are defined according to the list published as part of the MuM-PreDiCT study, in addition to others such as GDM that are not included in the MuM-PreDiCT study. However, mothers with GDM can face some similar issues to women with type 1 or type 2 diabetes when breastfeeding (e.g. neonatal hypoglycaemia, delayed lactogenesis, preterm birth).

Studies were included that reported any type of experiences relating to breastfeeding support in women with LTCs. This included breastfeeding support that is delivered/received in any setting (e.g. in hospital, at home or in the community). This may be formal or informal support that has been provided as part of a breastfeeding support intervention, routine care or in the context of women's personal support networks, including any subjective participant-reported outcomes and constructs such as attitudes, views, beliefs, perceptions, understandings or experiences.

There were no restrictions on publication date.

Exclusion criteria

We excluded articles only reporting on impact evaluation results of breastfeeding support interventions (i.e. effectiveness of interventions).

We excluded studies that included only women without LTCs (i.e. those that included general populations of healthy women).

Due to resource constraints, only studies published in English were eligible for inclusion.

Selection process

Two reviewers independently screened titles, abstracts and relevant full texts against the predetermined eligibility criteria. Any discrepancies were resolved through discussion and consultation with a third reviewer.

Data extraction and quality appraisal

Data extraction was undertaken independently by two reviewers using a piloted data extraction form. Any discrepancies were resolved through discussion and consultation with a third reviewer.

We assessed the quality of qualitative studies and qualitative components of mixed-methods studies using the Critical Appraisal Skills Programme (CASP) tool.[190] We used the Axis tool to assess the quality of cross-sectional surveys.[191] Quality assessments were conducted by one reviewer and checked by a second reviewer (AG or AmcF). Consensus was reached through discussion. No studies were excluded from the review because of poor quality.

Data synthesis

We adopted a mixed-methods synthesis approach. We first undertook two preliminary syntheses of quantitative (synthesis 1) and qualitative (synthesis 2) studies, and then integrated qualitative and quantitative data into a cross-study synthesis (synthesis 3).

For synthesis 1 (qualitative studies) we used an inductive approach to thematic synthesis to synthesise qualitative findings from included studies.[91] This involved three overlapping and interrelated stages: (1) line-by-line coding of findings from primary studies; (2) categorisation of codes into descriptive themes; and (3) development of analytical themes to describe or explain previous descriptive themes. To ensure the robustness of the synthesis, various techniques to enhance trustworthiness were undertaken, including audit trail, multiple coding, reviewer triangulation and team discussions. For synthesis 2 (quantitative studies) we used narrative methods to synthesise quantitative findings from included studies,[90] tabulating characteristics of included quantitative studies and developing a conceptual framework to organise the included quantitative studies. The overall data synthesis (synthesis 3) brought together quantitative and qualitative findings from primary studies included in syntheses 1 and 2. First, the conceptual frameworks developed in both syntheses were compared and combined

into a comprehensive framework to characterise the views and experiences of breastfeeding support in women with LTCs across multiple contexts/settings. Second, the qualitative and quantitative findings from syntheses 1 and 2 were integrated using the resulting framework. Two reviewers independently reviewed the categorisation of findings and refinements were discussed in review team meetings until a consensus was achieved and the final synthesis results were established.

Results

The searches identified 5058 records, which were assessed against the inclusion criteria. Title and abstract screening resulted in 119 records considered eligible or inconclusive. Full-text articles were then retrieved and assessed for eligibility. Three records could not be retrieved. Of the 116 records screened at full text, 92 were excluded. The main reason for exclusion was not reporting views and experiences of breastfeeding support (e.g. views and experiences of breastfeeding) (*n* = 37), followed by involving study designs not eligible for inclusion in this review (e.g. effectiveness studies) (*n* = 22). Other reasons for exclusion were abstract-only records (e.g. conference proceedings) (*n* = 19), focusing on ineligible populations (*n* = 8), not reporting on views and experiences (*n* = 5), and language of publication not being English (*n* = 1). The remaining 24 studies were included in the final synthesis (see *Figure 6*).

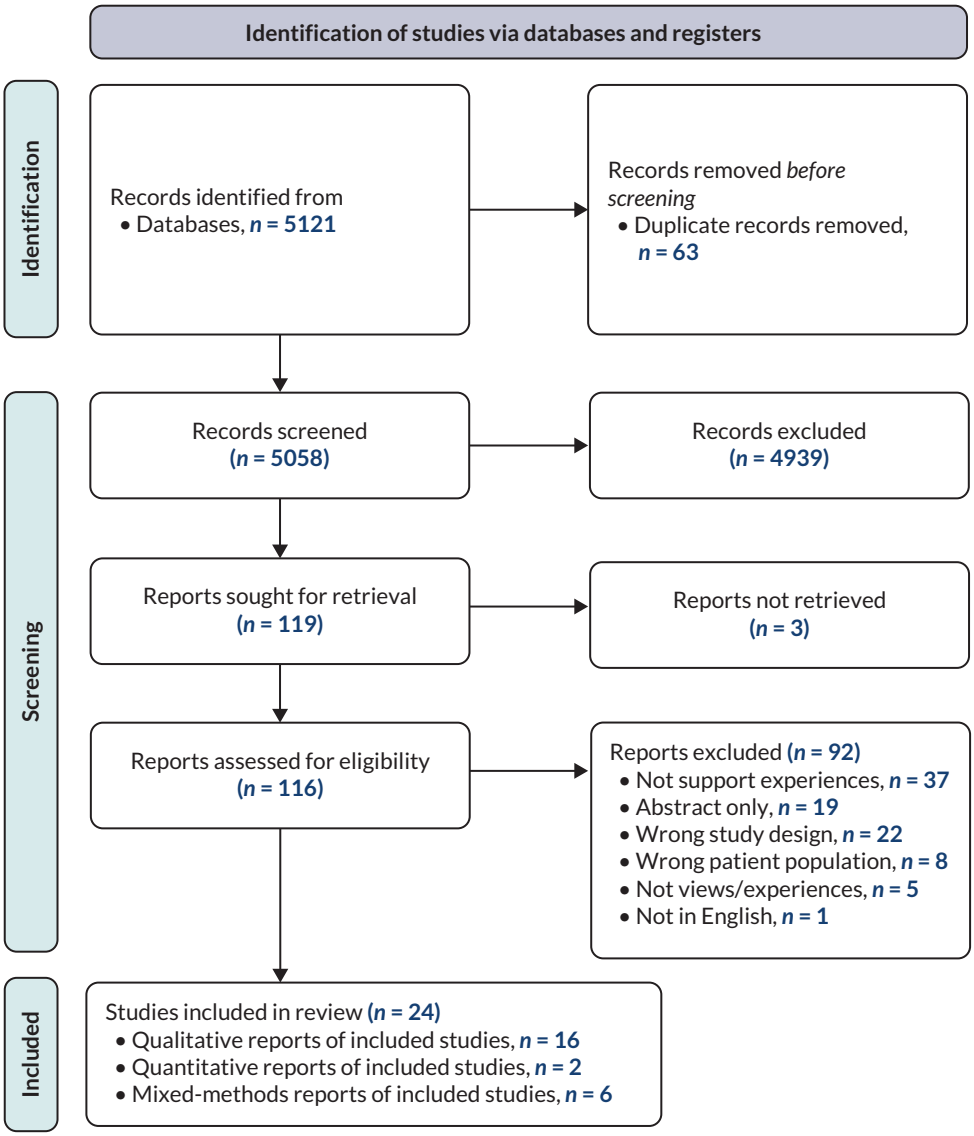

FIGURE 6 The PRISMA flow diagram.

Summary of included studies

A summary of key characteristics of included studies is presented in *Appendix 6*, *Table 25*.

Twenty-four studies contributed qualitative data to the synthesis, comprising 16 qualitative,[192–206,209] two quantitative[208,210] and six mixed-methods[181,207,211–214] studies. Studies reported data from 12 countries (Australia, Canada, Ghana, Ireland, Japan, Kenya, Malawi, South Africa, Uganda, UK, USA and Zambia). Study samples in intervention groups ranged from 6 to 296 participants. Study settings included hospitals, community settings and population-based studies. Long-term conditions covered were HIV (eight studies),[192,197,199,203–205,212,213] obesity and overweight (five studies),[195,196,201,206,210] substance use (five studies),[181,194,198,202,207] diabetes in pregnancy (three studies),[200,208,214] disabilities (two studies)[193,209] and a rare genetic disorder (one study).[211] The eight studies of HIV-positive women were all from LMICs, while studies of women with all other conditions were all from HICs.

Quality appraisal

We assessed 16 qualitative studies[192–206,209] and the qualitative components of 5 mixed-methods studies.[181,211–214] Four cross-sectional surveys were assessed.[207,208,210,211] The quantitative components of four mixed-methods studies[181,212–214] did not provide data relevant to our review and were not assessed for quality.

The quality of qualitative studies was mixed. Although all studies had clear objectives for which qualitative methodology was appropriate, the specific study design was not always explained or justified (see *Appendix 6*, *Table 26*). Three studies[192,196,213] provided full details of methods for recruitment, data collection and rigorous analysis; most other studies had at least partially addressed these aspects. Three studies[199,211,212] provided insufficient information to assess the rigour of data analysis. O'Reilly *et al.*[206] was the only study that adequately considered the relationship between researchers and participants. Most studies confirmed ethics approval and at least partially discussed ethical issues. Andrews *et al.*[193] failed to report ethics approval and provided no discussion of ethical issues other than the use of consent forms. Howard *et al.*[198] stated that their study was exempt from Institutional Review Board approval without giving reasons and did not discuss any ethical issues. All but one study[199] at least partially addressed the credibility and transferability of findings.

The quality of the cross-sectional surveys was weak with poor reporting (see *Appendix 6*, *Table 27*). Laws *et al.*[211] and Rasmussen *et al.*[210] provided very little information with which to assess quality and did not address key quality criteria. Matsunaga *et al.*[208] was the only survey for which the sampling strategy was clear, although the low response rate raised concerns about non-response bias. None of the studies used previously tested or published instruments/measurements. Ethics approval was reported for all surveys except Rasmussen *et al.*[210] Three studies[207,208,211] discussed some limitations of their studies, but only Matsunaga *et al.*[208] presented conclusions that were justified by the results.

Stakeholders' perceptions and experiences

Stages 1 and 2 of our mixed-methods synthesis resulted in the categorisation of primary quantitative and qualitative data from included studies into 70 descriptive themes. Building on these findings, further analytical work was undertaken to develop analytical themes, resulting in four overarching analytical themes: (1) additional breastfeeding support needs for mothers with LTCs; (2) the availability of breastfeeding support for mothers with LTCs; (3) the role and practice of breastfeeding support for mothers with LTCs; and (4) suggested strategies to improve breastfeeding support for mothers with LTCs. The four themes are described below. *Appendix 6*, *Table 28*, illustrates the distribution of primary studies underpinning each analytical theme and provides exemplar data extracts from primary studies.

Additional breastfeeding support needs for mothers with long-term conditions

Included studies highlighted a range of challenges that breastfeeding mothers with LTCs face, which are compounded by more general individual, social and cultural challenges commonly reported as faced by all breastfeeding mothers.

Challenges of specific relevance to breastfeeding mothers with LTCs reported in included studies comprised issues relating to mother and infant health conditions and treatments; stigma, misconceptions and misinformation; and emotional distress.

Health-condition-related barriers included a range of concerns and difficulties with breastfeeding due to the mother's condition or treatment,[196,198,201,208,209] as well as concerns and difficulties relating to any conditions or medical interventions needed for the infant.[200,207,208] These circumstances, either mother or infant related, could also be associated with hospital episodes and hospital stays (e.g. admission to critical care), which raised additional barriers and difficulties in terms of breastfeeding; for example, in one study length of infant hospital stay was inversely correlated with breastfeeding duration.

Concerns relating to stigma, misconceptions and misinformation about the interplay of illness, treatment and breastfeeding (e.g. perceptions of breast milk safety while taking antiretroviral medicine) were reported in several studies.[194,197,198,203,204] These experiences could result in women feeling pressure to stop breastfeeding and adopt other feeding options, with the potential for abrupt weaning and breast complications.[197,198,203,204] In some contexts, breastfeeding practices were reported as more driven by financial or family pressures than by health information.[203]

The emotional implications of breastfeeding challenges experienced by those living with a LTC were reported in several studies.[196,205,211,212,214] These impacts included difficulties with contact and bonding,[198,201] which were associated with treatment and recovery, birth complications, and mothers' histories of abuse and trauma. Some of these emotional implications translated into some effects on mothers' self-efficacy,[198] with a few studies reporting issues associated with perceived breast milk insufficiency[193,197,200,209] and latching.[193, 209] One study found that emotional comorbidity was linked to perceived failure to breastfeed,[211] and two other studies reported that women with LTCs were less likely to fully breastfeed[214] and more likely to breastfeed for a shorter duration[212] than mothers in the general population.

Availability of breastfeeding support for mothers with long-term conditions

Several studies reported variable or insufficient availability of breastfeeding support for mothers with LTCs,[194,200,206,207,209,211,213] particularly when taking multiple healthcare settings beyond maternity care into consideration. For example, one study[213] found that health professionals in a mother-to-child HIV transmission programme infrequently advised women on breastfeeding (41% of visits), and in another study[207] only 23.3% of women reported that healthcare staff at an opioid-dependence treatment centre had discussed breastfeeding with them. Alongside insufficient breastfeeding support, some of these studies also reported that women perceived a lack of or limited information from professionals or available in hospital settings.[194,199,200,208,209]

Health professionals' training and knowledge on specific issues and risks to breastfeeding success for women with LTCs and their infants can be limited, and not necessarily seen to warrant a tailored approach to breastfeeding support.[203,210,211] Conversely, one study found that specialist breastfeeding clinics were perceived as useful by women; however, these were found to be underused.[202] The hospital environment can be a source of both support and tension for breastfeeding mothers with LTCs,[198] and a range of organisational barriers were reported,[208] including lack of resources (staffing and time) for breastfeeding support; competing in-hospital systems and policies that hinder the promotion of breastfeeding; and lack of continuous interprofessional support system, particularly following discharge and in terms of collaborating and co-ordinating with other facilities. However, how supportive of breastfeeding hospital settings are perceived to be may depend on women's own feeding choices; for example, one study found that women who breastfed for shorter amounts of time or not at all were more likely to report that the hospital encouraged breastfeeding.[207] More generally, postnatal care experiences may also influence maternal attitude to and receptiveness of breastfeeding support, particularly on aspects of care that relate to privacy and confidentiality.[181,201]

The role and practice of breastfeeding support for mothers with long-term conditions

The experiences of breastfeeding support of mothers with LTCs reported in the included studies involved a wide range of interactions, individuals, settings and factors that could align to impact (positively or negatively) the complex journeys of breastfeeding mothers with LTCs.

Some studies reported a range of positive interactions with breastfeeding supporters,[181,192,193,200,202,207] including several strategies and forms of support that had enabled women to successfully breastfeed, such as adaptations (e.g. adapted positioning), equipment/aids (e.g. use of breast pumps), physical assistance from others (e.g. physical help with positioning) and access to peer support (e.g. women with the same health condition). There were examples of positive breastfeeding support accounts that highlighted the element of psychological and emotional support embedded in breastfeeding support.[181,202,205] One study found that women who were encouraged to breastfeed by healthcare staff were more likely to breastfeed for longer durations.[207]

Most studies, however, reported support experiences shaped by a range of negative interactions (e.g. communication difficulties)[181,192,193,200,202,209] as well as barriers faced by breastfeeding supporters. Breastfeeding support could sometimes be overshadowed by condition-related support.[203,212] The provision of breastfeeding support for women with LTCs was described as requiring more time and effort and being more challenging personally and in terms of competence.[196,208] Some studies reported that breastfeeding supporters lacked specialist training,[194,199,203,210] with some women not feeling well understood by health professionals[211] and reporting that trust in health professionals as a source of advice was an important factor.[213] Persistent barriers could hinder the effectiveness of breastfeeding support interventions; for example, one study found that several barriers remained after participation in a peer counselling intervention to promote exclusive breastfeeding, which contributed to a preference for mixed feeding.[204]

Several studies reported issues relating to perceived pressures or biases in favour of certain feeding options. This was identified in a range of directions: one study reported that women perceived an intense pressure to breastfeed and felt like breastfeeding was characterised as the only acceptable choice, which led to expressions of fear and anxiety about not being able to breastfeed successfully.[193] In another study, health professionals reported that encouraging mothers to practise exclusive breastfeeding was a policy directive, and concluded that mothers were not given an opportunity to weigh the pros and cons of other feeding options;[197] there were also examples where avoiding breastfeeding was promoted as the ideal option.[212] Other studies identified inconsistent and inaccurate messaging about complementary[199,213] and mixed[204,214] feeding options; and some studies identified encouragement of formula supplementation, which some women associated with difficulties in establishing breastfeeding.[200,201,206]

Information and knowledge provision was reported as one key aspect of breastfeeding support to help empower informed maternal feeding decisions.[198,206,212] However, within the healthcare community, women obtained information and misinformation about breastfeeding in the context of their health condition.[194,199,200,202,208,209] The understanding of the perceived benefits of breastfeeding was reported as an important driver of successful breastfeeding support,[194,212] which could in turn drive the motivation,[194] determination,[206] self-confidence[195] and resilience[198] needed to breastfeed in the context of living with an LTC.

Suggested strategies to improve breastfeeding support for mothers with long-term conditions

Studies echoed a range of suggestions from participants regarding potential strategies for improving breastfeeding support, with the most widely reported suggestion being the need to acknowledge the role and influence of other sources of support (e.g. partners, family, friends, peers, external professionals, web-based resources) and involve them in the provision of breastfeeding

support.[192,194,195,200,201,205–209,213,214] Another important suggestion was to increase the provision of education and raise awareness among health professionals[196,206,210,211] to improve their understanding of the specific breastfeeding support needs of mothers with LTCs and to help them identify feeding problems earlier. One study sought women's views[202] and feasibility tested[181] a proposed set of intervention components (including practical skills, emotional support, availability of accurate and accessible information, individualised support provision and a low-stimuli environment) with positive results. Another suggestion for improvement reported across several studies was that breastfeeding support for women with LTCs should be established early on antenatally and carried on postnatally, ensuring continuity and consistency throughout.[196,197,200,214]

Chapter summary

This review comprised 24 studies reporting primary research on the views and experiences of breastfeeding women with LTCs and/or support providers.

The health conditions covered were HIV-positive, obesity and overweight, substance use, diabetes in pregnancy, disabilities and a rare genetic disorder. The overall quality of included studies was mixed, with some studies rated as weak and/or with poor reporting.

Four key themes were identified: (1) additional breastfeeding support needs for women with LTCs; (2) availability of breastfeeding support for mothers with LTCs; (3) the role and practice of breastfeeding support for mothers with LTCs; and (4) suggested strategies to improve breastfeeding support for mothers with LTCs.

Included studies highlighted a range of additional support needs for women with LTCs, such as issues relating to treatments or medical interventions for women's/infant's health conditions, misconceptions, misinformation or emotional distress. Studies reported variable or insufficient availability of breastfeeding support for mothers with LTCs, particularly when support was needed across multiple healthcare settings beyond maternity care. The data suggest complex breastfeeding journeys involving a wide range of interactions, individuals, settings and factors that could impact women's experiences.

Chapter 8 Review of economic evidence for women with long-term conditions

Overview

The previous two chapters reported a systematic review identifying (1) which interventions were effective in providing breastfeeding support for women with single LTCs, and (2) the barriers to and facilitators of breastfeeding support to women with LTCs. This chapter builds on this evidence by assessing how well breastfeeding support interventions for women with LTCs work in relation to how much they cost health services. As evidence was expected to be limited, a systematic review of economic evidence was planned to appraise and synthesise what is known about the cost-effectiveness of breastfeeding support interventions for mothers with LTCs.

Aim and objectives

The aim of this review of economic evidence was to gain an understanding of whether breastfeeding support interventions for mothers with LTCs were considered value for money. The overarching review question was: What are the incremental costs and cost-effectiveness of breastfeeding support interventions in comparison to standard care, no intervention, or an alternative intervention for mothers with LTCs? The review objectives were to:

1. identify and synthesise the evidence base for incremental costs and cost-effectiveness of breastfeeding support interventions
2. assess the applicability of the evidence to a UK setting
3. identify limitations of and uncertainties in the applicable economic evaluations
4. examine the level of consistency between applicable economic evaluations.

Methods

Eligibility criteria

The methods for conducting the systematic review of economic evidence followed those reported in *Chapter 5*, with guidance on searching for economic evidence and conducting reviews of economic evidence adhered to,[87,110–112] along with the PRISMA 2020 statement for reporting systematic reviews.[113] The eligibility criteria mirrored those for the systematic review of evidence of effect for women with LTCs, reported in *Chapter 6*, in terms of the population, intervention and comparator.[113] For the population, studies were included if they related to pregnant women with long-term physical or mental health conditions considering or intending to breastfeed or mothers who were breastfeeding. For the intervention criterion, studies were included if they involved contact with professional(s) or volunteer(s) offering support that was supplementary to the standard care offered in that setting. The support could include elements such as reassurance, praise, information and the opportunity to discuss and to respond to the mother's questions. Interventions could be provided in the antenatal or postnatal period or both. In relation to the comparator criterion, studies were included if the comparison received standard care, an alternative intervention or no comparator.

The outcomes of interest for the review included the health effects recorded for the corresponding systematic review of effect (any and/or exclusive breastfeeding), as well as any outcomes associated with supporting women with LTCs to breastfeed that were selected and measured within the economic evaluation. These included, but were not limited to, health-related quality of life and healthcare resource

use. Economic outcomes of interest were those that were selected, measured and valued, such as incremental costs (cost savings), ICERs, net benefit ratios and QALYs. Finally, the types of studies included were full economic evaluations (cost-effectiveness, cost–benefit and cost–utility analyses) and partial economic evaluations (cost–consequences analyses, cost analyses, cost description). Economic analyses excluded from the review were non-comparative studies such as cost-of-illness studies, as it was considered that the objectives and results of these study designs would not align with the review question.

Search strategy

The search strategy developed for the systematic review of economic evidence reported in *Chapter 5* was used for this review. In brief, this encompassed three domains, (1) breastfeeding, (2) support and (3) costs/economics, under which relevant index terms and text words were identified and collated. It was decided that search terms related to LTCs would not be included in the search, as records returned without this domain were manageable for screening. The domain of costs/economics made use of the search filter for economic studies used by the Scottish Intercollegiate Guidelines Network, which was adapted from the search filter designed by the NHS Centre for Reviews and Dissemination at the University of York. Within each domain, search terms were combined with the Boolean operator 'OR', and then across domains with the Boolean operator 'AND'. An example of the list of search terms used for one of the bibliographic database searches can be found in *Appendix 1*. The full search strategies are available from the corresponding author on request.

Five electronic bibliographic databases were searched using all three search domains: MEDLINE via Ovid, EMBASE via Ovid, CINAHL via EBSCO*host*, HMIC via Ovid and MIDIRS via Ovid. Electronic databases for economic literature were searched with a modified search syntax without the need for the search filter for economic studies: American Economic Association's electronic bibliography (EconLit) via EBSCO*host*, NHS EED, Paediatric Economic Database Evaluation (PEDE), IDEAS economics database via RePEc and EconPapers via RePEc. A modified search syntax relating to all three domains was developed and used with the following search engines: ClinicalTrials.gov, WHO International Clinical Trials Registry Platform, the Virginia Henderson International Nursing Library (VHL), GreyNet International and OISter. No language or date restrictions were applied, other than those inherent in each database; for example, NHS EED contains economic evaluations of health and social care interventions published between 1994 and the end of 2014.

The search was last updated on 18 August 2022. Reference lists of systematic reviews identified during the search and reference lists of eligible studies were consulted to identify any relevant studies missed from the database searches. In addition, eligible studies were forward searched using the 'cited by' tab in Google Scholar. This process was completed in November 2022.

Selection process

Returned records from database searches were transferred into the reference management software EndNote version 20.3 (Clarivate Analytics, Philadelphia, PA, USA) and duplicate records were removed. All unfiled references were then screened for eligibility for inclusion. Two reviewers independently screened titles and abstracts against the inclusion criteria. All potentially relevant records were brought forward for the full-text sift. During the full-text sift, two reviewers independently read all full papers and reports to assess for eligibility. Any conflicts were discussed, and consensus was reached. Any unresolved conflicts were discussed with the broader project team for final consensus to be reached. Reasons for exclusion at this stage were recorded, with reasons for exclusion at full-text screen noted. A PRISMA flow diagram was completed to illustrate the selection process.

Data extraction and quality assessment

All studies eligible for inclusion were progressed to data extraction and quality assessment. Two review authors independently extracted and recorded data in Microsoft Excel using the data extraction form developed for the review reported in *Chapter 5*. Items extracted included the type of economic

evaluation, perspective taken, currency, price year, year of conversion, time horizon, discount rate, data sources, model assumptions, measurement of uncertainty, consideration of heterogeneity, sensitivity analyses, base-case results in terms of incremental costs, cost-effectiveness and/or net-benefit estimates, where available. Data were summarised in tabular form for each included study.

Quality assessment of the economic evaluations was conducted using the checklist provided by NICE,[111] which is separated into two sections. Section 1 assesses the applicability of each included study to the review question. Those judged directly or partially applicable progress to section 2, which assesses the limitations of the economic evaluation. For section 1, economic evaluations were reviewed independently by two authors and rated as directly applicable, partially applicable or not applicable. Disagreements were resolved by discussion until consensus was reached. For those judged to be directly or partially applicable, section 2 was completed, again independently by two authors. Section 2 allowed for an overall assessment of the methodological quality of the studies, judging them to have minor limitations, potentially serious limitations or very serious limitations. Quality assessments for each section were summarised in tabular form.

Synthesis methods

Economic evidence profiles were created for those studies deemed directly or partially applicable, with limitations and uncertainty summarised for each study, along with incremental costs, incremental effects and ICERs. In terms of the estimates of costs extracted from individual studies, these were adjusted to GBP 2022 prices using the Campbell and Cochrane Economics Methods Group – EPPI-Centre Cost Converter web-based tool, which was created by the Campbell and Cochrane Economics Methods Group and is available at https://eppi.ioe.ac.uk/costconversion/. A narrative synthesis summarised the characteristics and results of the applicable economic evaluations. Inconsistency between results of economic evaluations were considered, with the potential impact of including methodologically weak studies explored as part of the narrative synthesis.

This review of economic evidence was not registered; however, the review protocol can be accessed via the repository held by Queen's University Belfast Research Portal (https://pure.qub.ac.uk/).

Results

Study selection

Figure 7 presents the PRISMA flow diagram for the study selection process. Following the removal of duplicate records, 5732 records were screened at the title and abstract stage. Of these, 5713 were excluded and the full text of 19 records were sought. One record, which was an ongoing study, could not be retrieved (Jacobson, 2020). Of the 18 records screened at full text, 13 were excluded. The main reason for exclusion was the wrong study design (n = 7), followed by wrong population (n = 4) and wrong intervention (n = 2). The systematic search, identification and screening process resulted in five studies eligible for inclusion.

Study characteristics

An evidence table of the five economic evaluations identified for inclusion is presented in *Appendix 7*, *Table 29*. Each evaluation is described in terms of the setting, intervention, comparator and participant characteristics. Detailed methods of economic analysis are provided, along with a summary of results and the judgment of applicability to the review question. Of the five studies, one was conducted in a UK setting and included women with a BMI of > 25 kg/m^2.[215] Two were conducted in OECD settings of the USA: one that addressed women–infant dyads with prenatal use of opioids[216] and a second that presented data for a subgroup of medically high-risk women.[125] The remaining two studies were conducted in South Africa, addressing support for women living with HIV.[217,218]

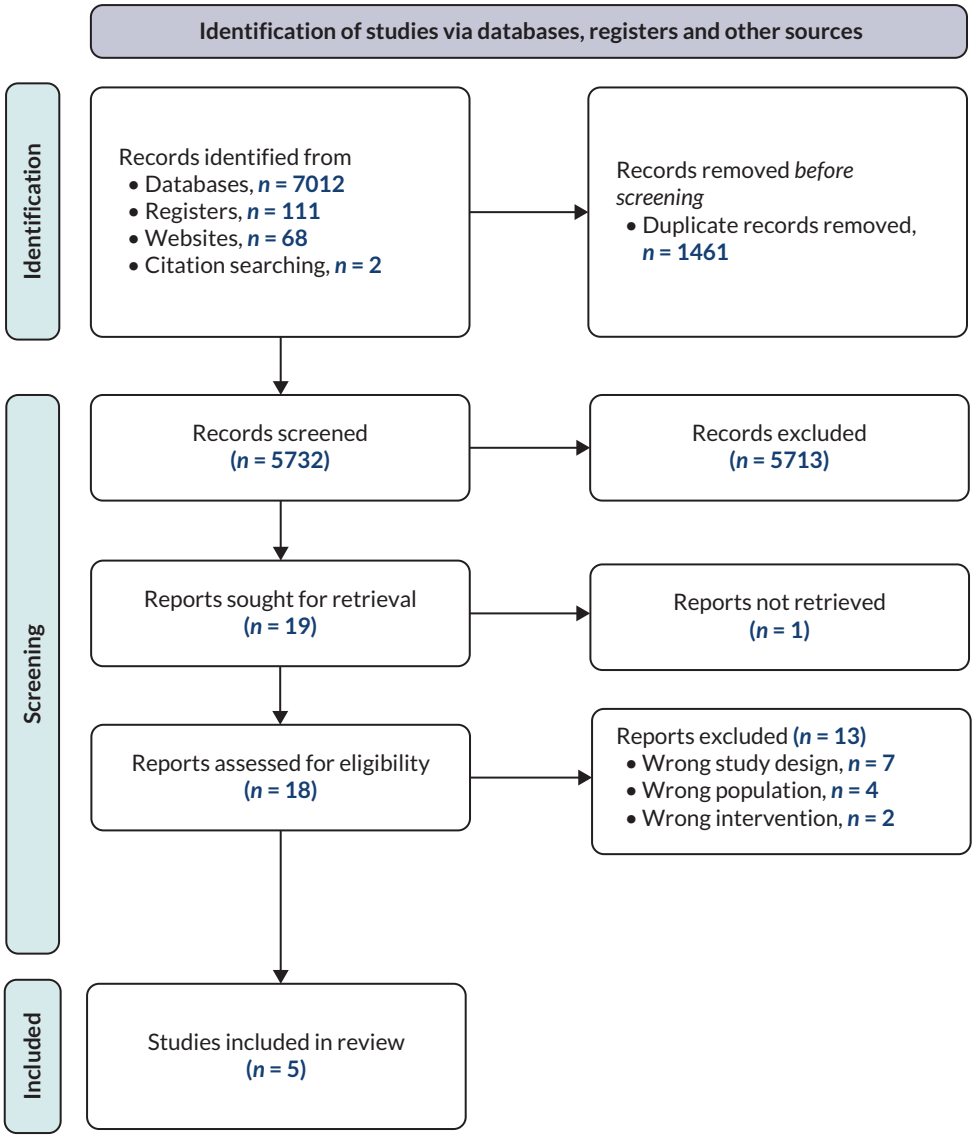

FIGURE 7 The PRISMA 2020 flow diagram for review of economic evidence for breastfeeding support interventions for women with LTCs.

Three studies assessed 'breastfeeding only' support interventions.[216–218] Avram *et al.*[216] assessed the short-term intervention of rooming-in following birth in hospital to support women to breastfeed their infants with neonatal opioid withdrawal. Desmond *et al.*[217] assessed an intervention to promote exclusive breastfeeding through home and clinic visits from late pregnancy to 6 months postpartum, which were delivered by a lay breastfeeding counsellor. Maredza *et al.*[218] assessed three infant-feeding strategies to prevent mother-to-child transmission of HIV, which included a strategy of actively supporting breastfeeding with extended nevirapine prophylaxis for 12 months. 'Breastfeeding plus support' interventions were assessed in two of the five evaluations, with a broader programme of weight management at 8–16 weeks postpartum,[215] and doula support during pregnancy and up to 8 weeks postpartum.[125]

A range of methods were used for the economic evaluations. One study reported a partial economic evaluation alongside a feasibility RCT, with a cost-outcome description comparing two alternatives.[215] Full economic evaluations were reported in the remaining four studies, with one study reporting a trial- and model-based cost-effectiveness analysis assessing cost per increased month of exclusive breastfeeding,[217] one reporting a trial-based cost–benefit analysis with the return on investment,[125] and

one study reporting a model-based cost–utility analysis with incremental cost per disability-adjusted life-year averted reported, respectively,[216] and a model-based cost–utility analysis with cost per QALY gained.[216]

Evidence of cost-effectiveness

Of the four studies that conducted a full economic evaluation, all judged the breastfeeding support interventions assessed for the base case to be cost-effective at given WTP thresholds, when cited,[216–218] or reported a positive return on investment. Avram *et al.*,[216] in assessing rooming-in to support mothers to breastfeed their infant with neonatal opioid withdrawal, concluded that the intervention led to reduced costs and increased effects. The cost savings were largely due to the reduced need for pharmacotherapy from an increase in breastfeeding with rooming-in. When the sensitivity of the ICER was tested to a change in the risk ratio of need for pharmacotherapy, the ICER held.

In assessing peer counselling breastfeeding support for women living with HIV, Desmond *et al.*[217] calculated ICERs for a range of intervention scenarios. While the base case was considered cost-effective in terms of cost per increased month of exclusive breastfeeding, the ICER was sensitive to a change in the intensity of the intervention. Moving from a basic scenario to a simplified and full scenario increased the intervention cost; however, it was balanced by an increase in effect. The most efficient scenario in terms of cost per increased month of exclusive breastfeeding was judged to be the simplified scenario that combined clinic and home visits. Maredza *et al.*[218] similarly modelled the cost–utility of various infant-feeding strategies for women living with HIV compared with current practice. The provision of breastfeeding support for those living in an urban setting was a dominant intervention and considered cost-effective in terms of cost per disability-adjusted life-year averted. However, the ICER did not hold in a one-way sensitivity analysis for a range of modelled study parameters. Those living in a rural setting and provided with breastfeeding support had lower estimated costs than those receiving current practice; however, this was offset by an increase in the number of HIV infections.

Mottl-Santiago *et al.*[125] recruited women from low-income communities and subsequently conducted a subgroup analysis to consider heterogeneity in the results of the return on investment for doula support. The author reported a higher return on investment (US$276:$1) when assessing doula support during pregnancy up to 8 weeks postpartum for women considered medically high risk, compared with full sample's return on investment (US$18:$1) at 2018 prices. However, the evaluation did not consider health resource use and costs (cost savings) beyond the study time horizon.

Applicability

In terms of the applicability criteria assessed, all the studies fulfilled the criteria of the study population and intervention being relevant to the review question. Two studies were judged not applicable because the system in which the studies were conducted was too different from the UK context, making it difficult to translate findings of cost-effectiveness.[217,218] Two further studies were deemed not applicable due to the payer perspective taken for the costing of the intervention and/or healthcare resource use in an organisational setting that is too diverse from the UK NHS and Personal Social Services.[125,216] Failing to meet these criteria for applicability to the UK would likely change the conclusions about cost-effectiveness; thus, they were excluded from further consideration. One study[219] was applicable in terms of the country setting (UK) and the provider perspective taken of the NHS and Personal Social Services; however, with the aim of assessing the feasibility of collecting economic data, the findings were not applicable to the review question to understand the incremental costs and cost-effectiveness of breastfeeding support interventions for mothers with LTCs compared with a control. If at a future date the study progressed to a full trial and conducted a cost–utility analysis as planned, the findings would likely be judged applicable.

Appraisal of limitations

None of the included studies progressed to section 2 of the quality assessment process, to judge study limitations and uncertainty in results, because of their lack of applicability to the UK system and context.

Strengths and limitations

To the best of our knowledge, this is the only systematic review of economic evidence on breastfeeding support interventions for women with LTCs, and it has identified a lack of evidence on incremental cost and incremental cost-effectiveness that is applicable to a UK setting.

We followed methods recommended for identifying, assessing and reviewing economic evidence;[87,110,112,220] however, there is a potential for bias. While we attempted to identify all published and unpublished economic evaluations on breastfeeding support for women with LTCs, it is possible that not all studies were identified.

Chapter summary

Five studies were identified that examined the incremental cost and/or cost-effectiveness of breastfeeding support interventions for women with LTCs compared with a control or provided a cost–outcome description. The conditions assessed in the studies were HIV, obesity, prenatal opioid use and medically high risk (maternal hypertension and diabetes prior to birth). Interventions provided only breastfeeding support or also provided support for the LTC or provided care across the continuum. Each of the interventions assessed in the full economic evaluations was deemed cost-effective for the base case. On appraisal, none of the studies was judged to be applicable to the system and context of the UK.

Chapter 9 Co-creating a toolkit for implementation and evaluation of breastfeeding support interventions

Aims

The final stage of the research aimed to develop and refine a toolkit for the implementation and evaluation of effective breastfeeding interventions relevant to the UK, based on all evidence and stakeholder input from the previous work. An additional aim was to elicit stakeholders' preferences in terms of WTP for a breastfeeding support intervention. This stage of the research included both the main study and additional work for women with LTCs. See *Appendix 8* for the draft toolkit.

Methods

The co-creation of the toolkit built on the findings of the evidence syntheses and stakeholder engagement, as described in the previous chapters, as follows:

- effective breastfeeding support interventions for healthy women with healthy term babies from the updated Cochrane review[83]
- barriers to and enablers of implementing breastfeeding support derived from synthesising process evaluations of effective interventions (see *Chapter 4*)
- barriers to implementation and strategies to overcome them derived from the main study stakeholder engagement (see *Chapter 2*)
- key challenges for women with multimorbidities when accessing support for breastfeeding and for healthcare providers in offering support derived from the MLTC stakeholder engagement (see *Chapter 2*).

The next stage of developing the toolkit involved a wider group of stakeholders via co-creation workshops. The workshop activities revolved around a prototype breastfeeding support intervention drawn from elements of interventions from the Cochrane review.[83] The interventions that informed the prototype were selected as they were effective in reducing the number of women stopping breastfeeding and were judged to be at low risk of bias using allocation concealment as a proxy for this. This prototype is a composite of the characteristics of these seven interventions and together they provide a range of the ways breastfeeding support could effectively be implemented.[103,221–226]

Prototype intervention

The breastfeeding support intervention will be delivered one-to-one by infant-feeding advisors. It consists of one 30-minute antenatal appointment, one 30-minute postnatal visit in hospital, one 30-minute home visit within 48 hours of discharge and regular telephone calls. The antenatal session will focus on rapport building, education and identifying any concerns regarding breastfeeding. The hospital and discharge visits will involve checking latch, helping with positioning and observing a feed if requested by the mother. Infant-feeding advisors will also provide encouragement and reassurance during visits. Women will be given the chance to ask questions and raise any concerns.

Following the initial three contacts, support will be provided remotely unless a face-to-face visit is required. For the first 4 weeks there will be a weekly proactive telephone call, and beyond that support

will be provided monthly until 3 months or when breastfeeding ceases. Women can also contact infant-feeding advisors as needed via telephone or SMS during this 3-month period and beyond as new issues arise.

The infant-feeding advisor will also signpost women to the local breastfeeding peer support group, which provides support via WhatsApp and weekly face-to-face support groups and/or one-to-one peer support service. Infant-feeding advisors will receive training on the intervention delivery.

Workshops

Four 1-day workshops were held in November 2022 in Belfast, Birmingham, Cardiff and Edinburgh, representing the four nations of the UK. We aimed to include up to 30 participants in each workshop representing four key groups: (1) service users and their representatives, including third-sector advocacy organisations and lay/peer supporters; (2) health services including frontline practitioners (e.g. midwives, health visitors, doctors, lactation consultants, support workers), and service managers and commissioners; (3) national and local policy-makers, including government bodies, and public health and social care organisations; and (4) academic researchers. Invitations were disseminated via the research team's networks, members of the stakeholder working groups and third-sector organisations with a focus on participants who represent or work with communities where breastfeeding rates are low to maintain the focus on inequalities.

Workshop participants

There were 87 participants across the 4 workshops, and all sectors were represented as shown in *Table 8*, although there was no policy-maker at the Cardiff workshop. The health service participants included midwives, health visitors, lactation consultants, infant-feeding co-ordinators/leads and support workers. Health service participants made up the largest group, followed by service users/third-sector organisations. There were relatively few policy-makers. Participants were not all from the country in which the workshop was held. It can also be noted that the balance of participants at each workshop was different. For example, at the Edinburgh workshop the largest group of participants was parents and third-sector organisation representatives, whereas at the other three workshops the largest group was health services staff. Each workshop was facilitated by members of the research team.

Workshop activities

Following an overview of the main study and the additional work for women with LTCs, and an explanation of the prototype intervention, participants worked in small groups of six to eight people on four activities. Each group comprised participants from the four main groups of attendees as described above, and a member of the research team to facilitate and document key discussion points. Next was

TABLE 8 Workshop participants

	Belfast	Birmingham	Cardiff	Edinburgh	Total
Service user/third sector	3	4	5	13	**25**
Health services	13	10	12	7	**42**
National/local policy-makers	3	1	0	1	**5**
Academics	2	2	3	2	**9**
Student midwives			3		**3**
Information missing			3		**3**
Total	**21**	**17**	**26**	**23**	**87**

a description of each of the activities along with a summary of the key findings based on a synthesis from all four workshops. Throughout all the activities, participants were asked to focus on women from communities with low breastfeeding rates.

Activity 1: adaptation of the prototype intervention for women with multimorbidities

Participants were presented with a hypothetical case study of a woman with several LTCs (fibromyalgia, Crohn's disease and anxiety), which was drawn from the experiences of members of the MLTC parents' panel. Participants were asked to discuss what, if any, adaptations to the prototype intervention would be needed to meet the needs of breastfeeding women with multimorbidities.

The consensus across the workshops was that the intervention needed significant modifications. The greatest consensus was on three modifications: (1) the antenatal appointment should be longer than 30 minutes; (2) continuity, with the same person delivering the intervention antenatally and postnatally so that women do not have to repeat their stories; and (3) infant-feeding advisors should be included in joint obstetric and medical clinics.

Other modifications mentioned frequently were:

- The person delivering the intervention should have expertise in medications and breastfeeding, as well as in breastfeeding support.
- Antenatal appointments of 90 minutes would be more realistic, or several shorter appointments could be helpful.
- Starting discussions early in pregnancy could be beneficial to take account of the higher risk of preterm birth in women with multimorbidities and to give practitioners more time to find accurate information.
- Women require a medication review in early pregnancy, and this should involve a pharmacist who is knowledgeable about medications and breastfeeding.
- Women should be able to see all of their healthcare providers (e.g. midwife, obstetrician, physician, pharmacist) during one appointment to minimise women's time, effort and costs. Ideally, the appointment would include key members of the women's support network (e.g. partner, family).
- The antenatal appointment should focus on practical tips for managing varying levels of fatigue and pain, such as how to find comfortable feeding positions. Content should also be flexible to the women's needs, adaptable to changing circumstances and consistent across different healthcare providers.
- 30-minute postnatal appointments are too short.
- For the 3-month follow-up support, women should have the option of telephone or face-to-face contacts, and 24-hour telephone support should be available.
- Peer support could be offered antenatally, and group antenatal peer support could help normalise breastfeeding for women with LTCs. Women could be offered the choice of one-to-one or group peer support.
- Third-sector organisations could help with the provision of breastfeeding and emotional support.
- To be sustainable, peer supporters should be paid.
- Training is needed to increase knowledge of breastfeeding and multimorbidities in the multidisciplinary team, including GPs. Supporting women with multimorbidities to breastfeed should be included in routine breastfeeding training updates.
- Services should be co-ordinated, with the infant-feeding advisor as the key point of contact for the multidisciplinary team.

Activity 2: identified barriers to implementation of prototype intervention for healthy women and women with multimorbidities

Participants were asked within their groups to discuss and list barriers to implementing and, for parents, accessing the prototype intervention in their settings. Open discussion was encouraged; however,

facilitators were provided with a prompt sheet comprising the domains and constructs adapted from the CFIR[227] to stimulate consideration of all aspects of implementation and accessibility. The lists of barriers were collated and, along with the 18 barriers identified by the stakeholder working group and parents' panel (see *Chapter 2*), mapped to the updated CFIR.[92] There was a high degree of overlap within and across the workshops and between the workshops and stakeholder and parents' panel discussions. We present the main themes under each domain of the CFIR,[92] while acknowledging that there is overlap between constructs within a domain and between domains. Constructs of the CFIR are denoted in italics in the following text.

Innovation domain: Barriers relating to the innovation, defined as the 'thing being implemented',[92] mapped mainly to the constructs of *adaptability*, *complexity*, *design* and *cost*. The most frequently mentioned barrier referred to *adaptability* in that the schedule and length of appointments lacked flexibility and would need to be tailored to individual women's needs and circumstances. The next most frequently mentioned barrier was that the *design* of the intervention did not include the women's partner and/or other family members who could be important sources of breastfeeding support. Further frequently mentioned concerns with the intervention *design* were lack of continuity across the intervention and lack of intensity in the first 2 weeks postnatally. Barriers related to *cost* highlighted concerns that costs to the service could be high and may not represent value for money or be sustainable. Regarding *complexity*, the intervention was perceived to be multifaceted and to necessitate multiple appointments that may not be convenient for women. The stakeholder working group identified that the intervention may not be perceived to offer *relative advantage* compared with existing or alternative approaches to breastfeeding support.

Outer setting domain: Barriers related to *local attitudes* to breastfeeding were discussed by all groups across the four workshops and were one of the most frequently mentioned of all barriers across all domains. Typically, barriers were phrased as 'negative societal attitudes to breastfeeding' or the existence of a 'bottle-feeding culture'. These were said to result in family or peer pressure for women to formula feed based on unhelpful beliefs. Linked to this were *external societal pressures*, including the impact of social media influencers and formula company marketing. Lack of political priority and/or strategy for breastfeeding and failure to monitor and enforce the International Code of Marketing of Breastmilk Substitutes were common themes that mapped to *policies and laws*. A further frequently mentioned barrier related to the challenges of developing *partnerships and connections* between health services and other sectors such as third-sector organisations or local authorities. Outer setting barriers are also related to *local conditions*, for example lack of good transport and/or childcare, digital poverty and the current cost-of-living crisis. Lack of *financing* for breastfeeding along with funding targets was mentioned, but it was often unclear when this referred to the outer (funding from external entities) or the inner setting (funding to implement and deliver the innovation). Finally, the impact of COVID-19-related restrictions, particularly on group settings, was seen to be a barrier reflecting *critical incidents*.

Inner setting domain: There were twice as many barriers identified under the inner setting domain as under any of the other domains. The most frequent themes are linked to *work infrastructure*, *culture* and *available resources*. Workforce challenges such as staff shortages, high turnover of staff and lack of time/protected time were the most frequently mentioned. Other barriers related to *work infrastructure* included a lack of the right skill mix and overdependency on one or a small group of individuals. Overlapping with *work infrastructure* were barriers relating to *relational connections* and *communications*, for example poor communication and working practices across the multidisciplinary team, fragmented services and challenges to embracing peer support within the health settings. The last of these included peer support not being valued and a reliance on unpaid volunteers. Regarding *culture*, a very frequent theme (linked to *human equality-centredness* and *recipient-centredness*) was barriers relating to the lack of accessibility of services to diverse populations, including lack of language support, sensitivity to women's backgrounds and stereotyping, as well as the cost of the intervention (e.g. travel costs) to women who have little resource. Also linked to *culture* were issues of *learning-centredness*, such as lack of visibility of data to staff (e.g. breastfeeding rates), lack of data sharing and lack of sharing of good practice.

Regarding *available resources*, the most frequently mentioned barriers were lack of *funding* and lack of *space*, such as appropriate venues to deliver the intervention with consideration of space for women to breastfeed and accessible locations for groups to meet. Other themes were lack of *compatibility* of the innovation with existing policies and guidelines or with the practice of early postnatal discharge. Workshop participants and the stakeholder working group identified that the innovation overlapped with current provision and may not fit with existing workflows or system values.

Individuals domain: The most common theme in this domain is mapped to the *capability* (knowledge, skills, interpersonal competence) of *innovation deliverers*, resulting in conflicting information for breastfeeding women. The main concern was a lack of experience and training of many of the staff who would be delivering the intervention. This included a lack of access to high-quality education. A frequently mentioned barrier was some staff's negative attitudes to breastfeeding, which could impact on their interactions with women. Second to the capability of staff was that some staff lacked *motivation* either because they did not value breastfeeding or due to professional fatigue. Lack of confidence of staff to implement the innovation was identified as a barrier by the stakeholder working group and at two workshops. The second most common theme of barriers related to the buy-in, understanding and valuation (*capability and motivation*) of the innovation by *high- and mid-level leaders*, that is key strategic decision-makers and those whose remit is to operationalise strategic decisions, without whose support the implementation would be unlikely to succeed. The stakeholder working group identified a lack of champions and skilled implementation leads as a further barrier. A final theme under individuals related to *innovation recipients* with barriers to *opportunity* such as lack of time and lack of knowledge of or access to services.

Implementation process domain: At the workshops, fewer barriers were linked to this domain than to the other domains. The only barriers mentioned by more than one group related to *engaging*, for example staff lack of engagement or resistance to change, and *planning* in the lack of management oversight to ensure that the innovation is being implemented as intended. The stakeholder working group identified concerns regarding the lack of feedback to staff to evaluate the quality of the intervention (*reflecting and evaluating*), the need to assess accurately the needs of parents and families (assessing needs) and poor communication of the goals, policies and procedures related to the innovation (*planning*).

Activity 3: prioritised strategies to overcome implementation barriers

In this activity, participants were presented with the 34 implementation strategies adapted from the Expert Recommendations for Implementing Change framework,[82] derived from the stakeholder and parent consensus-building exercise (see *Chapter 2*). The task was to select the most relevant strategies to overcome each of the barriers identified in activity 2. Participants selected multiple strategies for each barrier, and each strategy multiple times. Given that so many barriers were related to the inner setting domain and were therefore context driven, we here present those strategies that were most frequently selected, giving examples of the barriers that they might address. Participants were also invited to add any additional strategies they thought were missing from the those provided. A full list of strategies and the number of times each was selected, along with additional strategies suggested by participants, can be found in *Report Supplementary Material 1*, *Table 9* presents the five strategies chosen most frequently, along with examples of the barriers these were selected to overcome.

While *Table 9* shows the most frequently selected strategies across all four workshops, there were differences between the workshops. For example, the two most frequently selected strategies at the Edinburgh workshop did not feature in the top five strategies across the workshop. They were:

1. start with pilots (in Baby-Friendly Initiative and non-Baby-Friendly Initiative accredited settings) to refine implementation and resources required as a means of phasing in the intervention and change in a sustainable way (#6 in the overall strategy ranking)
2. use new survey and routine data to assess the impact and monitor the quality of the breastfeeding support intervention (#12 in the overall strategy ranking).

TABLE 9 Most frequently selected strategies with examples of barriers

Strategy	Number of times selected	Examples of barriers
Deliver realistic, evidence-based information in multiple formats on how to deliver the breastfeeding support intervention and why it is important	84	Lack of staff training, knowledge and skills Lack of consistency of information Lack of continuity of care Challenges to accessing the intervention for women and families Lack of buy-in from senior managers
Assign a key practitioner to raise awareness about the intervention to ensure a consistent message	75	Challenges to working with sectors outside the health system Poor communication across the multidisciplinary team Lack of joined-up vision and working
New or existing funding for breastfeeding support should be a general health investment for local councils and the government, and not just the NHS	72	Lack of funding within the health system Cost of the service to the NHS Lack of relationship between the health system and the community Lack of sustainability Cost of the intervention to women Reliance on non-paid peer supporters
Create an infant-feeding team in every NHS organisation to lead the intervention, working collaboratively with multidisciplinary practitioners and lay supporters	72	Lack of availability of good-quality training Time and capacity issues Professional boundaries – especially working with peer supporters Lack of confidence of those delivering the intervention Lack of integration across the continuum (antenatal/postnatal) and across the multidisciplinary team
Revise roles as needed to support the intervention; for example, integrate peer supporters with NHS infant-feeding teams, and consider upskilling maternity staff to specialist lactation training levels	70	Barriers to integrating peer support with health services, including lack of valuing peer support Lack of right skill mix Lack of knowledge and skills of staff delivering the intervention Infant-feeding specialists overloaded

The second most frequently selected strategy at the Cardiff workshop was:

- involve parents, peer supporters and charities in adapting the intervention for the local area and to encourage uptake (#10 in the overall strategy ranking).

The differences between the workshops can most likely be explained by a combination of the different balance of participants at each workshop (with more parents and third-sector representatives at the Edinburgh workshop) and the different policy contexts of the four nations.

Activity 4: considerations for evaluating breastfeeding support interventions

Participants discussed how the prototype intervention could be evaluated and were prompted to consider outcomes that are important to parents, the timing of breastfeeding outcome data collection, the important data related to processes, and how to assess the impact on health inequalities.

Important outcomes for parents were suggested to be meeting their feeding goals and expectations, whether the support and information was helpful, and how confident or empowered a woman felt after the intervention.

With regard to the timing of breastfeeding outcomes data collection, the most frequently mentioned was to collect data on 'any' and 'exclusive' breastfeeding at the following time points:

- first feed within 1 hour after birth
- discharge from hospital
- 6–8 weeks
- 6 months.

Other suggestions with high consensus were 10–12 days (to coincide with discharge from routine midwifery care), 3–4 months and 1 year. Other comments on collecting breastfeeding outcome related to definitions of any and exclusive and whether these needed to be subdivided further.

Other outcomes felt to be important included health outcomes, for example the number of infants admitted to hospital and the reasons for stopping breastfeeding.

Process data

The most frequently mentioned were the views and experiences of those receiving and delivering the intervention (including women, healthcare practitioners and peer supporters), women's satisfaction, and intervention fidelity (did women receive all components of the intervention). There was discussion that data could be collected early to capture those who cease to engage with the intervention and to gain feedback from those who declined the intervention. Many methods for collecting data were suggested, including digital options such as WhatsApp, and there was high consensus that participants in studies should be offered options for follow-up, for example between online, telephone, e-mail, post or a phone app.

Impact on inequalities

Discussions about evaluating the impact on health inequalities centred around gathering background information such as maternal characteristics (age, ethnicity, socioeconomic status) and making sure that the intervention and evaluation are inclusive, for example by addressing language barriers.

Activity 5: willingness to pay for a breastfeeding support intervention

To evaluate stakeholders' preferences for a breastfeeding support intervention, participants in the workshop were presented with a stated preference discrete choice experiment (DCE). A DCE is a method of eliciting preferences for a given product or service by presenting a series of scenarios to individuals; each scenario presents two or more alternatives that differ in the attributes of the product/service, and the individual chooses their preferred alternative.[228] The theoretical underpinnings of the experiment are derived from (1) random utility maximisation,[229] where it is assumed that individuals' choice behaviours are made to maximise their satisfaction while allowing for unobserved sources of utility; and (2) Lancaster's economic theory of value, which posits that an individual's utility for a whole product or service can be separated into utilities for each component or attribute of that service.[230] If a change thus occurs in one of the attributes of the service, the individual may choose an alternative product if they deem it of greater value, while acting to minimise cost.[231] DCEs have been used increasingly over the last 20 years in health-related research and are useful for informing health policy, providing preferences for clinical outcomes of a service, as well as the process and cost attributes.[232] The aim of the experiment presented during the workshops was to estimate the value of a breastfeeding support intervention to participants, as well as the relative importance of each attribute and attribute level of the intervention.

Guidance on constructing the experimental design for DCEs was followed.[233,234] Careful consideration was given to the selection of attributes and suitable levels to be presented within the DCE. While DCEs present participants with hypothetical scenarios to choose from, it is important that the scenarios reflect practice and are recognisable to participants to ensure that the exercise is capable of deriving preferences.[228] The attributes (n = 7) and attribute levels (range 3–5) that were used to create the alternative choices presented in each scenario are outlined in *Table 10*.

The attributes and levels were informed by the findings from the systematic reviews reported in *Chapters 3* and *5*, the findings from the stakeholder engagement, which comprised online discussions, the modified Delphi study and face-to-face focus groups, and the resulting prototype intervention. The intervention components included process attributes of the number of contacts between service users and service providers, provider of the intervention, mode of support and approach to support. The clinical outcome attributes were the percentage reduction in drop-off for any, or exclusive,

TABLE 10 Attributes and levels used to elicit preferences for an additional breastfeeding support intervention

	Attribute levels				
Attributes	**1**	**2**	**3**	**4**	**5**
Number of contacts	≤ 3	4–8	≥ 9	–	–
Provider	Peer supporter	Breastfeeding counsellor	Health professional	Lactation consultant	Combined provision
Mode of support	Telephone	Face to face	Online	Hybrid	–
Approach to support	Reactive	Proactive	Blended	–	–
Reduction in drop-off for any breastfeeding at 6 weeks	1%	5%	10%	15%	–
Reduction in drop-off for exclusive breastfeeding at 6 weeks	No reduction	1%	5%	10%	–
Additional cost per woman	£25	£50	£100	£150	–

breastfeeding at 6 weeks. Only one of the two clinical outcome attributes was presented in any given experiment to each participant. Finally, the cost attribute indicated the additional cost to the NHS per woman supported.

A fractional factorial design was then used to create the experiment to limit participant fatigue and the length of time required to complete it. An orthogonal main effects plan, using Statistical Package for Social Sciences version 27 (IBM Corporation, Armonk, NY, USA) software, generated profiles for the alternatives and 12 choice sets. Participants were presented with an unlabelled DCE with two alternative intervention options (A and B), which differed in their attribute levels, along with a third alternative of choosing neither intervention. This third alternative provided an unconditional choice set where participants could opt out if they preferred. *Figure 8* illustrates an example scenario designed to enable participants to trade across attributes and, thus, identify the relative value of each attribute and level for stakeholders.

Intervention	**A**	**B**	
Number of contacts	≤3	4–8	
Provider	Health professional	Combined provision	
Mode of support	Telephone	Face to face	
Approach to support	Reactive	Proactive	
Reduction in drop-off for exclusive BF at 6 weeks	1%	5%	
Additional cost per woman	£50	£150	**Neither intervention**
Which intervention do you prefer?	☐	☐	☐

FIGURE 8 Example scenario presented to workshop participants.

An interview-based format was used to administer the experiment to workshop participants, allowing the facilitator to answer any queries and clarify any issues. Before the activity commenced, the DCE was explained, and participants were introduced to each attribute and associated levels. They were informed that the breastfeeding support intervention was additional to current service provision and that several outcomes of effect may occur as a result of the additional support, such as a change in maternal satisfaction with care or a change in breastfeeding initiation rates. However, for the purposes of the exercise they were asked to consider a reduction in drop-off for breastfeeding (any or exclusive) at 6 weeks, which reflected the outcome of effect in the Cochrane review that had recently been updated as part of the study.[83]

Data from the experiment were entered into Microsoft Excel. Data entry was carried out using a multiple-line format, whereby data are divided into a number of blocks. Effects coding was used for the levels of the process attributes, while the clinical outcomes and cost attributes were maintained. Each block represented a participant's choice set and each row within that block corresponded to an alternative within the choice set, effectively clustering the data to allow for multiple observations from respondents to the experiment. The choice outcome was the variable that signified the decision made for each scenario and, as such, was the dependent variable within the model. The discrete choice analysis was undertaken using a random utility model and conducted in R (The R Foundation for Statistical Computing, Vienna, Austria) using guidance provided by Croissant.[235] Modelling the choice sets of participants produced choice probability estimates and an indirect utility function for choosing an alternative, an attribute and an attribute level. Estimated marginal rates of substitution enabled the interpretation of participants' WTP for each attribute and attribute level.

Results

A total of 87 workshop participants completed the DCE in November 2022. *Table 11* presents the results from the discrete choice modelling.

With regard to the estimated beta coefficients, preference formation was as expected a priori and resonated with the findings from the stakeholder engagement activities and the resulting prototype intervention. Stakeholders exhibited statistically significant preference for four to eight contacts over three or fewer (β = 0.35, SE 0.122, $p < 0.01$) and provision from a range of providers over healthcare professional alone (β = 0.46, SE 0.172, $p < 0.01$), and valued face-to-face support over telephone support (β = −0.29, SE 0.135, $p < 0.05$). Although there was a positive value for a proactive approach to support over reactive support, this was not statistically significant (β = 0.16, SE 0.117, $p > 0.05$), suggesting that stakeholders did not consider the different approaches to support (reactive, proactive, hybrid) in their decision-making process. Both clinical outcome attributes of reducing the number of women stopping any breastfeeding (β = 0.26, SE 0.018, $p < 0.01$) or exclusive breastfeeding (β = 0.52, SE 0.070, $p < 0.01$) at 6 weeks postpartum were statistically significant, suggesting that the greater the percentage reduction in drop-off, the greater the value to participants. For the additional cost per woman, participants valued a lower cost intervention over a higher cost (β = −0.02, SE 0.002, $p < 0.01$), upholding underlying assumptions of individuals acting to minimise cost.[231] The overall preference by stakeholders for introducing an additional breastfeeding support intervention into practice was reiterated by the lack of preference for the status-quo alternative, which displayed a negative beta coefficient (β = −1.16, SE 0.186, $p < 0.01$).

In terms of WTP for additional breastfeeding support, estimated marginal rates of substitution indicated that participants were willing to pay £67.40 per woman for additional breastfeeding support, regardless of how it was delivered or whether it was effective in reducing the number of women stopping breastfeeding at 6 weeks postpartum. *Table 12* presents the WTP for each clinical outcome attribute and each process attribute level valued by participants, which was represented by a statistically significant, positive beta coefficient in the model.

TABLE 11 Results of the modelling preferences derived from the DCE

Attribute and attribute level	Beta coefficient	Standard error
Number of contacts		
≥ 9	0.03	0.142
4–8	0.35**	0.122
≤ 3[a]	−0.38	
Provider		
Combined provision	0.46**	0.172
Lactation consultant	0.03	0.165
Breastfeeding counsellor	0.18	0.202
Peer supporter	−0.45*	0.196
Healthcare professional[a]	−0.22	
Mode of support		
Hybrid	−0.30	0.187
Online	0.11	0.187
Telephone	−0.29*	0.135
Face to face[a]	0.48	
Approach to support		
Blended	−0.15	0.148
Proactive	0.16	0.117
Reactive[a]	−0.01	
Reduction in drop-off for any breastfeeding at 6 weeks	0.26**	0.018
Reduction in drop-off for exclusive breastfeeding at 6 weeks	0.52**	0.070
Additional cost per woman	−0.02**	0.002
Neither intervention	−1.16**	0.186
Log-likelihood	−748.03	
Number of iterations	5	

*$p < 0.05$; **$p < 0.01$.
a Reference levels for effects-coded attributes were calculated as the negative sum of the estimated attribute levels.

TABLE 12 Participants' marginal rates of substitution between cost of additional breastfeeding support and intervention attributes

Attribute valued	Marginal WTP/woman
4–8 contacts	£20.29
Combined provision	£26.83
Face-to-face support[a]	£27.89
For each 1% reduction in drop-off for any breastfeeding at 6 weeks	£14.90
For each 1% reduction in drop-off for exclusive breastfeeding at 6 weeks	£30.03

a Reference level.

As an example, the estimated WTP by stakeholders was £89.91 per woman for a breastfeeding support intervention that realised a 1% reduction in drop-off for any breastfeeding at 6 weeks postpartum, and £105.04 per woman for an intervention that realised a 1% reduction in drop-off for exclusive breastfeeding at 6 weeks postpartum. The WTP thresholds would increase to £149.51 and £225.16 if the interventions realised a 5% reduction in drop-off of any or exclusive breastfeeding at 6 weeks postpartum, respectively.

Finalising the toolkit

Following the workshops, the study team collated the information presented above and synthesised it with the findings from the systematic reviews presented in this report. The findings were then combined to form the toolkit, a draft of which is presented in *Appendix 8*. The intention is that the toolkit will be developed into a digital version.

Chapter 10 Discussion and conclusions

Summary of findings

The aim of this study was to synthesise global and UK evidence to co-create with stakeholders a framework to guide the implementation and evaluation of cost-effective breastfeeding support interventions in the NHS. The original focus of the study was on women without LTCs; however, we broadened the scope to include women with MLTC when additional funding was awarded. Given the anticipated paucity in evidence for women with MLTC, our review work considered women with single LTCs.

In total, we conducted six systematic reviews:

- two systematic reviews and meta-analyses examining the effectiveness of breastfeeding support for healthy women and women with LTCs
- a theoretically informed mixed-methods synthesis of process evaluations of UK-relevant breastfeeding support intervention
- a mixed-methods synthesis of barriers to and facilitators of breastfeeding support in women with LTCs
- two economic evaluations of breastfeeding support for healthy women and women with LTCs.

This study also contained embedded stakeholder engagement in the form of stakeholder working groups, parents' panels, focus group discussions with women from socially disadvantaged groups and four workshops held across the UK.

The first work package was an update of the Cochrane review on breastfeeding support for healthy women with healthy term infants.[83] We included 116 studies in the review and 'breastfeeding only' interventions, which included breastfeeding support only (*n* = 86), and 'breastfeeding plus' interventions (*n* = 30), which included other aspects of maternal and child health such as vaccinations, well-baby clinics, intrapartum care and contraceptive services. We found moderate-certainty evidence that 'breastfeeding only' interventions probably led to a small reduction in the risk of women stopping exclusive breastfeeding at 6 months, 4–6 weeks, 2 months and 3–4 months, and stopping any breastfeeding at 6 months, 4–6 weeks and 3–4 months. Effect estimates ranged from RR 0.93 (95% CI 0.89 to 0.97) for stopping any breastfeeding at 6 months to RR 0.81 (95% CI 0.77 to 0.95) for stopping exclusive breastfeeding at 3–4 months. Effect estimates were generally greater for exclusive breastfeeding than for any breastfeeding.

For 'breastfeeding plus' the evidence was less consistent. Support probably reduced the number of women stopping any breastfeeding or exclusive breastfeeding at 6 months. The evidence suggests that 'breastfeeding plus' support probably results in little to no difference in any of the other outcomes. Effect estimates ranged from RR 0.94 (95% CI 0.91 to 0.97) for stopping any breastfeeding at 6 months to RR 0.73 (95% CI 0.57 to 0.95) for stopping exclusive breastfeeding at 4–6 weeks. Again, effect estimates were generally greater for exclusive breastfeeding than for any breastfeeding. It is not clear why 'breastfeeding plus' interventions tended to have less of an impact on the number of women stopping breastfeeding. The proportion of interventions categorised as low, medium and high intensity was broadly similar for 'breastfeeding only' and 'breastfeeding plus'. However, it is feasible that the time spent providing breastfeeding support was less in the 'breastfeeding plus' interventions as other aspects of maternal and infant care were also included. There was a lack of information in the intervention characteristics to explore this issue fully. Moreover, although interventions were categorised into 'breastfeeding only' and 'breastfeeding plus', there was still substantial heterogeneity in interventions.

Meta-regression was conducted to further explore heterogeneity. This suggested that moderate-intensity (four to eight visits) compared with low-intensity (three or less), support may be beneficial for reducing the number of women stopping exclusive breastfeeding at 4–6 weeks or 6 months. Additionally, women in LMICs were less likely to have stopped exclusive breastfeeding at 6 months, and this may be explained by the higher background breastfeeding rates at 6 months in LMICs.[14] However, beyond this the meta-regression did not explain the high levels of heterogeneity. As we did not want to increase the likelihood of false positives from the meta-regression, we limited the number of variables to four,[88] and these were determined in conjunction with stakeholders. There is, therefore, a possibility that variables not included in the meta-regression may be contributing to the high levels of heterogeneity. For example, just under half of the included studies focused on populations described as high poverty, deprivation and poor health outcomes, and it is possible that this may explain some of the heterogeneity as breastfeeding rates typically are lower in groups of high levels of deprivation in HICs.[14]

The second work package comprised a mixed-methods synthesis of process evaluations of effective breastfeeding support interventions identified in work package 1. We included 16 studies linked to 10 effective interventions. The identified 18 factors affecting implementation of interventions, and data-driven analytical themes were mapped to a theoretical implementation framework resulting in three overarching, theoretically informed, analytical themes: (1) assessing the needs of those delivering and receiving breastfeeding support interventions; (2) assessing the context and optimising delivery and engagement with breastfeeding support interventions; and (3) reflecting and evaluating the success of implementing and providing breastfeeding support. Included studies identified implementation challenges relating to the needs, preferences and priorities of intervention providers and recipients. Overall, breastfeeding women perceived support as positive, important and needed. Breastfeeding supporter training was a commonly reported implementation strategy that enabled implementation teams to address breastfeeding supporters' needs. Studies reported contextual factors (e.g. alignment with local policies) affecting the implementation and delivery of breastfeeding support interventions as well as tailoring strategies (e.g. community involvement, use of lay language, responsive support content/information) to address contextual factors. Reports about implementation success focused on key implementation outcomes such as satisfaction, fidelity or usefulness.

The third work package comprised a review of economic evidence of both trial- and model-based evaluations of the incremental cost and incremental cost-effectiveness of breastfeeding support interventions. Of the 39 studies identified, nine were deemed directly or partially applicable to the UK system. Evidence of cost-effectiveness using the UK-recommended incremental cost per QALY gained was limited and inconsistent. For breastfeeding-only support, one study provided evidence that the estimated ICER for the intervention was not cost-effective, at £56,075 per QALY gained. This ICER held in deterministic and probabilistic sensitivity analyses. However, there were notable limitations to the model, with the exclusion of costs (cost savings) and benefits to infants beyond 1 year of age and clinical conditions that were excluded, such as obesity. A lack of good-quality epidemiological and cost data warranted the exclusion but highlights the uncertainty in the findings and the need for more robust evidence to inform future economic evaluations. There was evidence for the incremental cost per additional woman breastfeeding (any or exclusive) with ICERs ranging from £67 to £112 from 2 weeks up to 8 weeks postpartum and from £2446 to £4226 up to 6 months postpartum. However, we judged the findings to be uncertain because of the limited number of studies and the lack of good-quality evidence. None of these studies extrapolated data beyond the time horizon of the associated trial, and potential costs (cost savings) from health service use were not estimated and valued. Without WTP thresholds, whether or not the findings were cost-effective was unclear. Evidence for 'breastfeeding plus' support suggested that this was not cost-effective in terms of cost per QALY gained, with similar inconsistencies in results. The scope of costs and outcomes reported and the time horizon for many of the studies was limited. What is missing from the evidence is a high-quality trial-based economic evaluation that then models costs and outcomes beyond the trial period. If breastfeeding in itself is considered a cost-effective intervention, then the provision of additional effective support to populations or subgroups of women with lower rates of breastfeeding initiation is likely to be worth

the investment. Engagement with stakeholders during the workshops elicited a positive value for a breastfeeding support intervention, with a WTP of £89.91/£105.04 per woman for a 1% reduction in drop-off for any/exclusive breastfeeding at 6 weeks postpartum. If policy- and decision-makers are willing to pay this cost to realise this outcome, then such a breastfeeding support intervention, delivering four to eight face-to-face contacts with women by a combination of providers, would be considered value for money.

The first work package of the additional funding aimed to identify effective interventions that provide breastfeeding support for women with LTCs. We identified 22 studies that met the inclusion criteria, all of which were for women with single LTCs. A range of conditions were identified: overweight and obesity (nine studies), HIV (five studies), gestational diabetes (two studies), substance misuse (two studies) and depression (one study). Interventions varied in terms of whether they provided only breastfeeding support or if they also provided support for the LTC. No studies were identified for women with MLTC. In contrast to the Cochrane review of breastfeeding support,[83] most studies had an antenatal component. The importance of antenatal support, particularly having a flexible feeding plan, was raised by the stakeholder working group and parents' panel for women with MLTC. Effect estimates for the primary breastfeeding outcomes were generally small and crossed the 95% CI, which suggests that included interventions probably had little to no impact on the number of women stopping breastfeeding. Effect estimates ranged from RR 0.83 (95% CI 0.67 to 1.01) for stopping any breastfeeding at 6 months to RR 0.95 (95% CI 0.89 to 1.00) for stopping exclusive breastfeeding at 6 months. Findings for the additional breastfeeding outcomes were similar. Due to the small number of studies, meta-regression to explore the impact of the nature of the LTC on breastfeeding rates was not possible. Sensitivity analysis did not find a difference in findings when studies with women with HIV were excluded. Similarly, due to the small number of studies, meta-regression was not possible to explore possible causes of heterogeneity, such as nature of condition or socioeconomic deprivation. Moreover, only a few studies had beneficial intervention effects for at least one outcome.[184,185,187] It is, therefore, not possible to make any conclusions about support being more or less effective for specific conditions. Similarly, a narrative synthesis showed little to no beneficial effect on maternal and infant health outcomes.

The second work package for women with MLTC comprised a mixed-methods synthesis of experiences of breastfeeding support for women with LTCs. The 24 included studies covered health conditions including HIV, obesity and overweight, substance use, diabetes in pregnancy, disabilities and a rare genetic disorder. Key findings were that women with LTCs have additional breastfeeding support needs, but that breastfeeding support can be difficult to access. Women and healthcare providers reported challenges including the overshadowing of breastfeeding support by condition-related support and supporters lacking in knowledge and skills. Suggested strategies to improve breastfeeding support for mothers with LTCs included acknowledging the influence of partners, families and friends and training healthcare providers to improve their understanding of the specific breastfeeding support needs of women with LTCs.

The third work package for women with MLTC conducted a review of economic evidence for breastfeeding support interventions for women with LTCs. Five evaluations were identified that assessed cost and effect for women with a small range of health conditions: HIV, obesity, prenatal opioid use, and women considered medically high risk (maternal hypertension and diabetes prior to birth). There was a lack of evidence of cost-effectiveness from full economic evaluations, with limited scope in the costs and benefits valued. One cost-effectiveness analysis study reported a cost of US$88 per increased month of exclusive breastfeeding to support women living with HIV to breastfeed, while a cost–utility analysis study reported that promoting breastfeeding was less costly and more effective, in terms of disability-adjusted life-years averted, for women living with HIV in rural areas than the current scenario. A third cost–utility analysis study reported less cost and more effect, in terms of QALYs gained, for breastfeeding support using rooming-in after childbirth for women with prenatal opioid use.

However, none of the studies met the applicability criteria for the UK system, making it likely that these conclusions of cost-effectiveness would change if tested in a UK setting.

The final phase of the project involved developing and refining a toolkit for implementing and evaluating effective breastfeeding interventions relevant to the UK, based on synthesising the findings of the reviews and stakeholder and parent engagement along with the views of a broader group of stakeholders who attended workshops. The toolkit presents an example intervention based on high-quality evidence on effective breastfeeding support interventions. The intervention comprises structured, proactive antenatal and postnatal components, combines professional and peer support, and offers face-to-face and telephone follow-up. The toolkit proposes the most important considerations when adapting this evidence-based intervention for local services, which are acceptability to the local population, the quality of the primary evidence, and the sustainability of the intervention. Regarding tailoring the intervention for women with LTCs, the most important modifications to be considered are more time for antenatal breastfeeding support, continuity of support, and including infant-feeding specialists in combined obstetric and medical clinics.

The toolkit highlights barriers that may be encountered when implementing breastfeeding support interventions considering the intervention itself, the broader societal setting, the context of local services, the roles and capabilities of those implementing and receiving the intervention and, finally, the process of implementation (see *Appendix 8*). The toolkit proposes a range of strategies that can be used to address barriers, the most important of which are providing information on how to deliver the intervention and why it is important, assigning roles such as a key practitioner to raise awareness, having an infant-feeding team to lead implementation, integrating peer support with NHS services, and leveraging investment from local councils and government as well as the NHS.

Finally, the toolkit proposes considerations for evaluating the intervention, including whether women meet their infant-feeding goals and expectations and whether the support is helpful. The suggested times to measure breastfeeding outcomes are first feed, discharge from hospital, 6–8 weeks and 6 months. Other important outcomes to consider are infant admissions to hospital and the reason for stopping breastfeeding. Process data to be considered include views and experiences of the intervention deliverers and recipients, women's satisfaction and intervention fidelity. To assess impact on inequalities, data should be collected on women's characteristics and the intervention and evaluation should be inclusive, that is accessible to all women.

Agreements and disagreements with other reviews

First, in terms of the Cochrane review, both 'breastfeeding only' and 'breastfeeding plus' tended to have a greater impact on exclusive breastfeeding. One explanation for this comes from a realist review that suggested that more highly motivated mothers may benefit more from breastfeeding support.[236] In addition, effect estimates tended to be greater at earlier time points, which may be a consequence of support being primarily targeted at the first 1–2 months. At later time points, wider issues around returning to employment influence breastfeeding rates[237] and may not be considered in the interventions included. The results of this meta-analysis are similar to effect estimates reported in a review looking at breastfeeding counselling interventions.[238] Other systematic reviews looking at support interventions have shown greater effect estimates;[239] however, these reviews identified a much smaller number of studies due to limitations in search strategies and selection processes. In addition, previous systematic reviews have found greater effect estimates for multicomponent breastfeeding support (i.e. providing different aspects of breastfeeding support in a combination of settings such as BFHI).[40,240,241] We did initially aim to categorise the interventions based on breastfeeding support components; however, given the large number and heterogeneity of interventions we were unable to do this in any meaningful way. Interestingly, our review suggested slightly higher effect estimates than did a review looking at breastfeeding support that was provided on a remote basis only.[242] However, in our

review, meta-regression did not identify any clear differences between support provided remotely and that provided face to face, but the power to detect any differences was limited. Reviews of alternative methods to increase breastfeeding rates have identified a relatively small number of studies and no clear intervention effects, for example incentives[243] or workplace-based strategies.[244]

To the best of our knowledge, this is the first systematic review to focus on implementation research linked to breastfeeding support interventions for healthy women with healthy term babies that have shown effectiveness in RCTs. However, some existing reviews have looked more widely at the views and experiences of those delivering and receiving breastfeeding support interventions and have reported findings that are well aligned with our review. These include the importance of key intervention strategies that women perceive as supportive, such as those that rely on the provision of both practical/technical expertise[245–247] and emotional support/encouragement[245,246,248] and are person centred and socioculturally specific,[246,247,249] as well as key implementation issues such as the importance of contextual factors.[249,250] In terms of the review on effectiveness of breastfeeding support for women with LTCs, our findings are consistent with a Cochrane review of support targeted at women with overweight and obesity for which only a few small-scale studies were identified.[251] Meta-analysis likewise identified small effect estimates and imprecision. A further systematic review that included any intervention (e.g. support, breast pumps, education) designed to increase breastfeeding initiation and continuation in women with overweight/obesity also did not appear to show any impact on improving breastfeeding rates.[252] To the best of our knowledge, there are no existing reviews of breastfeeding support for any other form of LTC.

Our mixed-methods synthesis of experiences of breastfeeding support for women with LTCs is consistent with other review findings. This includes that overweight/obese women find breastfeeding challenging.[253,254] Similar to our review, Chang *et al.*[253] concluded that healthcare professionals require education to enable them to provide tailored, non-judgemental breastfeeding support. Cummins *et al.*[255] made similar recommendations based on their systematic review of in-hospital support for women with GDM. Tanganhito *et al.*[256] emphasised the influence of family and friends and professional support for women with postnatal depression.

In terms of the review of economic evidence, our findings resonate with one previous economic evidence review.[257] This review was conducted to inform NICE guidance on postnatal care and comprised seven studies. The authors judged the existing evidence to be inconclusive. While their inclusion criteria had a wider remit of breastfeeding education, advice and support interventions, which included financial incentives, their findings were consistent with the findings in the current review for 'breastfeeding only' support. The review highlighted similar limitations and inconsistencies between studies, such as the limited time horizon, the different economic outcomes estimated and the different scope of costs and benefits measured and valued, which have an impact on the strength of any conclusions.

Strengths and limitations

This study has several key strengths. First, a criticism of systematic reviews is a lack of uptake of review findings into policy and practice;[258] however, the mixed-methods reviews and stakeholder engagement have enabled to us to understand how interventions could be effectively implemented in practice. To address this, we included two mixed-methods syntheses that aimed to explore how such support could be implemented in the NHS for all women. We believe that this is the first comprehensive synthesis of evidence of effectiveness of breastfeeding support and of barriers to and strategies for implementing breastfeeding support for women with and women without LTCs. Furthermore, our work has been underpinned by implementation frameworks providing theoretically informed recommendations in the form of a toolkit. Finally, and perhaps most importantly, it had extensive PPI and stakeholder involvement that ensured a co-created output grounded in the realities of women's experiences of

breastfeeding, particularly those from socially disadvantaged groups, and NHS context and practice. Hopefully, this gives a sense of ownership to those involved in the project. The toolkit should be relevant and adaptable to the four UK nations. Second, the two effectiveness reviews and meta-analyses followed Cochrane methodology to ensure rigour. Third, the update of Cochrane review of breastfeeding support[83] included the use of a new trustworthiness checklist, which helps ensure that the findings of this review are not based on fraudulent data.[86]

However, there are several limitations that should be considered. With all systematic reviews there is the potential for bias to be introduced. First, although we did involve two reviewers in all review processes (e.g. study selection, data extraction, critical appraisal, synthesis, GRADE), these judgements are subjective. Second, except for the Cochrane review, studies not published in English were excluded, so there is a risk of language bias. Third, although we attempted to identify all available evidence meeting our inclusion criteria, it is possible that we did not identify all studies, and the Cochrane review in particular showed some evidence of funnel plot asymmetry, which may be suggestive of publication bias. Fourth, issues in reporting meant that there was often insufficient information about intervention characteristics (e.g. person providing the intervention, number of contacts, theoretical basis, definitions of exclusive breastfeeding, nature of standard care). Fifth, the systematic reviews on effectiveness identified a lack of digitally provided interventions. As the COVID-19 pandemic has led to an increase in remotely provided maternity care,[242] this evidence is perhaps limited in a post-COVID world. Sixth, our syntheses were limited by the mixed quality and lack of published process evaluations linked to effective interventions, as well as the relative dearth and poor quality of studies of experiences of breastfeeding support for women with LTCs. The latter body of evidence covers a very limited range of conditions, with many being studies of HIV-positive women in LMICs and of obese/overweight women in HICs. We did not find any studies of experiences of breastfeeding for women with mental health conditions. Seventh, there was a lack of evidence from the UK. This is representative of a long-standing problem whereby UK trials have failed to demonstrate benefits for breastfeeding outcomes, possibly due to the interventions tested and the way they were delivered rather than the trial design.[44] Eighth, the search for the Cochrane review on breastfeeding support was conducted in May 2021 and will not have included any studies that look at digital support post COVID-19. Ninth, a post hoc decision was made to exclude breastfeeding initiation from the review on effectiveness of support for women with LTCs. Studies that included this as an outcome used considerably different definitions (e.g. within 1 hour vs. ever), which gave rise to some nonsensical findings, such as in the same study more women breastfeeding at 4–8 weeks than had initiated it. Finally, there is unexplained heterogeneity in both the Cochrane review and the review on breastfeeding support for women with LTCs. In both these reviews, just under half of the studies were targeted at populations at risk of poorer outcomes (e.g. high levels of socioeconomic deprivation, ethnicity, young motherhood). As these factors influence breastfeeding rates,[14] it is possible that the impact of support is different in these populations. However, for the Cochrane review this was not included as a variable in our meta-regression and for the LTC review there were insufficient studies to investigate this. In addition, the review for women with LTCs has additional heterogeneity due to the different conditions included.

Strengths and limitations of patient and public involvement and stakeholder involvement

We used the GRIPP2 (Guidance for Reporting Involvement of Patients and Public) checklist to inform our account of PPI in the study.[259] There was significant involvement of stakeholders and PPI in this project. In addition to the research team's reflections, we sought the views of the main study stakeholder working groups and parents' panels on their engagement.

First, our research team included a PPI co-applicant (PB) who was involved at all stages from the initial design to writing the final report and disseminating the findings. This ensured the PPI voice in all team meetings, providing valuable advice and feedback and influencing decisions. Furthermore, PB

participated in the systematic reviews, including study selection, data extraction, quality appraisal and interpreting the results, and is a co-author of the Cochrane review.[260]

Stakeholder engagement and PPI were identified as a cross-cutting theme in the study protocol, co-led by co-applicants PB and JM, ensuring that it was a standing agenda item in all team discussions and study steering committee meetings. A key responsibility of the full-time project manager was co-ordinating the stakeholder working group and PPI meetings ensuring sufficient administration time was dedicated to it.

A considerable strength was the range of individuals involved in the stakeholder working groups and parents' panels. Members of the parents' panels had a wide range of breastfeeding experiences, and experiences of breastfeeding with a range of comorbidities. We also included two fathers in the main study parents' panel. Members of the stakeholder working groups represented the main health professions involved in breastfeeding support as well as the key national breastfeeding support third-sector organisations, and a national policy-maker. This work was enhanced by conducting focus group discussions in an area of high deprivation and ethnic diversity to ensure that we gained perspectives from communities that have low breastfeeding rates and to complement the parents' panels. A further strength was that 87 people attended the co-creation workshops, covering extensive geographies, NHS and third-sector organisations, and parents.

All parents' panels and stakeholder working group meetings were held virtually, by necessity at the outset of the project, which removed geographical barriers from inclusion. We worked hard to keep participants engaged in the work, as can be seen from the level of engagement across the 2-year study. Focus group participants were offered a choice of face-to-face or virtual meetings, and we ran both modes at each of the three time points. Holding the workshops face to face was a huge advantage, and participants provided very positive feedback about the activities and the benefits of working with others on such an important topic. For many, it was their first experience of a face-to-face event since the COVID-19 restrictions were lifted.

All those involved have been remunerated for attending meetings, as well as for expenses incurred travelling to the workshops. NHS organisations were reimbursed for releasing staff to attend meetings and workshops.

We were transparent at every stage of the study about how the PPI and stakeholder involvement influenced the study, including in co-creation of the toolkit. Feedback from the main study parents' panel and stakeholder working group was that they felt proud to be involved and enjoyed seeing how the project evolved, that the meetings were very inclusive, and that the communication from the team both during and between meetings was very informative and clear.

There were several limitations to this component of the study. We acknowledge that recruiting parents via a third-sector organisation could have resulted in participants who were mainly from middle-class backgrounds. We feel that we mitigated this by conducting the focus group discussions. However, we did not collect sociodemographic data from participants in the parents' panels and focus groups. We did not recruit any women to the parents' panels and focus group discussions who had exclusively formula-fed their babies, and this could be considered a limitation. However, this was because the focus of our work was supporting women who had chosen to breastfeed in continuing longer and increasing exclusivity. Nevertheless, our parents' panels and focus group discussion participants included several women who had combined formula feeding and breastfeeding, and those who had breastfed initially but had switched to formula feeding because of the challenges they had faced. We believe that this brought a wide range of views to our work. We had originally intended to conduct the initial meeting of the main study stakeholder working group face to face, but this was not possible due to COVID-19 restrictions. A face-to-face meeting may have helped build rapport and allowed for informal conversations. We were aware that some participants accessed meetings on their mobile phones and tried to plan

activities accordingly, but it was still challenging for some. Finding a convenient time for meetings was difficult, and although we offered evening times for the parents' panels, this option was not taken up. Nevertheless, some parents were disappointed that they could not attend all meetings. Several members of the stakeholder working group changed roles during the study, and offered replacements, but this inevitably resulted in some lost continuity. The university processes for reimbursement were bureaucratic and time-consuming for the participants and the project manager. Although our workshops had good attendance, many more people registered than attended. The workshops were held in November 2022, a time of high levels of winter illnesses (COVID-19 and flu), travel disruption and high demand in the NHS, all of which affected attendance. Some members of the parents' panels were disappointed that they could not attend a workshop because of distance and full-time employment. One suggestion from the parents' panel was to have a combined meeting with the parents' panel and the stakeholder working group. We held the meetings separately to ensure that the parents' voices were heard but will consider at least one combined meeting in future projects.

Implications for practice

Considering the importance of breastfeeding for public health and the existence of high-quality, moderate-certainty evidence of what works to support healthy women to breastfeed, the key challenge is overcoming the barriers to implementing breastfeeding support interventions. Decision-makers and frontline practitioners can use the toolkit to inform implementation efforts and to overcome barriers specific to their settings. Further co-development work is ongoing with an extended set of stakeholders to refine the draft toolkit and produce a user-friendly output that will support NHS and third-sector organisations to implement evidence-based breastfeeding support for women in the UK. Key to success will be addressing the system barriers and enhancing the skills, knowledge and confidence of practitioners. To reduce inequalities, interventions must be adapted to be accessible to all women, for example by ensuring that venues are accessible at a low cost and that language and cultural barriers are considered. Breastfeeding peer support is lacking across much of the UK.[33] Addressing barriers to integrating peer support with health service support is needed, as suggested by Trickey *et al.*[236] This requires action by health service strategic and operational decision-makers to adequately resource and value peer support as integral to effective breastfeeding support.

While less research evidence is available on how to provide effective breastfeeding support for women with LTCs, our stakeholder engagement and PPI work highlighted additional support needs and proposed possible strategies for achieving this. Health services could consider implementing proposals to integrate an infant-feeding specialist with the multidisciplinary team to give infant feeding a higher profile in obstetric and medical care.

The lack of knowledge, skills and confidence of those providing breastfeeding support is a frequent theme in research on breastfeeding support. Our stakeholder work suggested that training to UNICEF UK Baby-Friendly Initiative standards[261] should be a minimum level for those providing care to mothers and infants. However, our workshop participants also proposed enhancing the training of those delivering breastfeeding support to lactation consultant level. Any upskilling strategies should incorporate the needs of women with LTCs.

The toolkit can be used by those leading breastfeeding support services to guide implementation efforts. This will probably necessitate rethinking existing roles and skill mix and involve finding ways to work with other sectors such as third-sector and community organisations. According to our work, a key to effective implementation is providing feedback to staff through data sharing.

The societal and commercial influences on women's breastfeeding experiences are well recognised.[17,262] Although this needs a whole-system approach beyond the scope of our work, one strategy emphasised by our project is to involve partners and wider families in breastfeeding support interventions, as found

in Bengough *et al.*[249] Regarding reducing inequalities in breastfeeding, the current economic climate and cost-of-living crisis is likely to exacerbate inequalities and necessitate the consideration of minimising costs to breastfeeding women such as ensuring that venues are accessible and helping with travel costs. Digital poverty must also be considered if the breastfeeding service has a digital component. Exploring the needs and preferences of the local population and working with a wide range of third-sector organisations and local government could address this.

Suggested future research

Crucially, this study found only a small number of studies on breastfeeding support for women with LTCs and a lack of evidence on cost-effectiveness in this group, compared with the large number of studies looking at support for healthy women. Moreover, both reviews identified that effect estimates were generally small. There is therefore a need to develop support interventions that are effective for all women. While further inspection of the Cochrane review findings did identify specific interventions that had larger effects and could form the basis of a NHS intervention, many of the barriers to breastfeeding for women with LTCs identified by our parents' panel and stakeholder working group, and the mixed-methods synthesis, would not be considered in these interventions. In particular, there is a greater need for antenatal support and development of a feeding plan, consistent communication between healthcare professionals regarding medication safety, and the consideration of breastfeeding as a physical activity. There is therefore a need to develop and test an intervention for women with MLTC that takes account of these aspects. In particular, this work identified a very small number of studies for women with mental health conditions. In addition, while many of our included studies did focus on women with overweight/obesity and GDM, the interventions were generally not effective. Given the prevalence and co-occurrence of these conditions, and the fact they are more likely to affect women from groups least likely to breastfeed, we would suggest these as priority areas.

Both systematic reviews on the effectiveness of breastfeeding support identified a lack of digitally provided interventions. As the COVID-19 pandemic has led to an increase in remotely provided maternity care,[242] there is also a need to consider how digital technologies could be utilised. However, both our work with stakeholders and existing research[263] suggest that remotely provided support cannot be a replacement for face-to-face support and thus it should be provided alongside face-to-face breastfeeding support.

More research is needed on the experiences of receiving and providing breastfeeding support among women with LTCs and those with multimorbidities.

Evidence for the effectiveness of breastfeeding feeding support interventions in the UK is lacking, and the toolkit can be used to guide evaluation design. This could be via implementation or effectiveness studies or by using quality improvement methodology. Studies could be based on the prototype intervention developed for this study (tailored to local contexts), as described in the draft toolkit, and could test different implementation strategies for effectiveness. Further evidence of value for money in a UK setting is also needed.

Future economic evaluations would need to address the current limitations in the evidence in terms of the short time horizon and limited scope of health service resource use measured and valued. A cost–utility analysis could be conducted alongside an effectiveness study, combining trial-based and model-based evidence with long-term follow-up of mother–child dyads to collect data on resource use and health-related quality of life, and modelling costs and benefits over the lifetime. A societal perspective should also be considered in conjunction with the provider (NHS) perspective to gain a better understanding of the opportunity cost of providing support to women to breastfeed.

Equality, diversity and inclusion

We addressed equality, diversity and inclusion in the following ways:

- Our work focuses on support for breastfeeding women; women of childbearing age and pregnant women are recognised as underserved groups.
- The stakeholder working groups included healthcare practitioners serving ethnically diverse and disadvantaged populations, and rural localities across the UK.
- The parents' panel for the main study included a Gypsy/Traveller mother (one the most socially marginalised groups in the UK) and two fathers (men are rarely included in breastfeeding research).
- The parents' panel for women with MLTC included women with multiple physical and mental health conditions and are a group who face additional challenges in accessing breastfeeding support and are often excluded from breastfeeding research.
- For the main study, we ensured the voices of women from ethnically diverse and socioeconomically deprived populations were included through conducting focus group discussions in West Yorkshire to supplement the views of the parents' panel.
- We ensured all communication was accessible for participants.
- We offered evening meetings for the parents' panels.
- We paid parents and third-sector organisation representatives for their involvement to value their contributions.
- In our workshops, we focused activities on the needs of populations with low breastfeeding rates.
- The co-applicant team involved a range of levels of experience, included male and female researchers, and a PPI representative.
- Our approach to the work was inclusive and everyone had the opportunity to contribute all aspects resulting in co-authorship of the report and development of knowledge and skills in evidence synthesis methods.
- We also included a wide range of early career researchers including doctoral students in the conduct of the reviews to develop skills and have co-authorship of the resulting publications including the Cochrane review.

Regarding limitations, the research team (co-investigators) was not ethnically diverse, and we will consider this in future research. We acknowledge that recruiting parents to the parents' panels via a variety of Facebook breastfeeding support groups, including those run by third-sector organisations, somewhat restricted those who engaged with us in terms of diversity of backgrounds. In future work, we will consider different strategies to optimise diversity.

Conclusions

'Breastfeeding only' support probably leads to a small reduction in the number of women stopping any and exclusive breastfeeding. 'Breastfeeding plus' support and breastfeeding support for women with LTCs probably leads to little or no reduction in the number of women stopping breastfeeding for most outcomes. As the work with stakeholders and mixed-methods review identified that women with LTCs face additional challenges when breastfeeding, more research is needed to develop effective support. In addition, evidence for the effectiveness and cost-effectiveness of breastfeeding feeding support interventions in the UK is lacking.

Additional information

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Contributions of authors

Anna Gavine (https://orcid.org/0000-0003-3750-2445) (Lecturer) led the systematic reviews on effectiveness of breastfeeding support for healthy women [update of Cochrane review (see *Chapter 3*)] and breastfeeding support for women with long-term conditions (see *Chapter 6*); participation in tasks related to mixed-methods review (see *Chapter 7*); design and running of stakeholder working groups, parents' panels and workshops.

Albert Farre (https://orcid.org/0000-0001-8970-6146) (Lecturer) led the mixed-methods systematic reviews for healthy women (see *Chapter 4*) and women with long-term conditions (see *Chapter 7*); design, running and analysis of stakeholder working groups, parents' panels and workshops; participation in tasks related to update of Cochrane review (see *Chapter 3*).

Fiona Lynn (https://orcid.org/000-0002-0216-643X) (Senior Lecturer) led the systematic reviews on cost-effectiveness (see *Chapters 5* and *8*); design and running of stakeholder working groups, parents' panels and workshops; participation in tasks related to update of Cochrane review (see *Chapter 3*).

Shona Shinwell (https://orcid.org/0000-0001-9369-9698) (Project Manager) participation in tasks related to update of Cochrane review (see *Chapter 3*) and mixed-methods systematic review (see *Chapter 4*); design and running of stakeholder working groups, parents' panels and workshops.

Phyllis Buchanan (https://orcid.org/0000-0002-1436-4396) (PPI Breastfeeding Network) participation in tasks related to update of Cochrane review (see *Chapter 3*) and effectiveness of breastfeeding support for women with LTCs (see *Chapter 6*); design, running and analysis of stakeholder working groups, parents' panels, focus groups and workshops.

Joyce Marshall (https://orcid.org/0000-0002-2784-1817) (Lecturer) design, running and analysis of focus groups, stakeholder working groups, parents' panels and workshops; participation in tasks related to update of Cochrane review (see *Chapter 3*).

Sara Cumming (https://orcid.org/0000-0003-0714-128x) (Clinical Academic Fellow) participation in tasks related to update of Cochrane review (see *Chapter 3*), mixed-methods reviews (see *Chapters 4* and *7*) and effectiveness of breastfeeding support for women with LTCs (see *Chapter 6*); design and analysis of stakeholder working groups, parents' panels and workshops.

Louise Wallace (https://orcid.org/0000-0003-3770-0580) (Professor) study design and running of workshops.

Angie Wade (https://orcid.org/0000-0002-3944-8908) (Professor) design and analysis of update of Cochrane review (see *Chapter 3*); statistical advice for *Chapter 6*.

Elayne Ahern (https://orcid.org/0000-0001-9230-6776) (Lecturer) contributed to tasks related to the cost-effectiveness reviews (see *Chapters 5* and *8*).

Laura Hay (https://orcid.org/0000-0002-3259-9463) (Project Manager) design of and contribution to systematic review on effectiveness of breastfeeding support for women with LTCs (see *Chapter 6*); design and running of stakeholder working groups, parents' panels and workshops.

Marianne Cranwell (https://orcid.org/0000-0003-0605-3923) (Research Assistant) analysis of stakeholder working group and parents' panels; contribution of tasks related to mixed-methods review (see *Chapter 7*).

Alison McFadden (https://orcid.org/0000-0002-5164-2025) (Professor) led stakeholder and parent engagement work packages; participated in tasks related to update of Cochrane review (see *Chapter 3*), systematic review on effectiveness of breastfeeding support for women with LTCs (see *Chapter 6*), mixed-methods reviews (see *Chapters 4* and *7*); project oversight.

All authors were involved in drafting and/or commenting on the report.

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Data-sharing statement

Further anonymised data are available on request from the corresponding author.

Ethics statement

The stakeholder engagement and PPI components of the study were approved by the University of Dundee School of Health Sciences research ethics committee (UOD-SHS-2021-010) on 24 June 2021.

Information governance statement

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This monograph was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

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Appendix 1 Search strategies

MEDLINE search strategy for main study mixed-methods systematic review (see *Chapter 4*)

S1	TI OR AB ("wom#n" OR "mother*" OR "father*" OR "parent*" OR "famil*" OR "midwi*" OR "health professional*" OR "health provider*" OR "service provider" OR "maternity staff" OR "staff" OR "peer supporter*" OR "lay supporter*" OR "volunteer*" OR "manager*" OR "commissioner*" OR "policymaker*" OR "stakeholder*" OR "key informant*" OR "lactation consultant" OR "breast-feeding counsel#or" OR "infant-feeding lead*" OR "infant-feeding specialist*" OR "infant-feeding co-ordinator*")	3,268,371
S2	MH "Breast Feeding+"	41,413
S3	TI OR AB ("breastfe*" OR "breast feed*" OR "breast fed" OR "breast-fe*")	46,339
S4	S2 OR S3	60,438
S5	TI OR AB ("support*" OR "help" OR "assist*" OR "education*" OR "class*" OR "workshop*" OR "champion*" OR "promot*" OR "counsel#ing")	5,380,883
S6	S4 AND S5	19,542
S7	MH "Pregnancy+"	955,061
S8	MH "Maternal Health Services+"	54,923
S9	MH "Maternal-Child Health Services"	938
S10	MH "Perinatal Care+"	11,204
S11	MH "Postnatal Care"	6188
S12	MH "Postpartum Period+"	70,902
S13	S7 OR S8 OR S9 OR S10 OR S11 OR S12	988,993
S14	S6 AND S13	7333
S15	S6 OR S14	19,542
S16	S1 AND S15	15,537
S17	TI OR AB ("questionnaire*" OR "survey*" OR "interview*" OR "focus group*" OR "case stud*" OR "observ*" OR "ethnograph*" OR "hermeneutic*" OR "narrative*" OR "phenomenolog*" OR "grounded theory" OR "process evaluation" OR "implementation study" OR "implementation research")	5,274,651
S18	TI OR AB ("view*" OR "experienc*" OR "opinion*" OR "attitude*" OR "perception*" OR "perceive*" OR "belie*" OR "feel*" OR "know*" OR "understand*" OR "barrier*" OR "facilitator*" OR "enabler*" OR "obstacle*")	5,649,064
S19	MH "Qualitative Research+" OR TI ("qualitative" OR "mixed method*") OR AB ("qualitative" OR "mixed method*")	302,606
S20	(S17 OR S18) AND S19	9,474,588
S21	S16 AND S20	1399

MEDLINE search strategy for main study economic evidence review (see *Chapter 5*)

Ovid MEDLINE® ALL 1946 to 17 August 2022

n = 2911, searched on 2 February 2022

1. exp Breast Feeding/
2. breastfeed*.mp.
3. breastfed.mp.
4. breast-feed*.mp.
5. breast-fed.mp.
6. breast feed*.mp.
7. breast fed.mp.
8. infant feed*.mp.
9. exp Milk, Human/
10. Lactation/
11. lactat*.mp.
12. support.mp.
13. Social Support/
14. advice.mp.
15. advis*.mp.
16. help*.mp.
17. supportive adj2 relationship.mp
18. counsel*.mp.
19. educat*.mp.
20. consult*.mp.
21. Health Promotion/
22. Health Education/
23. Economics/
24. exp “Costs and cost analysis”/
25. “Cost allocation”/
26. Cost-benefit analysis/
27. “Cost control”/
28. “Cost savings”/
29. “Cost of illness”/
30. “Cost sharing”/
31. “deductibles and coinsurance”/
32. Medical savings accounts/
33. Health care costs/
34. Direct service costs/
35. Drug costs/
36. Employer health costs/
37. Hospital costs/
38. Health expenditures/
39. Capital expenditures/
40. Value of life/
41. exp economics, hospital/
42. exp economics, medical/
43. Economics, nursing/
44. Economics, pharmaceutical/
45. exp “fees and charges”/
46. exp budgets/
47. (low adj cost).mp.
48. (high adj cost).mp.
49. (health?care adj cost$).mp.
50. (fiscal or funding or financial or finance).tw.
51. (cost adj estimate$).mp.
52. (cost adj variable).mp.
53. (unit adj cost$).mp.

54. (economic$ or pharmacoeconomic$ or price$ or pricing).tw.
55. or/1-11
56. or/12-22
57. or/23-54
58. 55 and 56 and 57
59. exp animals/ not humans.sh.
60. 58 not 59

MEDLINE search strategy for LTCs effectiveness review (see *Chapter 6*)

Ovid MEDLINE® ALL 1946 to 17 August 2022

n = 1144, searched on 18 August 2022

1 exp Breast Feeding/ 42,543
2 (breastfeed* or breast-feed* or breast feed*).ab. 38,704
3 (breastfed or breast-fed or breast fed).ab. 12,845
4 lactation.ab. 35,254
5 infant feed*.ab. 4936
6 exp Lactation/ 46,504
7 exp Breast Milk Expression/ 385
8 exp Milk, Human/ 21,849
9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 129,346
10 ((support* or help or assist* or class* or workshop* or champion* or promot*) adj5 (breastfeed* or breast feed* or breastfed or breast fed or lactation or infant feed*)).ab. 7340
11 exp Social Support/ 78,157
12 anticipatory guidance.mp. 1527
13 exp Counseling/ 47,862
14 counsel*.mp. 152,131
15 exp Directive Counseling/ 4838
16 exp Health Promotion/ 83,692
17 exp Health Education/ 259,211
18 peer support.mp. 6270
19 professional support.mp. 2017
20 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 478,908
21 exp Chronic Disease/ 598,162
22 chronic disease*.mp. 339,068
23 chronic illness*.mp. 18,795
24 chronic condition*.mp. 23,438
25 (long term condition* or long-term condition*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 2409
26 exp Comorbidity/ 124,635
27 (comorbid* or co-morbid*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 306,350
28 exp Multimorbidity/ 2332
29 (multimorbid* or multi-morbid*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 8950

30 (multidiseas* or multi-diseas*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 265
31 cancer.mp. or exp Neoplasms/ 4,276,838
32 atrial fibrillation.mp. or exp Atrial Fibrillation/ 98,446
33 cardiomyopathy.mp. or exp Cardiomyopathies/ 141,244
34 heart failure.mp. or exp Heart Failure/ 240,900
35 exp Hypercholesterolemia/or exp Hyperlipidemias/ 69,579
36 (hypercholesterol?emia or hyperlipid?emia).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 75,870
37 exp Hypertension/or hypertension.mp. 541,419
38 exp Myocardial Ischemia/ 461,609
39 (isch?emic heart disease or myocardial infarction).mp. [mptitle, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 296,886
40 peripheral vascular disease.mp. or exp Peripheral Vascular Diseases/ 64,594
41 exp Stroke/or stroke.mp. 371,135
42 exp Ischemic Attack, Transient/ 21,493
43 transient isch?emic attack.mp. 12,427
44 congenital heart disease.mp. or exp Heart Defects, Congenital/ 176,482
45 valvular heart disease.mp. or exp Heart Valve Diseases/ 135,662
46 rheumatic heart disease.mp. or exp Rheumatic Heart Disease/ 14,973
47 exp Heart Diseases/ 1,235,397
48 (heart disease or cardiac disease).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 211,888
49 alopecia areata.mp. or exp Alopecia Areata/ 5330
50 vitiligo.mp. or exp Vitiligo/ 8844
51 exp Eczema/or eczema.mp. 23,857
52 psoriasis.mp. or exp Psoriasis/ 59,218
53 acne.mp. or exp Acne Vulgaris/ 20,890
54 hidradenitis suppurativa.mp. or exp Hidradenitis Suppurativa/ 3821
55 lichen planus.mp. or exp Lichen Planus/ 11,081
56 rosacea.mp. or exp Rosacea/ 4650
57 seborrheic dermatitis.mp. or exp Dermatitis, Seborrheic/ 3404
58 allergic rhinitis.mp. or exp Rhinitis, Allergic/ 31,279
59 allergic conjunctivitis.mp. or exp Conjunctivitis, Allergic/ 4460
60 exp Hearing Loss/ 75,766
61 (hearing loss or deaf*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 110,959
62 exp Addison Disease/ or addison* disease.mp. 5996
63 exp Adrenocortical Adenoma/ or adren* adenoma.mp. 3139
64 exp Pheochromocytoma/ 16,444
65 ph?eochromocytoma.mp. 23,761
66 exp Cushing Syndrome/ or cushing* syndrome.mp. 15,868

67 exp Diabetes Mellitus, Type 2/ or exp Diabetes, Gestational/ or exp Diabetes Mellitus/ or exp Diabetes Mellitus, Type 1/ 485,761
68 (diabetes or diabetic$1).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 796,593
69 exp Parathyroid Diseases/ or (parathyroid dis* or hyperparathyroid* or hypoparathyroid*).mp. 46,457
70 exp Thyroid Diseases/ or thyroid dis*.mp. 165,219
71 (hyperthyroid* or hypothyroid* or thyroiditis or graves disease).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 100,159
72 exp Pituitary Diseases/ or pituitary dis*.mp. 64,970
73 exp Endocrine System Diseases/ 1,088,901
74 exp Vision Disorders/ 77,172
75 (visual* impair* or blindness).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 58,699
76 exp Cataract/or cataract.mp. 71,192
77 exp Diabetic Retinopathy/ 28,274
78 (diabetic retinopathy or diabetic eye dis*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 38,358
79 glaucoma.mp. or exp Glaucoma/ 78,243
80 scleritis.mp. or exp Scleritis/ 2363
81 episcleritis.mp. 619
82 exp Uveitis/or uveitis.mp. 40,674
83 retinal detachment.mp. or exp Retinal Detachment/ 28,643
84 exp Eye Diseases/ 619,560
85 alcoholic liver disease.mp. or exp Liver Diseases, Alcoholic/ 18,468
86 autoimmune hepatitis.mp. or exp Hepatitis, Autoimmune/ 7214
87 sclerosing cholangitis.mp. or exp Cholangitis, Sclerosing/ 7796
88 primary biliary cirrhosis.mp. or exp Liver Cirrhosis, Biliary/ 10,926
89 chronic hepatitis.mp. or exp Hepatitis, Chronic/ 73,061
90 exp Hepatitis B, Chronic/ or hepatitis B.mp. 108,026
91 exp Hepatitis C, Chronic/ or hepatitis C.mp. 98,802
92 liver cirrhosis.mp. or exp Liver Cirrhosis/ 111,811
93 non-alcoholic fatty liver disease.mp. or exp Non-alcoholic Fatty Liver Disease/ 26,127
94 exp Liver Diseases/ 608,267
95 chronic pancreatitis.mp. or exp Pancreatitis, Chronic/ 16,961
96 c?eliac disease.mp. or exp Celiac Disease/ 26,258
97 food allergy.mp. or exp Food Hypersensitivity/ 25,939
98 cholelithiasis.mp. or exp Cholelithiasis/ 40,132
99 gallstones.mp. 20,398
100 inflammatory bowel disease.mp. or exp Inflammatory Bowel Diseases/ 112,247
101 exp Crohn Disease/ or crohn* disease.mp. 62,081
102 ulcerative colitis.mp. or exp Colitis, Ulcerative/ 55,469
103 proctitis.mp. or exp Proctitis/ 4698
104 irritable bowel syndrome.mp. or exp Irritable Bowel Syndrome/ 16,561

105 lactose intolerance.mp. or exp Lactose Intolerance/ 3642
106 peptic ulcer.mp. or exp Peptic Ulcer/ 88,760
107 chronic pelvic inflammatory dis*.mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 135
108 exp Pelvic Inflammatory Disease/ 11,366
109 dysmenorrhea.mp. or exp Dysmenorrhea/ 7265
110 endometriosis.mp. or exp Endometriosis/ 31,546
111 infertility.mp. or exp Infertility/ 103,527
112 assisted reproduction.mp. or exp Reproductive Techniques, Assisted/ 80,694
113 (in vitro fertili#ation or IVF).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 40,047
114 leiomyoma.mp. or exp Leiomyoma/ 25,329
115 fibroids.mp. 5638
116 exp Menopause/ or menopause.mp. 74,996
117 menorrhagia.mp. or exp Menorrhagia/ 6281
118 exp Urinary Incontinence/ or exp Pelvic Floor Disorders/ or exp Pelvic Organ Prolapse/ or exp Fecal Incontinence/ 54,690
119 (pelvic floor dysfunction or pelvic floor disorder*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 2942
120 (urinary incontinence or f?ecal incontinence).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 54,435
121 pelvic organ prolapse.mp. 7750
122 exp Polycystic Ovary Syndrome/ or polycystic ovar* syndrome.mp. 21,740
123 recurrent miscarriage.mp. or exp Abortion, Habitual/ 9651
124 exp Blood Coagulation Disorders/ or coagulation disorder.mp. 103,883
125 h?emophilia.mp. 28,903
126 exp Anemia, Sickle Cell/or sickle cell.mp. 31,815
127 thalass?emia.mp. or exp Thalassemia/ 30,118
128 thrombophilia.mp. or exp Thrombophilia/ 30,397
129 pernicious an?emia.mp. or exp Anemia, Pernicious/ 7005
130 exp Thrombocytopenia/ or primary thrombocytopenia.mp. 52,195
131 venous thromboembolism.mp. or exp Venous Thromboembolism/ 28,924
132 deep ve* thrombosis.mp. 31,151
133 pulmonary embolism.mp. or exp Pulmonary Embolism/ 59,166
134 HIV.mp. or exp HIV Infections/ 431,237
135 AIDS.mp. or exp Acquired Immunodeficiency Syndrome/ 231,823
136 exp Immunocompromised Host/ 27,296
137 exp Immunosuppression Therapy/ or exp Immunosuppressive Agents/ 386,330
138 immunosuppress*.mp. 247,166
139 exp Transplantation/ 558,640
140 transplant*.mp. 821,998
141 exp Alcohol-Related Disorders/ 119,529
142 (alcohol misuse or alcohol abuse or alcohol dependence or alcoholism).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 102,278

143 exp Substance-Related Disorders/ 303,321
144 (substance misuse or substance abuse or substance dependence).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 61,758
145 exp Anxiety/ or exp Anxiety Disorders/ 179,995
146 anxiety.mp. 287,258
147 panic disorder.mp. or exp Panic Disorder/ 11,686
148 phobic disorder.mp. or exp Phobic Disorders/ 12,239
149 phobia.mp. 9375
150 exp Stress Disorders, Post-Traumatic/ 39,160
151 (post traumatic stress disorder or post-traumatic stress disorder or PTSD).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 36,261
152 exp Mood Disorders/ 132,929
153 exp Depression/ or exp Depression, Postpartum/ 148,840
154 (depression or depressive disorder or mood disorder).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 504,128
155 dementia.mp. or exp Dementia/ 245,230
156 eating disorder.mp. or exp "Feeding and Eating Disorders"/ 38,341
157 (anorexia nervosa or bulimia nervosa).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 21,280
158 bipolar disorder.mp. or exp Bipolar Disorder/ 54,684
159 exp "schizophrenia spectrum and other psychotic disorders"/ 159,357
160 (schizophrenia or psychosis or psychotic disorder or schizoaffective disorder).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 182,203
161 dissociative disorder.mp. or exp Dissociative Disorders/ 4820
162 obsessive compulsive disorder.mp. or exp Obsessive-Compulsive Disorder/ 21,228
163 personality disorder.mp. or exp Personality Disorders/ 49,154
164 self harm.mp. or exp Self-Injurious Behavior/ 83,262
165 exp Mental Disorders/ 1,386,917
166 (mental disorder or psychiatric disorder).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 21,591
167 (serious mental illness or severe mental illness).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 9002
168 exp Attention Deficit Disorder with Hyperactivity/ 33,335
169 (attention deficit hyperactivity disorder or ADHD).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 36,926
170 exp Autism Spectrum Disorder/ 39,314

171 (autism or autistic).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 64,227
172 cerebral palsy.mp. or exp Cerebral Palsy/ 30,646
173 intellectual disabilit*.mp. or exp Intellectual Disability/ 113,325
174 exp Down Syndrome/ or down* syndrome.mp. 32,403
175 exp Brain Injuries/ or acquired brain injury.mp. 79,525
176 exp Headache Disorders/ 38,752
177 (cluster headache or tension headache or chronic headache or migraine).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 47,340
178 exp Epilepsy/ 122,463
179 (epilepsy or epileptic).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 167,049
180 idiopathic intracranial hypertension.mp. or exp Pseudotumor Cerebri/ 5202
181 multiple sclerosis.mp. or exp Multiple Sclerosis/ 94,760
182 peripheral neuropathy.mp. or exp Peripheral Nervous System Diseases/ 171,846
183 exp Parkinson Disease/ or parkinson* disease.mp. 126,506
184 exp Neurodegenerative Diseases/ 351,658
185 (huntington* disease or huntington* chorea).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 20,268
186 motor neurone disease.mp. 1091
187 exp Sleep Wake Disorders/ 104,157
188 (sleep disorder or narcolepsy or obstructive sleep apn?ea).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 41,903
189 spina bifida.mp. or exp Spinal Dysraphism/ 12,050
190 exp Fatigue Syndrome, Chronic/ 6142
191 (chronic fatigue syndrome or myalgic encephalomyelitis).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 6471
192 fibromyalgia.mp. or exp Fibromyalgia/ 13,310
193 exp Chronic Pain/ 20,443
194 exp Complex Regional Pain Syndromes/ 5884
195 exp Myofascial Pain Syndromes/ 6762
196 (chronic pain or pain syndrome).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 66,066
197 exp Back Pain/ or chronic back pain.mp. 44,337
198 osteoarthritis.mp. or exp Osteoarthritis/ 104,568
199 exp Osteoporosis/ 60,974
200 (osteoporosis or osteopenia).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism

supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 101,668
201 scoliosis.mp. or exp Scoliosis/ 28,225
202 exp Spinal Diseases/ 136,461
203 exp Fractures, Compression/ 2943
204 (compression fracture or collapsed vertebra*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 2462
205 intervertebral disc degeneration.mp. or exp Intervertebral Disc Degeneration/ 8378
206 sciatica.mp. or exp Sciatica/ 7190
207 spinal stenosis.mp. or exp Spinal Stenosis/ 9544
208 spondylosis.mp. or exp Spondylosis/ 11,155
209 spondylolisthesis.mp. or exp Spondylolisthesis/ 7445
210 amputation.mp. or exp Amputation/ 52,172
211 amputee.mp. 2992
212 paralysis.mp. or exp Paralysis/ 116,571
213 exp Hemiplegia/ or hemiplegia.mp. 16,538
214 exp Paraplegia/ or paraplegia.mp. 22,118
215 quadriplegia.mp. or exp Quadriplegia/ 10,093
216 exp Disabled Persons/ 71,645
217 (disabled or disabilit*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 362,858
218 chronic kidney disease.mp. or exp Renal Insufficiency, Chronic/ 162,815
219 h?emodialysis.mp. or exp Renal Dialysis/ 146,472
220 exp Urinary Calculi/ 37,823
221 (urinary tract stone* or kidney stone*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 7369
222 exp Asthma/ or asthma.mp. 191,929
223 exp Lung Diseases/ or chronic lung disease.mp. 1,147,038
224 bronchiectasis.mp. or exp Bronchiectasis/ 15,082
225 exp Pulmonary Disease, Chronic Obstructive/ 64,208
226 (chronic obstructive pulmonary disease or COPD).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 75,276
227 cystic fibrosis.mp. or exp Cystic Fibrosis/ 55,910
228 interstitial lung disease.mp. or exp Lung Diseases, Interstitial/ 87,153
229 pulmonary fibrosis.mp. 34,100
230 pulmonary hypertension.mp. or exp Hypertension, Pulmonary/ 56,630
231 exp Sarcoidosis/ or sarcoidosis.mp. 33,019
232 exp Tuberculosis/ or tuberculosis.mp. 272,422
233 exp Ehlers-Danlos Syndrome/ or ehlers-danlos.mp. 4661
234 rheumatoid arthritis.mp. or exp Arthritis, Rheumatoid/ 160,931
235 exp Sjogren's Syndrome/ 14,126
236 (sjogren* syndrome or sjogren* disease).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 19,617

237 exp Raynaud Disease/ or raynaud*.mp. 10,156
238 systemic sclerosis.mp. or exp Scleroderma, Systemic/ 26,894
239 scleroderma.mp. 29,230
240 primary systemic vasculitis.mp. or exp Systemic Vasculitis/ 18,109
241 marfan* syndrome.mp. or exp Marfan Syndrome/ 8617
242 spondyloarthritis.mp. or exp Spondylarthritis/ 31,153
243 psoriatic arthritis.mp. or exp Arthritis, Psoriatic/ 12,337
244 ankylosing spondylitis.mp. or exp Spondylitis, Ankylosing/ 21,066
245 systemic lupus erythematosus.mp. or exp Lupus Erythematosus, Systemic/ 79,628
246 autoimmune disease.mp. or exp Autoimmune Diseases/ 540,341
247 frailty.mp. or exp Frailty/ 22,139
248 exp COVID-19/ or long covid.mp. 181,547
249 post COVID syndrome.mp. 213
250 exp Obesity/ 247,988
251 (obese or obesity).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 411,960
252 polypharmacy.mp. or exp Polypharmacy/ 12,571
253 turner* syndrome.mp. or exp Turner Syndrome/ 9685
254 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123 or 124 or 125 or 126 or 127 or 128 or 129 or 130 or 131 or 132 or 133 or 134 or 135 or 136 or 137 or 138 or 139 or 140 or 141 or 142 or 143 or 144 or 145 or 146 or 147 or 148 or 149 or 150 or 151 or 152 or 153 or 154 or 155 or 156 or 157 or 158 or 159 or 160 or 161 or 162 or 163 or 164 or 165 or 166 or 167 or 168 or 169 or 170 or 171 or 172 or 173 or 174 or 175 or 176 or 177 or 178 or 179 or 180 or 181 or 182 or 183 or 184 or 185 or 186 or 187 or 188 or 189 or 190 or 191 or 192 or 193 or 194 or 195 or 196 or 197 or 198 or 199 or 200 or 201 or 202 or 203 or 204 or 205 or 206 or 207 or 208 or 209 or 210 or 211 or 212 or 213 or 214 or 215 or 216 or 217 or 218 or 219 or 220 or 221 or 222 or 223 or 224 or 225 or 226 or 227 or 228 or 229 or 230 or 231 or 232 or 233 or 234 or 235 or 236 or 237 or 238 or 239 or 240 or 241 or 242 or 243 or 244 or 245 or 246 or 247 or 248 or 249 or 250 or 251 or 252 or 253 14,314,773
255 randomized controlled trial.pt. 575,118
256 controlled clinical trial.pt. 94,989
257 randomi#ed.ab. 684,071
258 placebo.ab. 230,860
259 drug therapy.fs. 2,521,208
260 randomly.ab. 389,335
261 trial.ab. 612,686
262 groups.ab. 2,394,830
263 255 or 256 or 257 or 258 or 259 or 260 or 261 or 262 5,455,224
264 exp animals/ not humans.sh. 5,037,553
265 263 not 264 4,753,806
266 9 and 20 and 254 and 265 1144

MEDLINE search strategy for LTCs mixed-methods systematic review (see *Chapter 7*)

Ovid MEDLINE® ALL 1946 to 23 November 2022

n = 2187, searched on 24 November 2022

1 exp Breast Feeding/ 42,954
2 (breastfeed* or breast-feed* or breast feed*).ab. 39,367
3 (breastfed or breast-fed or breast fed).ab. 13,012
4 lactation.ab. 35,775
5 infant feed*.ab. 4996
6 exp Lactation/ 46,965
7 exp Breast Milk Expression/ 385
8 exp Milk, Human/ 22,053
9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 130,890
10 ((support* or help or assist* or class* or workshop* or champion* or promot*) adj5 (breastfeed* or breast feed* or breastfed or breast fed or lactation or infant feed*)).ab. 7474
11 exp Social Support/ 78,607
12 anticipatory guidance.mp. 1545
13 exp Counseling/ 48,142
14 counsel*.mp. 154,556
15 exp Directive Counseling/ 4882
16 exp Health Promotion/ 84,136
17 exp Health Education/ 260,144
18 peer support.mp. 6522
19 professional support.mp. 2070
20 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 483,065
21 exp Chronic Disease/ 602,943
22 chronic disease*.mp. 342,009
23 chronic illness*.mp. 19,105
24 chronic condition*.mp. 24,060
25 (long term condition* or long-term condition*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 2474
26 exp Comorbidity/ 125,267
27 (comorbid* or co-morbid*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 312,919
28 exp Multimorbidity/ 2454
29 (multimorbid* or multi-morbid*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 9346
30 (multidiseas* or multi-diseas*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 278
31 cancer.mp. or exp Neoplasms/ 4,329,926
32 atrial fibrillation.mp. or exp Atrial Fibrillation/ 100,464
33 cardiomyopathy.mp. or exp Cardiomyopathies/ 143,152
34 heart failure.mp. or exp Heart Failure/ 245,181

35 exp Hypercholesterolemia/ or exp Hyperlipidemias/ 69,913
36 (hypercholesterol?emia or hyperlipid?emia).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 76,793
37 exp Hypertension/or hypertension.mp. 547,959
38 exp Myocardial Ischemia/ 464,415
39 (isch?emic heart disease or myocardial infarction).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 299,852
40 peripheral vascular disease.mp. or exp Peripheral Vascular Diseases/ 65,062
41 exp Stroke/ or stroke.mp. 378,102
42 exp Ischemic Attack, Transient/ 21,618
43 transient isch?emic attack.mp. 12,655
44 congenital heart disease.mp. or exp Heart Defects, Congenital/ 177,949
45 valvular heart disease.mp. or exp Heart Valve Diseases/ 136,981
46 rheumatic heart disease.mp. or exp Rheumatic Heart Disease/ 15,031
47 exp Heart Diseases/ 1,245,391
48 (heart disease or cardiac disease).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 214,566
49 alopecia areata.mp. or exp Alopecia Areata/ 5456
50 vitiligo.mp. or exp Vitiligo/ 8980
51 exp Eczema/ or eczema.mp. 24,134
52 psoriasis.mp. or exp Psoriasis/ 60,070
53 acne.mp. or exp Acne Vulgaris/ 21,180
54 hidradenitis suppurativa.mp. or exp Hidradenitis Suppurativa/ 3951
55 lichen planus.mp. or exp Lichen Planus/ 11,203
56 rosacea.mp. or exp Rosacea/ 4729
57 seborrheic dermatitis.mp. or exp Dermatitis, Seborrheic/ 3431
58 allergic rhinitis.mp. or exp Rhinitis, Allergic/ 31,617
59 allergic conjunctivitis.mp. or exp Conjunctivitis, Allergic/ 4493
60 exp Hearing Loss/ 76,292
61 (hearing loss or deaf*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 112,157
62 exp Addison Disease/ or addison* disease.mp. 6034
63 exp Adrenocortical Adenoma/ or adren* adenoma.mp. 3177
64 exp Pheochromocytoma/ 16,529
65 ph?eochromocytoma.mp. 23,936
66 exp Cushing Syndrome/ or cushing* syndrome.mp. 15,980
67 exp Diabetes Mellitus, Type 2/ or exp Diabetes, Gestational/ or exp Diabetes Mellitus/ or exp Diabetes Mellitus, Type 1/ 492,036
68 (diabetes or diabetic$1).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 809,517
69 exp Parathyroid Diseases/ or (parathyroid dis* or hyperparathyroid* or hypoparathyroid*).mp. 46,799
70 exp Thyroid Diseases/ or thyroid dis*.mp. 166,479

71 (hyperthyroid* or hypothyroid* or thyroiditis or graves disease).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 100,991
72 exp Pituitary Diseases/ or pituitary dis*.mp. 65,344
73 exp Endocrine System Diseases/ 1,099,839
74 exp Vision Disorders/ 77,726
75 (visual* impair* or blindness).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 59,580
76 exp Cataract/ or cataract.mp. 71,946
77 exp Diabetic Retinopathy/ 28,637
78 (diabetic retinopathy or diabetic eye dis*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 39,000
79 glaucoma.mp. or exp Glaucoma/ 79,199
80 scleritis.mp. or exp Scleritis/ 2393
81 episcleritis.mp. 624
82 exp Uveitis/ or uveitis.mp. 41,131
83 retinal detachment.mp. or exp Retinal Detachment/ 28,930
84 exp Eye Diseases/ 624,904
85 alcoholic liver disease.mp. or exp Liver Diseases, Alcoholic/ 18,612
86 autoimmune hepatitis.mp. or exp Hepatitis, Autoimmune/ 7336
87 sclerosing cholangitis.mp. or exp Cholangitis, Sclerosing/ 7900
88 primary biliary cirrhosis.mp. or exp Liver Cirrhosis, Biliary/ 10,999
89 chronic hepatitis.mp. or exp Hepatitis, Chronic/ 73,739
90 exp Hepatitis B, Chronic/ or hepatitis B.mp. 109,029
91 exp Hepatitis C, Chronic/ or hepatitis C.mp. 99,589
92 liver cirrhosis.mp. or exp Liver Cirrhosis/ 113,060
93 non-alcoholic fatty liver disease.mp. or exp Non-alcoholic Fatty Liver Disease/ 27,321
94 exp Liver Diseases/ 613,804
95 chronic pancreatitis.mp. or exp Pancreatitis, Chronic/ 17,127
96 c?eliac disease.mp. or exp Celiac Disease/ 26,440
97 food allergy.mp. or exp Food Hypersensitivity/ 26,232
98 cholelithiasis.mp. or exp Cholelithiasis/ 40,302
99 gallstones.mp. 20,545
100 inflammatory bowel disease.mp. or exp Inflammatory Bowel Diseases/ 114,088
101 exp Crohn Disease/ or crohn* disease.mp. 62,863
102 ulcerative colitis.mp. or exp Colitis, Ulcerative/ 56,412
103 proctitis.mp. or exp Proctitis/ 4741
104 irritable bowel syndrome.mp. or exp Irritable Bowel Syndrome/ 16,860
105 lactose intolerance.mp. or exp Lactose Intolerance/ 3661
106 peptic ulcer.mp. or exp Peptic Ulcer/ 88,964
107 chronic pelvic inflammatory dis*.mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 135
108 exp Pelvic Inflammatory Disease/ 11,423
109 dysmenorrhea.mp. or exp Dysmenorrhea/ 7392
110 endometriosis.mp. or exp Endometriosis/ 31,997
111 infertility.mp. or exp Infertility/ 104,859

112 assisted reproduction.mp. or exp Reproductive Techniques, Assisted/ 81,518
113 (in vitro fertili#ation or IVF).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 40,612
114 leiomyoma.mp. or exp Leiomyoma/ 25,551
115 fibroids.mp. 5762
116 exp Menopause/ or menopause.mp. 75,624
117 menorrhagia.mp. or exp Menorrhagia/ 6342
118 exp Urinary Incontinence/ or exp Pelvic Floor Disorders/ or exp Pelvic Organ Prolapse/ or exp Fecal Incontinence/ 55,156
119 (pelvic floor dysfunction or pelvic floor disorder*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 3030
120 (urinary incontinence or f?ecal incontinence).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 54,896
121 pelvic organ prolapse.mp. 7917
122 exp Polycystic Ovary Syndrome/ or polycystic ovar* syndrome.mp. 22,165
123 recurrent miscarriage.mp. or exp Abortion, Habitual/ 9737
124 exp Blood Coagulation Disorders/ or coagulation disorder.mp. 104,538
125 h?emophilia.mp. 29,136
126 exp Anemia, Sickle Cell/ or sickle cell.mp. 32,225
127 thalass?emia.mp. or exp Thalassemia/ 30,381
128 thrombophilia.mp. or exp Thrombophilia/ 30,589
129 pernicious an?emia.mp. or exp Anemia, Pernicious/ 7018
130 exp Thrombocytopenia/ or primary thrombocytopenia.mp. 52,629
131 venous thromboembolism.mp. or exp Venous Thromboembolism/ 29,575
132 deep ve* thrombosis.mp. 31,577
133 pulmonary embolism.mp. or exp Pulmonary Embolism/ 59,857
134 HIV.mp. or exp HIV Infections/ 434,875
135 AIDS.mp. or exp Acquired Immunodeficiency Syndrome/ 233,377
136 exp Immunocompromised Host/ 27,383
137 exp Immunosuppression Therapy/ or exp Immunosuppressive Agents/ 388,928
138 immunosuppress*.mp. 250,351
139 exp Transplantation/ 562,203
140 transplant*.mp. 829,484
141 exp Alcohol-Related Disorders/ 120,079
142 (alcohol misuse or alcohol abuse or alcohol dependence or alcoholism).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 102,885
143 exp Substance-Related Disorders/ 305,479
144 (substance misuse or substance abuse or substance dependence).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 62,218
145 exp Anxiety/ or exp Anxiety Disorders/ 182,212
146 anxiety.mp. 293,708
147 panic disorder.mp. or exp Panic Disorder/ 11,740
148 phobic disorder.mp. or exp Phobic Disorders/ 12,318

149 phobia.mp. 9483
150 exp Stress Disorders, Post-Traumatic/ 39,810
151 (post traumatic stress disorder or post-traumatic stress disorder or PTSD).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 37,152
152 exp Mood Disorders/ 133,816
153 exp Depression/ or exp Depression, Postpartum/ 151,065
154 (depression or depressive disorder or mood disorder).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 512,446
155 dementia.mp. or exp Dementia/ 249,440
156 eating disorder.mp. or exp "Feeding and Eating Disorders"/ 38,866
157 (anorexia nervosa or bulimia nervosa).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 21,488
158 bipolar disorder.mp. or exp Bipolar Disorder/ 55,305
159 exp "schizophrenia spectrum and other psychotic disorders"/ 160,377
160 (schizophrenia or psychosis or psychotic disorder or schizoaffective disorder).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 184,089
161 dissociative disorder.mp. or exp Dissociative Disorders/ 4851
162 obsessive compulsive disorder.mp. or exp Obsessive-Compulsive Disorder/ 21,507
163 personality disorder.mp. or exp Personality Disorders/ 49,545
164 self harm.mp. or exp Self-Injurious Behavior/ 84,338
165 exp Mental Disorders/ 1,400,314
166 (mental disorder or psychiatric disorder).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 22,024
167 (serious mental illness or severe mental illness).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 9183
168 exp Attention Deficit Disorder with Hyperactivity/ 33,703
169 (attention deficit hyperactivity disorder or ADHD).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 37,625
170 exp Autism Spectrum Disorder/ 40,143
171 (autism or autistic).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 65,738
172 cerebral palsy.mp. or exp Cerebral Palsy/ 31,036
173 intellectual disabilit*.mp. or exp Intellectual Disability/ 114,299
174 exp Down Syndrome/ or down* syndrome.mp. 32,674
175 exp Brain Injuries/ or acquired brain injury.mp. 80,562
176 exp Headache Disorders/ 39,158

177 (cluster headache or tension headache or chronic headache or migraine).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 47,919
178 exp Epilepsy/ 123,445
179 (epilepsy or epileptic).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 168,992
180 idiopathic intracranial hypertension.mp. or exp Pseudotumor Cerebri/ 5277
181 multiple sclerosis.mp. or exp Multiple Sclerosis/ 96,126
182 peripheral neuropathy.mp. or exp Peripheral Nervous System Diseases/ 173,401
183 exp Parkinson Disease/ or parkinson* disease.mp. 128,663
184 exp Neurodegenerative Diseases/ 356,554
185 (huntington* disease or huntington* chorea).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 20,536
186 motor neurone disease.mp. 1097
187 exp Sleep Wake Disorders/ 105,644
188 (sleep disorder or narcolepsy or obstructive sleep apn?ea).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 42,731
189 spina bifida.mp. or exp Spinal Dysraphism/ 12,140
190 exp Fatigue Syndrome, Chronic/ 6267
191 (chronic fatigue syndrome or myalgic encephalomyelitis).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 6552
192 fibromyalgia.mp. or exp Fibromyalgia/ 13,499
193 exp Chronic Pain/ 21,039
194 exp Complex Regional Pain Syndromes/ 5902
195 exp Myofascial Pain Syndromes/ 6785
196 (chronic pain or pain syndrome).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 67,401
197 exp Back Pain/ or chronic back pain.mp. 44,796
198 osteoarthritis.mp. or exp Osteoarthritis/ 106,483
199 exp Osteoporosis/ 61,530
200 (osteoporosis or osteopenia).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 102,970
201 scoliosis.mp. or exp Scoliosis/ 28,584
202 exp Spinal Diseases/ 137,686
203 exp Fractures, Compression/ 3022
204 (compression fracture or collapsed vertebra*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 2523
205 intervertebral disc degeneration.mp. or exp Intervertebral Disc Degeneration/ 8566

206 sciatica.mp. or exp Sciatica/ 7238
207 spinal stenosis.mp. or exp Spinal Stenosis/ 9721
208 spondylosis.mp. or exp Spondylosis/ 11,295
209 spondylolisthesis.mp. or exp Spondylolisthesis/ 7552
210 amputation.mp. or exp Amputation/ 52,820
211 amputee.mp. 3034
212 paralysis.mp. or exp Paralysis/ 117,463
213 exp Hemiplegia/ or hemiplegia.mp. 16,665
214 exp Paraplegia/ or paraplegia.mp. 22,286
215 quadriplegia.mp. or exp Quadriplegia/ 10,148
216 exp Disabled Persons/ 72,228
217 (disabled or disabilit*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 368,071
218 chronic kidney disease.mp. or exp Renal Insufficiency, Chronic/ 165,323
219 h?emodialysis.mp. or exp Renal Dialysis/ 147,868
220 exp Urinary Calculi/ 38,075
221 (urinary tract stone* or kidney stone*).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 7526
222 exp Asthma/ or asthma.mp. 193,826
223 exp Lung Diseases/ or chronic lung disease.mp. 1,172,810
224 bronchiectasis.mp. or exp Bronchiectasis/ 15,266
225 exp Pulmonary Disease, Chronic Obstructive/ 65,000
226 (chronic obstructive pulmonary disease or COPD).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 76,565
227 cystic fibrosis.mp. or exp Cystic Fibrosis/ 56,480
228 interstitial lung disease.mp. or exp Lung Diseases, Interstitial/ 88,055
229 pulmonary fibrosis.mp. 34,669
230 pulmonary hypertension.mp. or exp Hypertension, Pulmonary/ 57,397
231 exp Sarcoidosis/ or sarcoidosis.mp. 33,257
232 exp Tuberculosis/ or tuberculosis.mp. 274,528
233 exp Ehlers-Danlos Syndrome/ or ehlers-danlos.mp. 4735
234 rheumatoid arthritis.mp. or exp Arthritis, Rheumatoid/ 162,479
235 exp Sjogren's Syndrome/ 14,277
236 (sjogren* syndrome or sjogren* disease).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 19,871
237 exp Raynaud Disease/ or raynaud*.mp. 10,222
238 systemic sclerosis.mp. or exp Scleroderma, Systemic/ 27,173
239 scleroderma.mp. 29,499
240 primary systemic vasculitis.mp. or exp Systemic Vasculitis/ 18,247
241 marfan* syndrome.mp. or exp Marfan Syndrome/ 8688
242 spondyloarthritis.mp. or exp Spondylarthritis/ 31,559
243 psoriatic arthritis.mp. or exp Arthritis, Psoriatic/ 12,555
244 ankylosing spondylitis.mp. or exp Spondylitis, Ankylosing/ 21,291
245 systemic lupus erythematosus.mp. or exp Lupus Erythematosus, Systemic/ 80,550
246 autoimmune disease.mp. or exp Autoimmune Diseases/ 545,468

247 frailty.mp. or exp Frailty/ 23,160
248 exp COVID-19/ or long covid.mp. 199,512
249 post COVID syndrome.mp. 288
250 exp Obesity/ 251,605
251 (obese or obesity).mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] 419,142
252 polypharmacy.mp. or exp Polypharmacy/ 12,907
253 turner* syndrome.mp. or exp Turner Syndrome/ 9757
254 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123 or 124 or 125 or 126 or 127 or 128 or 129 or 130 or 131 or 132 or 133 or 134 or 135 or 136 or 137 or 138 or 139 or 140 or 141 or 142 or 143 or 144 or 145 or 146 or 147 or 148 or 149 or 150 or 151 or 152 or 153 or 154 or 155 or 156 or 157 or 158 or 159 or 160 or 161 or 162 or 163 or 164 or 165 or 166 or 167 or 168 or 169 or 170 or 171 or 172 or 173 or 174 or 175 or 176 or 177 or 178 or 179 or 180 or 181 or 182 or 183 or 184 or 185 or 186 or 187 or 188 or 189 or 190 or 191 or 192 or 193 or 194 or 195 or 196 or 197 or 198 or 199 or 200 or 201 or 202 or 203 or 204 or 205 or 206 or 207 or 208 or 209 or 210 or 211 or 212 or 213 or 214 or 215 or 216 or 217 or 218 or 219 or 220 or 221 or 222 or 223 or 224 or 225 or 226 or 227 or 228 or 229 or 230 or 231 or 232 or 233 or 234 or 235 or 236 or 237 or 238 or 239 or 240 or 241 or 242 or 243 or 244 or 245 or 246 or 247 or 248 or 249 or 250 or 251 or 252 or 253 14,494,082
255 (questionnaire* or survey* or interview* or focus group* or case stud* or observ* or ethnograph* or hermeneutic* or narrative* or phenomenolog* or grounded theory or process evaluation or implementation study or implementation research or view* or experienc* or opinion* or attitude* or perception* or perceive* or belie* or feel* or know* or understand* or barrier* or facilitator* or enabler* or obstacle*).tw. 9,977,739
256 exp Qualitative Research/ or (qualitative or mixed method*).tw. 332,065
257 255 or 256 10,059,034
258 9 and 20 and 254 and 257 2187

MEDLINE search strategy for LTCs economic evidence review (see *Chapter 8*)

Ovid MEDLINE® ALL 1946 to 17 August 2022

n = 3077, searched on 17 August 2022

1. exp Breast Feeding/
2. breastfeed*.mp.
3. breastfed.mp.
4. breast-feed*.mp.
5. breast-fed.mp.
6. breast feed*.mp.
7. breast fed.mp.
8. infant feed*.mp.
9. exp Milk, Human/
10. Lactation/

11. lactat*.mp.
12. support.mp.
13. Social Support/
14. advice.mp.
15. advis*.mp.
16. help*.mp.
17. supportive adj2 relationship.mp
18. counsel*.mp.
19. educat*.mp.
20. consult*.mp.
21. Health Promotion/
22. Health Education/
23. Economics/
24. exp “Costs and cost analysis”/
25. “Cost allocation”/
26. Cost-benefit analysis/
27. “Cost control”/
28. “Cost savings”/
29. “Cost of illness”/
30. “Cost sharing”/
31. “deductibles and coinsurance”/
32. Medical savings accounts/
33. Health care costs/
34. Direct service costs/
35. Drug costs/
36. Employer health costs/
37. Hospital costs/
38. Health expenditures/
39. Capital expenditures/
40. Value of life/
41. exp economics, hospital/
42. exp economics, medical/
43. Economics, nursing/
44. Economics, pharmaceutical/
45. exp “fees and charges”/
46. exp budgets/
47. (low adj cost).mp.
48. (high adj cost).mp.
49. (health?care adj cost$).mp.
50. (fiscal or funding or financial or finance).tw.
51. (cost adj estimate$).mp.
52. (cost adj variable).mp.
53. (unit adj cost$).mp.
54. (economic$ or pharmacoeconomic$ or price$ or pricing).tw.
55. or/1-11
56. or/12-22
57. or/23-54
58. 55 and 56 and 57
59. exp animals/ not humans.sh.
60. 58 not 59

Appendix 2 Study characteristics, risk-of-bias assessments and behaviour change techniques for mixed-methods synthesis (see *Chapter 4*)

TABLE 13 Study characteristics for mixed-methods synthesis (see *Chapter 4*)

Author year	RCT paper(s)	Country setting/target population	Intervention description	Methods		
				Study objective	Participants and data collection	Data analysis
Ahmed *et al.* 2012[101]	Ahmed and Roumani 2020[264]	USA, hospital	Interactive web-based breastfeeding monitoring system	To develop an interactive web-based breastfeeding monitoring system (LACTOR) and examine its feasibility, usability and acceptability among breastfeeding mothers	Convenience sample of women (n = 26) Online survey incorporating the System Usability Scale and a perception survey with open-ended questions	Descriptive statistics; Fisher's exact tests; content analysis
Andaya *et al.* 2012[93]	Bonuck *et al.* 2014[221]	USA Urban Primary healthcare venue Low-income population	Two intervention arms (1) Lactation consultant and electronic prompts; (2) lactation consultant only Lactation counselling and electronic pumps	To examine women's perceptions and reported effects of routine, primary-care-based interventions to increase breastfeeding	*Quantitative* Prenatal and 1-month follow-up questionnaires (number not reported) *Qualitative* Semi structured exit interviews at 6 months (n = 67 women)	Interview data coded and analysed in MAX. qdA
Teich *et al.* 2014[100]				To examine women's perceptions of early infant-feeding experiences and identified early postpartum barriers to breastfeeding		
Bronner *et al.* 2001[105]	Gross *et al.* 1998[265]	USA Urban Community Low-income women enrolled in WIC	Three intervention arms (1) Motivation video; (2) peer support; (3) motivational video and peer support	To examine breastfeeding peer counselling within the context of the organisational structure of state and local WIC agencies	Convenience sample of programme managers/co-ordinators (n = 409) and peer counsellors (n = 254) Survey	Descriptive statistics
Chapman *et al.* 2004[106]	Chapman *et al.* 2004[266]	USA Urban Hospital and community Low-income Latina women	Peer counsellors – hospital and home visits and telephone contact	To report a process evaluation focusing on coverage	Peer counsellor contact logs (number not reported)	Cox regression Descriptive statistics
Cramer *et al.* 2017[102]	McLachlan *et al.* 2016[224]	Australia Urban and rural community Areas with low breastfeeding rates	Two interventions One early home-based visiting by a maternal and child health nurse to women identified at risk of breastfeeding cessation Two home-based visiting and access to a drop-in centre	To describe drop-in centres established during the trial; and the profile of women who accessed them To explore the views and experiences of the drop-in centre staff, and the challenges faced in establishing and maintaining a breastfeeding drop-in centre in the community	*Quantitative* Survey of nurses running drop-in centres (n = 7) Visitor logbooks *Qualitative* Focus groups with nurses running drop-in centres (n = 6) Semi structured interviews with drop-in centre co-ordinators (n = 4) Observational visits, nurses' reflective diaries and visitor comments	Quantitative data analysed using Stata version 11 (no further details reported) Inductive thematic analysis

TABLE 13 Study characteristics for mixed-methods synthesis (see *Chapter 4*) (*continued*)

Author year	RCT paper(s)	Country setting/target population	Intervention description	Methods		
				Study objective	Participants and data collection	Data analysis
Ridgway *et al.* 2016[108]				To describe the content of the home visits	*Quantitative* Pre-coded data collection forms completed at each home visit (*n* = 1043 forms)	Descriptive statistics
Dennis *et al.* 2002[107]	Dennis *et al.* 2002[267]	Canada Urban Community hospitals	Telephone support by volunteer with breast-feeding experience	To describe maternal and peer volunteer perceptions of their experience while participating in a breastfeeding peer support trial	*Quantitative* Questionnaires – mothers (*n* = 130) Peer supporter weekly activity logs (*n* = 78) Questionnaires – peer supporters (*n* = 30)	Descriptive statistics Content analysis for open-ended questions
Hoddinott *et al.* 2012[103]	Hoddinott *et al.* 2012[118]	UK Urban and rural Community Disadvantaged population	Proactive telephone calls daily for 1 week following hospital discharge	To assess the feasibility, acceptability and fidelity of a feeding team intervention of team-initiated (proactive) and woman-initiated (reactive) telephone support after hospital discharge	*Quantitative* Telephone call log and workload diaries *Qualitative* Interviews with women (*n* = 40) with follow-up (*n* = 11) and staff (*n* = 17) Ward observations Recorded telephone calls (*n* = 16) Steering group meetings notes (*n* = 9) Trial case notes (*n* = 69) Telephone interviews (*n* = 372)	Descriptive statistics Framework analysis
Nankunda *et al.* 2006[95]	Tylleskar *et al.* 2011[109]	Uganda Rural Community and healthcare settings	Peer counselling Minimum of five home visits form late pregnancy up to 6 months postnatal Intervention delivered in three areas and adapted to local circumstances	To assess the feasibility of training community-based peer counsellors to support exclusive breastfeeding in a rural district in Uganda	Focus group discussions with peer counsellors (*n* = 2 groups); mothers (*n* = 2 groups) and men (*n* = 2) groups)	Transcripts were used to develop general impressions
Nankunda *et al.* 2010[96]				To describe the experience of establishing individual peer counselling including training and retaining peer counsellors for exclusive breastfeeding	Pre-test and post-test questionnaire (*n* = 12) Observation, field notes and records of interactions	Descriptive analysis Thematic analysis
Nankunda *et al.* 2010[104]				To describe women's experiences of peer counselling for exclusive breastfeeding	Interviews guided by a structured questionnaire with closed and open-ended questions	Chi-square or Fisher's exact test Coding of open-ended responses

continued

TABLE 13 Study characteristics for mixed-methods synthesis (see *Chapter 4*) (*continued*)

Author year	RCT paper(s)	Country setting/target population	Intervention description	Methods		
				Study objective	Participants and data collection	Data analysis
Rujumba *et al.* 2020[99]				To explore the barriers to, facilitators of and solutions to scaling-up of peer counselling support for exclusive breastfeeding in Uganda	Key informant interviews (*n* = 15) Focus groups with peer counsellors (*n* = 7 groups with 6–8 participants in each)	Content thematic approach
Daniels *et al.* 2010[94]	Tylleskar *et al.* 2011[109]	South Africa Community Poor areas with high HIV prevalence	Peer counselling Minimum of five home visits form late pregnancy up to 6 months postnatal Intervention delivered in three areas and adapted to local circumstances	To report the experience of three community health worker supervisors who were responsible for supporting infant-feeding peer counsellors	Semi structured interviews (*n* = 3)	Framework analysis
Nkonki *et al.* 2010[97]				To describe the experiences of peer supporters who promote exclusive infant feeding	Focus group discussions with peer supporters (*n* = 19)	Thematic analysis
Rahman *et al.* 2012[98]	Sikander *et al.* 2015[268]	Pakistan Rural community Low literacy, with low rates of exclusive breastfeeding	Seven psycho-educational sessions integrated into the routine work of lady health workers	To explore the integration of cognitive-behavioural therapy in the routine breastfeeding counselling practice of community health workers	*Quantitative* Lady health worker questionnaires (*n* = 40) *Qualitative* Focus group discussions with lady health worker trainers (*n* = 28) Interviews with managers (*n* = 2)	Quantitative– not reported Qualitative Coding and themes based on inductive and a priori theory

WIC, supplemental nutrition programme for women, infants and children.

TABLE 14 Quality appraisal of included studies (see *Chapter 4*)

Study	1. Were steps taken to increase rigour/minimise bias and error in the sampling?	2. Were steps taken to increase rigour/minimise bias and error in the data collected?	3. Were steps taken to increase rigour/minimise bias and error in the analysis of the process data?	4. Were the findings of the process evaluation grounded in/supported by the data?	5. Please rate the findings of the process evaluation in terms of their breadth and depth	6. To what extent does the process evaluation privilege the perspectives and experiences of breastfeeding women?	7. What weight would you assign to this process evaluation in terms of the reliability of its findings?	8. What weight would you assign to this process evaluation in terms of the usefulness of its findings?
Ahmed *et al.* 2012[101]	Yes – a few steps were taken	Yes – several steps were taken	Yes – fairly thorough attempt	Reasonably well grounded/supported	Good/fair breadth but very little depth	A lot	Medium	Medium
Andaya *et al.* 2012[93]	Yes – fairly thorough attempt	Yes – fairly thorough attempt	Yes – fairly thorough attempt	Reasonably well grounded/supported	Limited breadth or depth	Somewhat	Medium	Medium
Bronner *et al.* 2000[105]	Yes – several steps were taken	Yes – several steps were taken	Yes – several steps were taken	Fairly well grounded or supported	Good/fair breadth but very little depth	Not at all	High	Medium
Chapman *et al.* 2004[106]	Yes – several steps were taken	Unclear	Yes – a few steps were taken	Reasonably well grounded/supported	Limited breadth or depth	A little	Medium	Medium
Cramer *et al.* 2017[102]	Yes – several steps were taken	Yes – several steps were taken	Yes – fairly thorough attempt	Reasonably well grounded/supported	Good/fair depth but very little breadth	Not at all	High	Medium
Daniels *et al.* 2010[94]	Yes – fairly thorough attempt	Yes – a few steps were taken	Yes – several steps were taken	Reasonably well grounded/supported	Good/fair depth but very little depth	Not at all	Low	Low
Dennis *et al.* 2002[107]	Yes – fairly thorough attempt	Yes – fairly thorough attempt	Yes – fairly thorough attempt	Fairly well grounded/supported	Good/fair breadth but very little depth	Somewhat	Medium	Medium
Hoddinott *et al.* 2012[103]	Yes – fairly thorough attempt	Yes – fairly thorough attempt	Yes – fairly thorough attempt	Reasonably well grounded/supported	Good/fair breadth and depth	A lot	High	High
Nankunda *et al.* 2006[95]	Unclear	Yes – fairly thorough attempt	Unclear	Fairly well grounded/supported	Good/fair breadth and depth	Somewhat	Low	Medium

continued

TABLE 14 Quality appraisal of included studies (see *Chapter 4*) (*continued*)

Study	1. Were steps taken to increase rigour/minimise bias and error in the sampling?	2. Were steps taken to increase rigour/minimise bias and error in the data collected?	3. Were steps taken to increase rigour/minimise bias and error in the analysis of the process data?	4. Were the findings of the process evaluation grounded in/supported by the data?	5. Please rate the findings of the process evaluation in terms of their breadth and depth	6. To what extent does the process evaluation privilege the perspectives and experiences of breastfeeding women?	7. What weight would you assign to this process evaluation in terms of the reliability of its findings?	8. What weight would you assign to this process evaluation in terms of the usefulness of its findings?
Nankunda *et al.* 2010a[96]	Yes – several steps were taken	Yes – several steps were taken	Yes – fairly thorough attempt	Fairly well grounded/supported	Good/fair breadth but very little depth	Not at all	Medium	Medium
Nankunda *et al.* 2010b[104]	Yes – fairly thorough attempt	Yes – fairly thorough attempt	Yes – fairly thorough attempt	Reasonably well grounded/supported	Good/fair breadth and depth	A lot	High	High
Nkonki *et al.* 2010[97]	Yes – fairly thorough attempt	Yes – fairly thorough attempt	Yes – fairly thorough attempt	Fairly well grounded/supported	Good/fair depth but very little breadth	Not at all	High	High
Rahman *et al.* 2011[98]	Yes – a few steps were taken	Yes – a few steps were taken	Yes – fairly thorough attempt	Reasonably well grounded/supported	Good/fair depth but very little breadth	Not at all	High	Medium
Ridgway *et al.* 2016[108]	Unclear	Yes – a few steps were taken	Yes – a few steps were taken	Reasonably well grounded/supported	Limited breadth or depth	Not at all	Medium	Medium
Rujumba *et al.* 2020[99]	Yes – several steps were taken	Yes – several steps were taken	Yes – fairly thorough attempt	Reasonably well grounded/supported	Good/fair breadth and depth	A lot	High	High
Teich *et al.* 2014[100]	Yes – fairly thorough attempt	Yes – fairly thorough attempt	Yes – fairly thorough attempt	Reasonably well grounded/supported	Good/fair breadth but very little depth	A lot	Medium	High

TABLE 15 Behaviour change techniques for breastfeeding support interventions

Linked intervention study included in Cochrane review (WP1) (first author and year)	Implementation research articles included in WP2 review (first author and year)	Behaviour change techniques identified in Cochrane study articles
Ahmed 2020[264]	Ahmed 2012[101]	1.2. Problem-solving 2.2. Feedback on behaviour 2.3. Self-monitoring of behaviour 2.4. Self-monitoring of outcome(s) of behaviour 2.7. Feedback on outcome(s) of behaviour 3.1. Social support (unspecified) 3.2. Social support (practical) 4.1. Instruction on how to perform the behaviour 4.2. Information about antecedents 7.1. Prompts/cues 9.1. Credible source 10.4. Social reward
Bonuck 2014[221]	Andaya 2012[93]	1.2. Problem-solving 3.1. Social support (unspecified) 4.1. Instruction on how to perform the behaviour 5.1. Information about health consequences 10.4. Social reward
Chapman 2004[266]	Chapman 2004[106]	1.2. Problem-solving 1.3. Goal setting (outcome) 1.4. Action planning 1.5. Review behaviour goal(s) 2.1. Monitoring of behaviour by others without feedback 2.2. Feedback on behaviour 2.7. Feedback on outcome(s) of behaviour 3.1. Social support (unspecified) 3.2. Social support (practical) 7.1. Prompts/cues 7.2. Cue signalling reward 9.1. Credible source 10.4. Social reward 16.3. Vicarious consequences
Dennis 2002[267]	Dennis 2002[107]	1.2. Problem-solving 3.1. Social support (unspecified) 3.2. Social support (practical)
Gross 1998[265]	Bronner 2001[105]	1.1. Goal setting (behaviour) 1.2. Problem-solving 1.3. Goal setting (outcome) 3.1. Social support (unspecified) 3.2. Social support (practical) 3.3. Social support (emotional) 4.1. Instruction on how to perform the behaviour 5.1. Information about health consequences 5.6. Information about emotional 6.1. Demonstration of the behaviour 7.1. Prompts/cues 7.2. Cue signalling reward 9.1. Credible source 9.2. Pros and cons
Hoddinott 2012[118]	Hoddinott 2012[103]	2.2. Feedback on behaviour 2.7. Feedback on outcome(s) of behaviour 3.1. Social support (unspecified) 3.2. Social support (practical) 3.3. Social support (emotional) 4.1. Instruction on how to perform the behaviour 6.1. Demonstration of the behaviour

continued

TABLE 15 Behaviour change techniques for breastfeeding support interventions (*continued*)

Linked intervention study included in Cochrane review (WP1) (first author and year)	Implementation research articles included in WP2 review (first author and year)	Behaviour change techniques identified in Cochrane study articles
McLachlan 2016[224]	Cramer 2017[102] Ridgeway 2016[108]	1.1. Goal setting (behaviour) 1.2. Problem-solving 3.1. Social support (unspecified) 15.1. Verbal persuasion about capability
Sikander 2015[268]	Rahman 2012[98]	1.1. Goal setting (behaviour) 1.2. Problem-solving 1.4. Action planning 1.5. Review behaviour goal(s) 2.1. Monitoring of behaviour by others without feedback 2.2. Feedback on behaviour 2.3. Self-monitoring of behaviour 3.1. Social support (unspecified) 3.2. Social support (practical) 4.1. Instruction on how to perform the behaviour 5.1. Information about health consequences 8.2. Behaviour substitution 9.1. Credible source 9.2. Pros and cons 9.3. Comparative imagining of future outcomes 12.2. Restructuring the social environment 13.2. Framing/reframing 13.5. Identity associated with changed behaviour
Tylleskar 2011[109]	Nankunda 2006[95] Rujumba 2020[99] Nankunda 2010[96] Nankunda 2010[104] Nkonki 2010[97] Daniels 2010[94]	1.2. Problem-solving 1.4. Action planning 2.1. Monitoring of behaviour by others without feedback 2.2. Feedback on behaviour 2.3. Self-monitoring of behaviour 2.4. Self-monitoring of outcome(s) of behaviour 3.1. Social support (unspecified) 3.3. Social support (emotional) 4.1. Instruction on how to perform the behaviour 4.2. Information about antecedents 5.1. Information about health consequences 12.2. Restructuring the social environment

Appendix 3 Characteristics of included economic evaluation studies

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Barnes 2017 (Barnes *et al.*, 2017[116]) England Seven study sites: London (two sites), the Midlands (two sites), the north-east (one site) and the north-west of England (two sites) Community healthcare setting	**Group family-nurse partnership (FNP) + usual care** **Support**: Breastfeeding plus **Description**: Content aimed to improve maternal health and pregnancy outcomes, improve child health and development by helping parents provide more sensitive and competent care; and to improve parental life course by helping parents develop effective support networks, plan future pregnancies, complete their education and find employment	**Usual care** **Description**: Offers every family a programme of screening tests, immunisations, developmental reviews, and information and guidance to support parenting and healthy choices. There are core universal elements provided for all families with additional progressive, preventive elements for those at medium or high risk. The universal programme includes a neonatal examination, a new-baby review at about 14 days, a 6- to 8-week baby examination and a review by the time the child is 1 year old and at 2–2.5 years old	**Inclusion criteria**: Expectant mothers at 16–20 weeks' gestation, with expected delivery date within ≈ 10 weeks, aged either (1) < 20 years at last menstrual period with one or more previous live births, or (2) 20–24 years at last menstrual period with no previous live births and with low educational qualifications	**Type of economic evaluation**: CUA and CEA (trial-based) **Perspective**: Provider (NHS and PSS) **Currency, price year**: GBP, 2014–15 **Time horizon**: Pregnancy to infant aged 12 months **Discount rate**: 3.5% for costs and benefits accrued beyond the first 12 months of follow-up **Primary outcome**: Incremental cost per QALY gained **Secondary outcomes**: Incremental cost per gain in AAPI-2 score (attitudes to parenting), incremental cost per gain in CARE Index score (maternal sensitivity)	**Base-case results**: ICER = −£247,485 per QALY gained, ICER = £111,334 per gain in AAPI-2 score, ICER = −£2382 per gain in CARE Index score For the primary outcome, intervention dominated (more costly and less effective than usual care) with a 2.3% probability of being cost-effective at a threshold of £20,000	**Directly applicable**: UK setting, provider perspective, cost per QALY gained reported, time horizon from pregnancy up to infant aged 12 months

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
	Provider: Professional (two FNPs) **Mode of delivery**: Face to face with groups **Intensity**: High (44 contacts) **Duration**: From first trimester of pregnancy until infants were 12 months old		**Exclusion criteria**: Women who had previously received FNP and those with psychotic mental illness **Sample size**: Total, *N* = 166 (IG, *n* = 99; CG, *n* = 67) **Baseline characteristics**: Baseline characteristics of participants appear balanced. Participants appear in keeping with target population	**Data sources**: *Outcome of effect*: Within trial (EQ-5D-5L valued using UK tariffs) *Resource use*: Within trial *Unit costs*: National sources **Measurement of uncertainty**: 10,000 replications of incremental costs and benefits generated to determine level of sampling uncertainty around the mean ICERs **Consideration of heterogeneity**: Subgroup analyses by (1) completers (attended ≥ 17 sessions) and (2) programme phase (1, 2, 3) to examine effects of organisational learning **Sensitivity analyses**: (1) Adopting a wider societal perspective, (2) restricting analyses to complete cases and (3) recalculating the average cost per group FNP session per attending woman by varying (a) mean number of group FNP sessions attended to the highest and lowest observed mean values across all groups across all sites and (b) number of group FNP group participants to the greatest and smallest number of observed values across all groups and sites	**Findings from subgroup analyses**: No evidence that the subgroups had a positive effect on the ICER **Findings from sensitivity analyses**: Little effect on the results, with the mean ICER holding in the north-west quadrant and the probability of cost-effectiveness remaining < 20% at a threshold of £20,000	

continued

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Brown 2020 (Brown *et al.*, 2020[128]) Australia and New Zealand Urban areas Community settings	**Obesity prevention interventions + usual care** **Support**: Breastfeeding plus **Description**: Five early obesity prevention interventions, three of which fulfilled the eligibility criteria: (1) Healthy Beginnings (HB) trial – see Hayes 2014 for description; (2) Communicating Healthy Beginnings Advice by Telephone (CHAT) trial – see Wen 2017 for description; (3) Prevention of Overweight in Infancy (POI) trial – see Tan 2020 for description	**Usual care** **Description**: HB trial – see Hayes 2014; CHAT trial – see Wen 2017; POI trial – see Tan 2020	**Inclusion criteria**: HB trial – see Hayes 2014; CHAT trial – see Wen 2017; POI trial – see Tan 2020 **Exclusion criteria**: HB trial – see Hayes 2014; CHAT trial – see Wen 2017; POI trial – see Tan 2020 **Sample size**: HB trial – see Hayes 2014; CHAT trial – see Wen 2017; POI trial – see Tan 2020	**Type of economic evaluation**: Cost comparison of intervention delivery costs across five trials (three eligible for this review) **Perspective**: Provider/funder **Currency, price year**: AUD, 2018 **Time horizon**: Birth to infant age 2 years **Discount rate**: 5% for costs **Primary outcome**: Intervention cost **Secondary outcomes**: Not applicable **Data sources**: *Outcome of effect*: Not applicable *Resource use*: Within trial *Unit costs*: National sources	**Base-case results**: From most to least costly: HB AU$1135 (AU$1059–1189); POI-combined AU$602 (AU$577–624); POI-FAB alone AU$429 (AU$409–449); CHAT-Telephone AU$394 ($373–382); CHAT-SMS AU$80 (AU$77–82) Interventions varied widely in terms of resource use and costs	**Not applicable**: Intervention costs reported with a comparison, OECD setting. Provider perspective, time horizon from birth up to infant age 2 years
	Provider: Professional **Mode of delivery**: Face to face and/or telephone/SMS **Intensity**: Moderate to high (8–10 contacts) **Duration**: From late pregnancy/birth to infant age 2 years (POI 18 months; 2 years on request)		**Baseline characteristics**: HB trial – see Hayes 2014; CHAT trial – see Wen 2017; POI trial – see Tan 2020	**Measurement of uncertainty**: Estimated 95% uncertainty intervals around mean costs for the base case and sensitivity analyses using Monte Carlo simulation (2000 iterations) **Consideration of heterogeneity**: Not reported **Sensitivity analyses**: (1) Adopting a wider perspective with inclusion of family costs, (2) discount rate of 3%	**Findings from sensitivity analyses**: Little effect on the results of the cost comparison, with the sensitivity analyses demonstrating similar variance and the same order of most to least costly	

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Delgado 2018 (Delgado *et al.*, 2018[121]) USA One study site in city of San Antonio, Texas Community setting	**Baby Café** **Support**: Breastfeeding only **Description**: *Authors state: The Baby Café breastfeeding support model was developed in the UK with the primary purpose of working with mothers for the first 8 weeks after birth … located in a facility of easy access to mother 'Partners', where weekly demonstration sessions take place in a relaxed environment conducive to open discussions on breastfeeding approaches*	**No comparator** **Description**: Not applicable	**Inclusion criteria**: No inclusion criteria – personnel promoted the Baby Café to low-income pregnant women and postnatal mothers **Exclusion criteria**: Not applicable	**Type of economic evaluation**: Cost description **Perspective**: Provider (state funder) **Currency, price year**: USD, 2010 **Time horizon**: Birth to infant age 8 weeks **Discount rate**: 3.5% for delivery costs across 5 years **Primary outcome**: Cost per mother **Secondary outcomes**: Cost per session	**Base-case results**: Cost per mother = US$105; cost per session = US$22.53 **Findings from sensitivity analyses**: Cost per mother ranged from US$65–247 suggesting results sensitive to weekly number of baby sessions and number of mothers attending	**Not applicable**: Cost of one alternative reported, time horizon of intervention costed from birth to 8 weeks; OECD setting, provider perspective
	Provider: Professional (lactation specialist) and lay person (peer counsellor) **Mode of delivery**: Face to face in groups **Intensity**: Low to moderate (2–8 contacts) **Duration**: From birth to infant age 8 weeks		**Sample size**: A total of 95 mothers visited the café during the 1-year data collection period **Baseline characteristics**: Not applicable; however, 95% of mothers attending came from the WIC clinic catchment area, indicating low-income status	**Data sources**: *Outcome of effect*: Not applicable *Resource use*: Programme data *Unit costs*: Programme data **Measurement of uncertainty**: Not reported **Consideration of heterogeneity**: Not reported **Sensitivity analyses**: 'A two-way sensibility [sic] analysis was completed, varying the weekly number of baby sessions and number of mothers attending each Baby Café session'		

continued

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
DelliFraine 2011 (DelliFrane *et al.*, 2011[122]) USA Nationwide Hospital setting	**BFHI-accredited hospitals** **Support**: Breastfeeding plus **Description**: BFHI steps 1–9 for organisations to promote successful breastfeeding	**Usual care** **Description**: Non-BFHI accredited hospitals. No further information provided	**Inclusion criteria**: All baby-friendly hospital and birthing sites in the USA in 2009 with data available in the public data files (intervention group) and matched with similar size and type non-baby-friendly hospitals in the same city (control group)	**Type of economic evaluation**: Cost analysis of two alternatives **Perspective**: Payer **Currency, price year**: USD, 2007 **Time horizon**: 1 year **Discount rate**: Not applicable **Primary outcome**: Mean cost per nursery plus labour and delivery **Secondary outcomes**: Not applicable	**Base-case results**: Differential cost of US$35 per nursery plus labour and delivery For the primary outcome, no statistically significant difference in mean cost per delivery identified (US$2205 vs. US$2170) for baby-friendly hospitals compared with non-baby-friendly hospitals	**Not applicable**: Payer perspective, differential cost reported and limited to one category of resource use with gross costing methods used; OECD setting, time horizon 1 year
	Provider: Professional **Mode of delivery**: Face to face **Intensity**: Not reported, but organisational level intervention focused on nursery, labour and delivery **Duration**: Hospitalisation for labour and delivery		**Exclusion criteria**: Baby-friendly hospital and birthing sites in the USA in 2009 without data available in the public data files **Sample size**: Total, $N = 124$ (IG, $n = 62$; CG, $n = 62$) **Baseline characteristics**: Hospitals matched on city, state, bed size and number of deliveries to minimise differences. No other differences observed in length of stay, case-mix index, and percentage Medicaid and self-pay deliveries	**Data sources**: *Outcome of effect*: Not applicable *Resource use*: Data from the 2007 American Hospital Association *Unit costs*: National sources **Measurement of uncertainty**: Not reported **Consideration of heterogeneity**: Not reported **Sensitivity analyses**: Not reported		

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Frick 2012[123] USA Two hospitals (one university and one community hospital) serving urban areas in Baltimore, MD, USA	**Usual care plus a structured programme of education and support + usual care** **Support**: Breastfeeding only **Description**: In addition to usual care, a structured programme of education and support comprising postnatal visits by a breastfeeding team (community nurse and peer counsellor)	**Usual care** **Description**: Usual care included access to a lactation consultant in hospital and phone access after discharge home	**Inclusion criteria**: Mother English-speaking, with telephone access and living within 25 miles of the hospital, intending to breastfeed, family eligible for WIC programme, singleton term infant (> 37 weeks' gestation) **Exclusion criteria**: Infants or mothers with positive drug screen, infants with craniofacial abnormalities, infants admitted to NICU	**Type of economic evaluation**: CA **Perspective**: Societal perspective – limited to payer and family **Currency, price year**: USD, 2009, adjusted to 2011 prices **Time horizon**: Infant age 12 weeks **Discount rate**: N/A **Primary outcome**: Base-case per-person costs of the programme (personnel and transportation costs only) **Data sources:** *Outcome of effect*: Within trial *Resource use*: Within trial *Unit costs*: Within trial and national sources **Measurement of uncertainty**: Varied labour costs to upper and lower CI limits for time (assuming maximum and minimum expenditures, respectively)	**Base-case results**: Cost = US$296.54 (US$274.12–320.97) **Findings from sensitivity analyses**: (1) Cost at upper limit = US$320.97, (2) cost at lower limit = US$274.12	**Not applicable**: Cost of one alternative reported, time horizon from birth to infant age 12 weeks; OECD setting, payer and family perspective with costs presented separately
	Provider: Professional and paraprofessional with a community nurse and peer counsellor **Mode of delivery**: Face to face and telephone **Intensity**: High **Duration**: Birth to 24 weeks postpartum		**Sample size**: Total, *N* = 328 (intervention, *n* = 168; control, *n* = 160) **Baseline characteristics**: Baseline variables were measured using established valid instruments and were used as covariates to adjust for differences between randomisation groups in some of the analyses in the paper	**Consideration of heterogeneity**: None reported **Sensitivity analyses**: (1) Costs at upper limit, (2) costs at lower limit		

continued

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Haider 2014 (Haider *et al.*, 2014[124]) USA 22 counties in the state of Michigan Community healthcare setting	**Peer counsellor breastfeeding support programme** **Support**: Breastfeeding only **Description**: Breastfeeding education and support to low socioeconomic status women using mothers recruited from the community to serve as peer counsellors. Support includes breastfeeding advice, access to technical advice from lactation consultants, and advice regarding nutrition, health and other local services for which the mothers are eligible	**Unclear** **Description**: Women had requested the peer counsellor support programme but did not receive it due to high demand and low capacity	**Inclusion criteria**: Women who requested the breastfeeding support programme, individuals for whom Medicaid claims data were available and who were recruited into the programme prenatally **Exclusion criteria**: Not reported **Sample size**: Total, *N* = 846 (IG, *n* = 274; CG, *n* = 572)	**Type of economic evaluation**: Cost outcome description of two alternatives **Perspective**: Payer **Currency, price year**: USD, price year not reported **Time horizon**: From birth to infant age 12 months **Discount rate**: Not applicable **Primary outcome**: Mean expenditures on health utilisation per infant **Secondary outcomes**: Programme cost per mother **Data sources**: *Outcome of effect*: Breastfeeding rates *Resource use*: Data from Medicaid administrative data	**Base-case results**: Adjusted differential expenditure of US$770 (−US$927, US$2467) on health utilisation per infant For the primary outcome, no statistically significant difference in mean expenditures on health utilisation per infant for women receiving peer counsellor support compared with those who requested support but did not receive it	**Not applicable**: Payer perspective, differential cost reported with gross costing methods used; OECD setting, time horizon from birth to infant age 12 months
	Provider: Lay person (peer counsellor) **Mode of delivery**: Face to face and telephone **Intensity**: High – aim for monthly home visits or telephone calls, depending on type of support needed **Duration**: Third trimester of pregnancy up to maximum infant age 12 months		**Baseline characteristics**: Appear balanced at baseline	*Unit costs*: Not applicable (total expenditure from Medicaid administrative data) **Measurement of uncertainty**: 95% CIs reported **Consideration of heterogeneity**: Regression model adjusted for potential confounders **Sensitivity analyses**: Not reported		

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Hanafin 2018[134] Ireland Country-wide Community healthcare setting	**PHN-facilitated breastfeeding groups + usual care** **Support**: Breastfeeding only **Description**: The PHN-facilitated breastfeeding groups aimed to provide support, knowledge and advice to breastfeeding mothers, maternal confidence and capacity to breastfeed. Mothers also have opportunities to meet other mothers and develop social networks **Provider**: Professional (lactation consultants) **Mode of delivery**: Face to face **Intensity**: High **Duration**: Antenatal through to postnatal duration of breastfeeding	**No comparator** **Description:** Not applicable	**Inclusion criteria**: N/A **Exclusion criteria**: N/A **Sample size**: N/A **Baseline characteristics**: N/A	**Type of economic evaluation**: CBA – SROI **Perspective**: Societal **Currency, price year**: Euros, price date and year of conversion unclear **Time horizon**: Costs and benefits are calculated and presented in terms of average annual figures for a group **Discount rate**: Outcomes beyond 1 year were discounted at 5% for those 2–5 years **Primary outcome**: Net present value SROI ratio in euros per annum for the PHN-facilitated breastfeeding groups **Data sources**: *Outcome of effect*: Within study and literature *Resource use*: Within study and literature *Unit costs*: Within study and literature **Measurement of uncertainty**: More optimistic assumptions related to prolongation of breastfeeding, and the value of lives saved due to lower incidence of invasive breast cancer and ovarian cancer **Consideration of heterogeneity**: No consideration of heterogeneity **Sensitivity analyses**: Sensitivity analysis assessed changes to valuations of key benefits: increased intelligence, improved lifetime earnings, reduced cancer incidence	**Base-case results**: SROI ratio in euros per annum for the PHN-facilitated breastfeeding groups €15.85:1 **Findings from sensitivity analyses**: SROI ratio per annum with prolongation of breastfeeding doubled to 2.58 months, SROI = €31.71:1; SROI ratio per annum with a social value for additional life years gained from a medical intervention estimated at €114,000, SROI = €15.95:1	**Not applicable**: Cost of one alternative provided, no ICER reported OECD setting, societal perspective, time horizon from birth to lifetime

continued

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Hayes 2014 (Hayes *et al.*, 2014;[129] Wen *et al.*, 2012[269]) Australia Socially and economically disadvantaged areas of Sydney Community setting with home visits	**Healthy beginnings + usual care** **Support**: Breastfeeding plus **Description**: Specifically trained research nurse delivered a staged home-based intervention in the antenatal and postnatal period. At each visit the research nurse spent 1–2 hours with the mother/infant and addressed four key areas: infant-feeding practices, infant nutrition and active play, family physical activity and nutrition, as well as social support)	**Usual care** **Description**: Usual childhood nursing service, comprising one home visit by a community nurse within a month of birth, if needed, plus visits to the local clinic. The control group also received home safety information sent by mail at five time points up to 18 months	**Inclusion criteria**: ≥ 16 years old, expecting first child, between weeks 24 and 34 of pregnancy, able to communicate in English, and lived in the local area **Exclusion criteria**: Women were excluded from the study if they had severe medical conditions as evaluated by their physicians	**Type of economic evaluation**: CEA (trial-based) **Perspective**: Provider (health funder) **Currency, price year**: AUD, 2012 **Time horizon**: Within trial – pregnancy to infant aged 2 years **Discount rate:** 5% for costs and benefits accrued beyond the first 12 months of follow-up **Primary outcome:** Incremental cost per unit BMI avoided **Secondary outcomes:** Incremental cost per 0.1 BMI *z*-score reduction **Data sources:** *Outcome of effect*: Within trial	**Base-case results**: ICER = AU$4230 per unit BMI avoided; ICER = AU$631 per 0.1 BMI-*z* score reduction Difficult to gauge cost-effectiveness, as no understanding of health providers' WTP for the prevention of BMI gain **Findings from scenario analyses**: A reduction in travel and administration time for the community nurse reduced intervention costs and led to a higher probability of Healthy Beginnings being cost-effective (66% vs. 30%) at a suggested WTP threshold of AU$500 for a 0.1 BMI *z*-score reduction	**Partially applicable**: OECD setting Provider perspective, cost per unit BMI avoided reported, within-trial time horizon from birth to infant age 2 years
	Provider: Professional (community nurse) **Mode of delivery**: Face to face with individuals via home visits **Intensity**: Moderate (eight contacts) **Duration**: From pregnancy until infant age 2 years		**Sample size**: Total *N* = 667 for the trial; subsample consenting to phase 2 with complete data available included in the economic evaluation [*N* = 324 (IG, *n* = 166; CG, *n* = 158)] **Baseline characteristics**: Baseline characteristics appear balanced for age, household income and education level, excepting marital status ($p = 0.046$) with a lower percentage (90% vs. 96%) of women being married/de facto in the intervention group	*Resource use*: Retrospective costing of trial data *Unit costs*: National sources **Measurement of uncertainty**: Bootstrapping was used to estimate a distribution around costs and health outcomes; CEAC was produced to examine uncertainty around the probability of being cost-effective at decision-makers' WTP **Consideration of heterogeneity**: Not reported **Sensitivity analyses**: No sensitivity analysis reported, a scenario analysis was conducted to examine costs in a 'real world' setting with travel and administration time reduced from 90 minutes to 20 minutes		

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Hoddinott 2009[117] UK 14 localities (of 66) in Scotland Community-based, primary care setting – GP practices	**BIG + usual care** **Support**: Breastfeeding only **Description**: A policy intervention aimed at locality areas rather than at individual women. The policy aimed to double the number of local breastfeeding support groups and to make weekly support groups open to all pregnant women and breastfeeding mothers, aiming to provide breastfeeding support and social interaction for women **Provider**: Health professional group facilitator **Mode of delivery**: Face to face **Intensity**: Low	**Usual care** **Description**: Control localities received no additional intervention; however, breastfeeding support postnatal groups existed in some control areas	**Inclusion criteria**: Pregnant women and breastfeeding mothers **Exclusion criteria**: Not stated **Sample size**: 14 clusters randomised, birth records supplied data for *n* = 9747 in intervention group and *n* = 9111 in control group **Baseline characteristics**: Localities varied in size, baseline breastfeeding rates, the number of pre-existing groups and how pregnancy and postnatal care were organised. The authors reported matching them in pairs by mean breastfeeding rate at 6–8 weeks in 2002 and 2003, rural classification, and existing number of breastfeeding groups per 1000 births. Considered intervention and control groups to be comparable	**Type of economic evaluation**: CA **Perspective**: Provider (e.g. NHS and PSS), patient (i.e. mother) **Currency, price year**: GBP, 2005/6 **Time horizon**: Not reported. Assume within-trial: Cost per year evaluated for the health service costs; costs per woman attending weekly group sessions evaluated, with attendance at a median of four times **Discount rate**: Not reported **Primary outcome**: Intervention cost per woman attending **Secondary outcomes**: Intervention cost per attendance at a group **Data sources**: *Outcome of effect*: Within trial *Resource use*: Within trial *Unit costs*: Not clear how unit costs were established **Measurement of uncertainty**: N/A **Consideration of heterogeneity**: N/A	**Base-case results**: Intervention cost per woman attending = £143; intervention cost per attendance at a group = £36	**Not applicable**: Cost of one alternative, time horizon within trial UK setting, provider and family perspective with data presented separately

continued

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Hoddinott 2012[118] Scotland Disadvantaged areas with a mix of urban and rural Hospital and community setting	**Feeding support team with proactive telephone support + usual care** **Support**: Breastfeeding only **Description**: Proactive telephone calls **Provider**: Professional and paraprofessional staff (two band 4 staff: a nursery nurse and a maternity care assistant) and a band 7 (midwife) team leader	**Feeding support team with reactive telephone support + usual care** **Description**: Reactive telephone calls; women could telephone the feeding team at any point over the 2 weeks following discharge. Text and answerphone messaging available	**Inclusion criteria**: Women admitted to the ward who lived in three most disadvantaged postcode area quintiles for the Scottish Index of Multiple Deprivation in 2009 and who were breastfeeding **Exclusion criteria**: Women aged < 16 years with serious medical or psychiatric problems or with insufficient spoken English to communicate by telephone	**Type of economic evaluation**: CEA (trial-based) **Perspective**: Provider (NHS) **Currency, price year**: GBP, unclear but likely 2010 **Time horizon**: within-trial (from discharge up to 6–8 weeks postpartum) **Discount rate**: Not applicable **Primary outcome**: Incremental cost per additional woman breastfeeding at 6–8 weeks **Secondary outcomes**: Incremental cost per additional woman exclusively breastfeeding at 6–8 weeks	**Base-case results**: ICER = £87 per additional woman breastfeeding at 6–8 weeks, ICER = £91 per additional woman exclusively breastfeeding at 6–8 weeks **Findings from scenario analyses**: Unclear how the scenario analyses may impact on ICER, due to reporting of total annual cost of each scenario	**Partially applicable**: UK setting, provider perspective, cost per additional woman (exclusively) breastfeeding at 6–8 weeks reported, within-trial time horizon from discharge to infant age 6–8 weeks
	Mode of delivery: Telephone **Intensity**: Moderate (median of eight contacts) **Duration**: From hospital discharge up to 14 days post discharge		**Sample size**: Total, *N* = 69 (IG, *n* = 35; CG, *n* = 34) **Baseline characteristics**: Concerns about baseline imbalances with women in IG a year older on average, more living in the most disadvantaged postcode areas (SIMD 1), and half a day longer hospital stays. Otherwise, groups were similar for parity, method of delivery, gestation and admission to the neonatal special care unit	**Data sources**: *Outcome of effect*: Within-trial data *Resource use*: Within-trial data *Unit costs*: Unclear, but states 'standard sources were used to assign costs' **Measurement of uncertainty**: Not reported **Consideration of heterogeneity**: Not reported **Sensitivity analyses**: Not reported, a scenario analysis was conducted to examine alternative intervention costing scenarios, varying staff requirements, using band 4 and band 5 grade nurse support, and period of coverage by varying hours of coverage per day		

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Mavranezouli 2022 (Mavranezouli *et al.*, 2022[119]) UK Nationwide Hospital and community healthcare setting	**Antenatal and postnatal education and support intervention + standard care** **Support**: Breastfeeding only **Description**: Authors state 'an intervention for women that comprised education, advice or support from a peer or professional, provided postnatally and initiated antenatally or within the first 8 weeks after birth'	**Standard care** **Description**: *Standard care variable across England. Authors state it: may include provision of written material, antenatal breastfeeding educational programmes, and postnatal breastfeeding support groups run by peers and/or health professionals; in most settings breastfeeding information and support is provided by midwives and health visitors as part of routine postnatal care visits*	**Inclusion criteria**: Pregnant women and women who have given birth to a healthy baby at term (or to healthy twins or triplets), from the birth of the baby to 8 weeks after birth, and their partners **Exclusion criteria**: Not reported **Sample size**: Not applicable	**Type of economic evaluation**: CUA with decision-analytic modelling **Perspective**: Provider (NHS and PSS) **Currency, price year**: GBP, 2018 **Time horizon**: From initiation up to 16–26 weeks postpartum, 1 year or lifetime, depending on the outcome **Discount rate**: 3.5% for costs and benefits accrued beyond the first 12 months of follow-up **Primary outcome**: Incremental cost per QALY **Secondary outcomes**: Not applicable **Data sources**: *Outcome of effect*: Age- and gender-specific UK population-based EQ-5D-derived utility values used	**Base-case results**: ICER = £51,946 per QALY, which suggests it is not cost-effective at the current lower NICE threshold of £20,000/QALY **Findings from sensitivity analyses**: Results of deterministic and probabilistic sensitivity analysis were similar. The two-way sensitivity analysis suggested that the cost-effectiveness of the intervention improved as its effectiveness increased and intervention cost decreased. Using a discount rate of 1.5% had the greatest impact on the value of the ICER (£22,667/QALY), which was explained by greater maternal benefits several years after breastfeeding takes place, for example incidence of breast cancer	**Directly applicable**: UK setting, provider perspective, cost per QALY gained reported, time horizon from birth up to 1 year or lifetime, depending on condition

continued

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
	Provider: Lay person and professional **Mode of delivery**: Face to face **Intensity**: Moderate (six contacts: four individual and two group-based) **Duration**: Initiated antenatally and provided postnatally. No indication of duration		**Baseline characteristics**: For modelling purposes, maternal mean age was 30 years for both groups	*Resource use*: Expert advice for the intervention, systematic review evidence for probability estimates on healthcare resource use *Unit costs*: National sources **Measurement of uncertainty**: 10,000 iterations of incremental costs and effects generated to determine level of sampling uncertainty around the mean ICER **Consideration of heterogeneity**: Sensitivity analysis considered scenario of different starting age (25 and 35 years) to examine effects on the ICER **Sensitivity analyses**: (1) Two-way sensitivity analysis for intervention cost (£20–100) and intervention effect (1.05–2.00), (2) one-way sensitivity analysis performed for (a) 1.5% discount rate, as recommended for public health interventions, (b) inclusion of post-mortem examination cost for baby deaths, (c) intervention effect retained for future births		

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Morrell 2000 (Morrell *et al.*, 2000[120] and 2000[155]) England Recruitment from one maternity hospital Community healthcare setting	**Community postnatal support worker + usual care** **Support**: Breastfeeding plus **Description**: Community postnatal support worker with 8 weeks' training provided home-based practical and emotional social support	**Usual care** **Description**: Standard UK care includes postnatal home visits from midwives and health visitors	**Inclusion criteria**: English-speaking women, aged ≥ 17 years, who gave birth at the study hospital **Exclusion criteria**: Baby spent > 48 hours on the SCBU **Sample size**: Total, *N* = 623 (IG, *n* = 311; CG, *n* = 312)	**Type of economic evaluation**: Cost analysis (conducted alongside a RCT) **Perspective**: Provider (NHS and PSS) **Currency, price year**: GBP, 1996 **Time horizon**: From birth up to infant aged 6 months **Discount rate**: Not applicable **Primary outcome**: Mean incremental costs at 6 months **Secondary outcomes**: Mean incremental costs at 6 weeks	**Base-case results**: Mean incremental costs at 6 months £178.61 (£79.60–272.40); Mean incremental costs at 6 weeks £179.58 (£125.85–232.34) Authors note 'There were no savings to the NHS over 6 months after the introduction of the community postnatal support worker service'	**Partially applicable**: UK setting, provider perspective, intervention costs reported only, time horizon limited to within trial (birth to infant age 6 months)
	Provider: Lay (postnatal support workers) **Mode of delivery**: Face to face **Intensity**: High (up to 10 contacts) **Duration**: The first 28 days after birth (maximum of 3 hours/visit)		**Baseline characteristics:** There were no significant differences between groups at baseline across 114 birth and socioeconomic variables, except for incidence of twins, use of transcutaneous electrical nerve stimulation machines during labour, and adults living with the mother	**Data sources**: *Outcome of effect*: Within trial (but not included in economic evaluation) *Resource use*: Within trial *Unit costs*: Local and national sources **Measurement of uncertainty**: Non-parametric bootstrap centile CIs were estimated for the difference in mean scores between the groups **Consideration of heterogeneity**: Not as part of the economic evaluation. **Sensitivity analyses**: No formal sensitivity analysis reported, although there was reference in the discussion to reducing the postnatal support workers time spent in the mother's home	**Findings from sensitivity analyses**: Authors state that reducing the postnatal support workers time spent in the mother's home to 120 minutes would reduce intervention costs from £179 to £151 at 6 weeks	

continued

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Mottl-Santiago 2020[125] USA Boston, MA Community healthcare setting	**Birth Sisters Best Beginnings for Babies program (doula support) + usual care** **Support**: Breastfeeding plus **Description**: Birth Sisters Best Beginnings for Babies provided doula support, health promotion and education for low-income women, connecting them with social and medical services that improve perinatal and maternal outcomes	**Usual care** **Description**: Usual prenatal, intrapartum and postpartum maternity care	**Inclusion criteria**: Being a pregnant woman at 16–24 weeks' gestational age, first-time mother, singleton, public insurance, no known fetal anomaly. Described as 'a healthy population of nulliparous pregnant women'	**Type of economic evaluation**: CBA (study-based) **Perspective**: Payer **Currency, price year**: USD, 2018 **Time horizon**: From mid-pregnancy to 6–8 weeks postpartum **Discount rate**: N/A **Primary outcome**: Average incremental cost per additional person served over the 3 years **Secondary outcomes**: Return on investment	**Base-case results**: Incremental cost = US$433, ROI: 18% **Findings from subgroup analyses**: Variation in target population, ROI changed for social risk (70%), medical risk (276%), medical and social risk (471%) **Findings from sensitivity analyses**: Variations in wages, programme costs ranged from US$769 to US$1604	**Not applicable**: Payer perspective taken OECD setting, incremental costs reported and return on investment
	Provider: Lay (doula peer support) **Mode of delivery**: Face to face **Intensity**: High – up to 12 contacts **Duration**: 24 weeks' gestation through to 6–8 weeks postpartum		**Exclusion criteria**: < 18 years of age, high risk pregnancy defined by care in the high-risk prenatal clinic **Sample size**: Total, *N* = 411 (intervention, *n* = 207, control, *n* = 204) **Baseline characteristics**: No group differences observed at baseline	**Data sources**: *Outcome of effect*: Within trial *Resource use*: Within trial *Unit costs*: Local sources **Measurement of uncertainty**: Payments were winsorised to address outliers **Consideration of heterogeneity**: Variations in impact for different populations **Sensitivity analyses**: One-way sensitivity analyses were conducted for differences in wages and benefits. Data for labour input sensitivity analyses for the program were derived from the Bureau of Labor Statistics		

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Paranjothy 2017[47] UK (England and Wales) Community healthcare setting	**Mam-Kind intervention + usual care** **Support**: Breastfeeding only **Description**: Mam-Kind is a motivational interviewing-based breastfeeding peer-support intervention to support breastfeeding maintenance	**No comparator** **Description:** Not applicable	**Inclusion criteria**: Pregnant women considering breastfeeding **Exclusion criteria**: Women who did not plan to breastfeed, who had a clinical reason that precluded breastfeeding continuation or who were unable to consent were excluded	**Type of economic evaluation**: Cost–outcome descriptions **Perspective**: Societal **Currency, price year**: GBP, 2016 **Time horizon**: Bottom-up approach: pregnancy up to 10 weeks' postpartum; top-down approach: 6 months **Discount rate**: N/A **Primary outcome**: Total intervention costs	**Base-case results**: Total intervention costs = £33,595, intervention cost per participant = £480	**Not applicable**: UK-based study, societal perspective, costs for one alternative reported
	Provider: Lay (Mam-Kind buddy) **Mode of delivery**: Face to face **Intensity**: High – mean 16 contacts (0–44) **Duration:** Birth to 6 weeks postpartum		**Sample size**: Total, *N* = 70 (no control group) **Baseline characteristics**: N/A as no control group. Differences with population – 'women who were recruited may not be representative of the study sites' (94% white)	**Secondary outcomes**: Intervention cost per participant **Data sources**: *Outcome of effect*: Within trial *Resource use*: Within trial *Unit costs*: Within trial and national sources **Measurement of uncertainty**: N/A **Consideration of heterogeneity**: N/A		
Pramono 2021[146] Australia Canberra Hospital-based – one maternity unit	**Implementation of BFHI in a maternity unit + usual care** **Support**: Breastfeeding plus **Description**: BFHI focuses on providing a high standard of maternity services to enable every infant to attain the best nutrition standards available. BFHI status is awarded to hospitals that implement consistent high-quality and ethical maternity care through the Ten Steps to Successful Breastfeeding policy, while remaining independent from formula companies and their affiliates	**No comparator** **Description**: Not applicable	**Inclusion criteria**: N/A **Exclusion criteria**: N/A **Sample size**: One maternity hospital **Baseline characteristics**: N/A	**Type of economic evaluation**: CBA – SROI **Perspective**: Societal **Currency, price year**: AUD, 2019 **Time horizon**: 15 years **Discount rate**: 3.8%; adjusted to 6% for the sensitivity analysis **Primary outcome**: SROI ratio in AUD per annum at the maternity hospital **Data sources**:	**Base-case results**: SROI = AU$55.38:1 **Findings from sensitivity analyses**: SROI range AU$16–111:1	**Not applicable**: OECD setting, societal perspective, no cost per QALY gained reported

continued

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
	Provider: Professional **Mode of delivery**: Face to face **Intensity**: High			*Outcome of effect*: Within study and literature *Resource use*: Within study and literature *Unit costs*: Within study and national sources **Consideration of heterogeneity**: SROI approach enabled estimation of outcomes for mothers and infants separately, but no further consideration of heterogeneity **Sensitivity analyses**: A sensitivity analysis was conducted to check changes for estimates of deadweight, attribution, displacement, drop-off and discount rate, value of SIDS risk reduction, value of type 2 diabetes, value of ovarian cancer risk reduction and birth type		
Pugh 2002[126] USA City of Baltimore, Maryland Community healthcare setting	**Breastfeeding support programme + usual care** **Support**: Breastfeeding only **Description**: Breastfeeding support visits by community health nurse/peer counsellor team. Support offered daily in hospital, and at home during weeks 1, 2 and 4 and at team's discretion. Telephone support from peer counsellor twice weekly through to week 8 and monthly through to month 6	**Usual care** **Description**: Usual breastfeeding support consisted of support from hospital nurses, assistance by means of a telephone 'warm line' and if mothers gave birth on a weekday, one hospital visit from a LC	**Inclusion criteria**: Low-income women receiving financial medical assistance **Exclusion criteria**: Not reported **Sample size:** Total, *N* = 41 (intervention, *n* = 21; control, *n* = 20) **Baseline characteristics**: Authors state 'The intervention and usual care groups were not significantly different in major characteristics, including age, ethnicity, education, marital status, and breastfeeding goals'	**Type of economic evaluation**: Cost–outcome description of two alternatives **Perspective**: Provider and family **Currency, price year**: USD, not reported – used cost data from the National Compensation Survey, which was authored in 1998 and accessed on 25 January 2002. November 1999 was used as reference point when valuing the cost of concentrate/powder for formula feeding **Time horizon**: Birth to 6 months postpartum **Discount rate**: N/A **Primary outcome**: Incremental cost per mother (contact time and travel) **Secondary outcomes**: Incremental cost per mother (formula milk and Intervention + mother's time to feed)	**Base-case results**: Incremental cost per mother (contact time and travel) = US$646 (SE US$251); Incremental cost per mother (formula milk and intervention + mother's time to feed) = US$646 (SE US$251) **Findings from SA:** Alternative costing scenario suggest incremental costs would be sensitive to change in method of valuing staff time	**Partially applicable**: OECD setting, provider and family perspective with costs reported separately, within-trial time horizon from birth to 6 months, incremental costs reported

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
	Provider: Professional and lay (community health nurse/ peer counsellor team) **Mode of delivery**: Face to face and telephone **Intensity**: High **Duration**: From birth to infant age 6 months			**Data sources**: *Outcome of effect*: Within trial *Resource use*: Within trial *Unit costs*: Within trial, local and national sources **Measurement of uncertainty**: Measure of uncertainty (standard error) reported around incremental costs **Consideration of heterogeneity**: N/A **Sensitivity analyses:** Calculation of project costs using project records to ascertain what staff were paid, taking into account training and in-service education		
Spiby 2015[153] UK Five study sites, city Community healthcare setting	**Volunteer doula service + usual care** **Support**: Breastfeeding plus **Description**: Volunteer doula service **Provider**: Lay person **Mode of delivery**: Face to face **Intensity**: High **Duration:** Pregnancy to 6 weeks postpartum	**Usual care** **Description**: Not reported	**Inclusion criteria**: Mixed-methods study, so differed depending on method **Exclusion criteria**: As above **Sample size:** As above **Baseline characteristics**: N/A	**Type of economic evaluation**: CCA **Perspective**: Provider (NHS and PSS) **Currency, price year**: GBP, 2011–12 **Time horizon**: Antenatal up to 6 weeks postpartum **Discount rate**: N/A **Primary outcome**: Average cost to the doula service per woman supported **Secondary outcomes**: Cost differential for exclusive breastfeeding outcomes and potential NHS costs per birth per annum: doula service vs. comparators **Data sources**: *Outcome of effect*: Within study and literature *Resource use*: Within study and literature *Unit costs*: National sources **Measurement of uncertainty**: Not reported **Consideration of heterogeneity**: Not reported	**Base-case results**: Average cost to the doula service per woman supported = £2438.85, cost differential = –£6.66	**Partially applicable**: UK-based study, provider perspective, intervention costs and cost differentials only provided

continued

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Stevens 2006[133] Canada City of Toronto Hospital and community setting	**Home breastfeeding support** **Support**: Breastfeeding only **Description**: Planned early discharge from hospital (24–36 hours postpartum) and up to three home visits by community nurse LCs. Content of support unclear **Provider**: Professional (LC) **Mode of delivery**: Face to face with individual with home visits **Intensity**: Low (three contacts) **Duration**: From birth until infants age 1 week	**Standard care** **Description**: Standard discharge from hospital (48–60 hours postpartum) with in-hospital breastfeeding support	**Inclusion criteria**: Live, singleton, term or near-term infant delivered in 12 hours before recruitment; women aged ≥ 21 years residing in defined study area, intending to breastfeed and with satisfactory home circumstances (assessed by postpartum nurses) **Exclusion criteria**: Non-English-speaking women, caesarean delivery, postpartum complications, morbidities, chronic illness or disabilities; infants with congenital abnormalities or morbidities	**Type of economic evaluation**: Cost analysis (conducted alongside a RCT) **Perspective**: Healthcare provider and family **Currency, price year**: CAD, 2002 **Time horizon**: Birth to 5–12 days postpartum **Discount rate**: Not applicable **Primary outcome**: Incremental cost for term infants **Secondary outcomes**: Incremental cost for near-term infants	**Base-case results**: Healthcare provider and family (incremental cost for term newborns = CA$119, incremental cost for near-term newborns = CA$1352) Healthcare provider only (incremental cost for term newborns = CA$17, incremental cost for near-term newborns = –CA$309)	**Partially applicable**: OECD setting, provider and family perspective with costs reported separately, within-trial time horizon from birth to 5–12 days, incremental costs reported. Outcomes reported separately, but allowed for an estimation of the cost per additional infant exclusively breastfed at 5–12 days

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
			Sample size: Total, *N* = 138 (IG, *n* = 72; CG, *n* = 66) **Baseline characteristics**: Outcomes were not assessed at the same time in the intervention and control groups (mean day of follow-up was 8.4 days in the intervention group vs. 7.8 days for controls) and there was high attrition (26% overall, with 33% loss to follow-up in the control group)	**Data sources**: *Outcome of effect*: Within trial, % of mothers exclusive breastfeeding in past 24 hours (not incorporated into economic evaluation but used herein to estimate cost per additional infant exclusively breastfed at 5–12 days taking a provider perspective) *Resource use*: Within trial *Unit costs*: National sources **Measurement of uncertainty**: Not reported **Consideration of heterogeneity**: Incremental costs and outcomes reported separately for term infants and near-term infants **Sensitivity analyses**: Not reported	Estimated ICER = CA$78.70 per additional term infant exclusively breastfed at 5–12 days, ICER for additional near- term infant exclusively breastfed at 5–12 days was dominant for home breastfeeding support due to lower healthcare costs and greater effect	
Tan 2020 (Tan *et al.*, 2020;[130] Taylor *et al.*, 2018[270]) New Zealand City of Dunedin Community setting	**Combination of sleep + Food Activity Breastfeeding (FAB) programme + usual care** **Support**: Breastfeeding plus **Description**: Participants received infant sleep education and advice on food, physical activity and breastfeeding	**Usual care** **Description**: Standard maternity care and well-child care from a maternity care professional and a well-child provider of their choice	**Inclusion criteria**: All mothers booked into the maternity hospital invited to participate at 28–30 weeks' gestation with an 'opt out' recruitment strategy **Exclusion criteria**: Before birth, home address outside greater Dunedin area, planning to move away in next 2 years, unable to communicate in English or Te Reo Maori. After birth, identification of a congenital abnormality likely to affect feeding or growth, or infant born < 36.5 weeks' gestation	**Type of economic evaluation**: CUA and CEA (trial-based and modelled) **Perspective**: Provider (health sector) **Currency, price year**: AUD, 2018 **Time horizon**: Extrapolation of 5 years. Within trial data to 15 years **Discount rate**: 5% for costs and benefits accrued beyond 1 year **Primary outcome**: Incremental cost per QALY gained **Secondary outcomes**: Incremental cost per BMI avoided at age 15 years, incremental cost per BMI avoided at age 5 years **Data sources**: *Outcome of effect*: QALYs to age 15 years modelled using utility weights associated with child weight status	**Base-case results**: ICER = AU$94,667 per QALY gained, ICER = AU$5164 per BMI avoided at age 15 years, ICER = AU$6678 per BMI avoided at age 5 years For the primary outcome, the intervention was not considered to be cost-effective **Findings from sensitivity analyses**: Sensitivity analyses not conducted, as the ICER for the combination intervention was not considered cost-effective	**Partially applicable**: Non-OECD setting, provider perspective, cost per QALY gained reported

continued

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
	Provider: Professional (lactation consultant provided the FAB intervention) **Mode of delivery**: Face to face with individuals **Intensity**: Moderate for breastfeeding support (five sessions) but overall high for the broader combination intervention at 10 parent contacts **Duration**: Not reported		**Sample size**: Total, *N* = 405 (IG, *n* = 196; CG, *n* = 209) **Baseline characteristics**: No baseline imbalance apparent	*Resource use*: Assumed same resource use for children under 5 years in the intervention and control groups; healthcare costs modelled from 5 years up to age 15 years using the EPOCH microsimulation model, which predicts healthcare costs using a top-down method *Unit costs*: Local and national sources of programme costs **Measurement of uncertainty**: 10,000 replications of incremental costs and benefits generated to determine level of sampling uncertainty around the mean ICERs **Consideration of heterogeneity**: Not reported **Sensitivity analyses**: One-way sensitivity analyses planned to determine whether the uncertainty in model and health economic parameters had any impact on shifting the calculated ICERs beyond the cost-effective threshold		
Wen 2017 (Killedar *et al.*, 2022;[271] Wen *et al.*, 2017;[131] Wen *et al.*, 2022[272]) Australia Recruitment from seven hospitals in four health districts in the metropolitan area of Sydney Community setting	**Telephone (IG1) or SMS (IG2) support + usual care** **Support**: Breastfeeding plus **Description**: The intervention was informed by the Health Belief Model providing six staged intervention booklets corresponding to key stages of child feeding and movement. The booklets were mailed to the intervention groups *IG1*: 1 week after mailing, a child and family health nurse called the participant to provide support, talk about the booklet and discuss issues raised. Each call was approximately 30–60 minutes long	**Usual care** **Description**: Usual care plus home safety promotion materials and a newsletter on 'kids' safety' were sent to the control group at the third trimester and at 3, 6 and 9 months of infant age. Usual care involved universal child and family health services provided by local health districts comprising one nurse home visit, multiple visits up to 2 years for high-risk families, or attendance at child and family health centres available to all families	**Inclusion criteria**: Women aged ≥ 16 years, 24–34 weeks' gestation, able to communicate in English, with a mobile telephone, and living in recruitment areas **Exclusion criteria**: Severe medical condition, could not give informed consent, expecting multiple births and had babies with known major fetal anomalies **Sample size**: Total, *N* = 1155 (IG1, *n* = 386; IG SMS, *n* = 384; CG, *n* = 385)	**Type of economic evaluation**: CEA (trial based – conducted alongside a three-arm RCT) **Perspective**: Provider (local government) **Currency, price year**: AUD, 2018 **Time horizon**: Pregnancy to infant age 2 years **Discount rate**: 5% for costs and benefits accrued beyond the first 12 months of follow-up **Primary outcome**: Incremental cost per unit BMI avoided **Secondary outcomes**: Incremental cost per 0.1 BMI z-units avoided	**Base-case results**: ICER = AU$10,664.89 per unit BMI avoided (IG1 vs. CG), ICER = AU$5154.14 per unit BMI avoided (IG2 vs. CG) SMS + usual care was more cost-effective than telephone support + usual care when compared with usual care alone. Difficult to gauge cost-effectiveness, as no understanding of health providers' WTP for the prevention of BMI gain	**Partially applicable**: OECD setting Provider perspective, incremental cost per unit BMI avoided reported. Time horizon within trial from birth to infant age 2 years

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
	IG2: 1 week after mailing, a set of SMS messages was sent to participants twice per week for 4 weeks to reinforce the information **Provider**: Professional (child and family health nurse) **Mode of delivery**: Telephone calls (IG1) or SMS (IG2) with individuals **Intensity**: Moderate (six contacts) **Duration**: From third trimester of pregnancy until infants were 10 months old		**Baseline characteristics**: No baseline imbalance. Participants in the economic evaluation (n = 662), who completed the 2-year follow-up with BMI measurements, appeared similar to baseline sample Maternal age grouped: < 24 years (IG1, 9%; IG2, 9%; CG, 8%), 25–34 years (IG1, 59%; IG2, 63%; CG, 64%), > 35 years (IG1, 32%; IG2, 28%; CG, 29%); primiparous (IG1, 54%; IG2, 56%; CG, 52%); married or de facto partner (IG1, 91%; IG2, 94%; CG, 94%); education – up to HSC to TAFE or diploma (IG1, 33%; IG2, 33%; CG, 37%), university degree (IG1, 67%; IG2, 67%; CG, 63%)	**Data sources**: *Outcome of effect*: Within trial *Resource use*: Within trial *Unit costs*: National sources **Measurement of uncertainty**: Joint uncertainty in costs and outcomes was determined using bootstrapping with replacement **Consideration of heterogeneity**: Not reported **Sensitivity analyses**: Adopted a limited societal perspective with the inclusion of productivity losses for the mother	**Findings from sensitivity analyses**: Adopting a limited societal perspective increased the ICER, but the ICER for SMS support remained more favourable than for telephone support	

continued

TABLE 16 Characteristics of included economic evaluation studies (see *Chapter 5*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Wouk 2017[127] USA State of North Carolina	**Lactation consultant service + usual care** **Support**: Breastfeeding only **Description**: IBCLC support **Provider**: Professional (IBCLC) **Mode of delivery**: Face to face **Intensity**: Low (average 1.3 contacts) **Duration**: Between birth and 1 week postpartum	**Usual care** **Description**: Not reported	**Inclusion criteria**: Low-income mothers **Exclusion criteria**: Not reported **Sample size**: 174 maternity centres/WIC agencies **Baseline characteristics**: Overall characteristics reported	**Type of economic evaluation**: CBA (alongside geospatial analysis) **Perspective**: Payer **Currency, price year**: USD, 2010 data **Time horizon**: 1 year **Discount rate**: N/A **Primary outcome**: Cost savings for averted cases of lower respiratory tract infection, gastroenteritis, necrotising enterocolitis **Secondary outcomes**: Cost of service **Data sources**: *Outcome of effect*: Literature and state/national sources *Resource use*: Expert opinion for costing the intervention; literature and state sources for health service use *Unit costs*: Not reported **Measurement of uncertainty**: Not reported **Consideration of heterogeneity**: Not reported **Sensitivity analyses**: Not reported	**Base-case results**: Cost savings of US$7.1M; cost of service = US$4.77M	**Not applicable**: OECD setting, payer perspective, lack of detail with aggregate costs (cost savings) reported

CBA, cost–benefit analysis; CEA, cost-effectiveness analysis; CG, control group; CUA, cost–utility analysis; FNP, family-nurse partnership; HB, healthy beginnings; IBCLC, international board-certified lactation consultant; IG, intervention group; NICU, neonatal intensive care unit; PSS, Personal Social Services; ROI, return on investment; SCBU, special care baby unit; SIDS, sudden infant death syndrome; SROI, social return on investment; WIC, special supplemental nutrition program for women, infants and children.

Appendix 4 Study characteristics and risk-of-bias assessments of breastfeeding support interventions for women with long-term conditions (see *Chapter 6*)

Characteristics of included studies

TABLE 17 Characteristics of included studies for breastfeeding support interventions for women with LTCs (see *Chapter 6*)

Study	Country	Participant characteristics	Participants' condition	Total sample (*n*)	Intervention	Comparator
Aldana-Parra *et al.*[185,273]	Colombia	Not reported	Obesity (defined as BMI of ≥ 28.1 kg/m^2) and no diabetes	90	EBF counselling by certified counsellor; antenatal and postnatal; at least four contacts; face to face	Based on the institutional and national policy for breastfeeding
Bartu *et al.*[178]	Australia	Median age SG 27 (IQR 17–39) years Median age CG 25 (IQR 18–41) years Ethnicity SG: 68 (90%) Caucasian, 8 (10%) other (not further specified) Ethnicity CG: 67 (88%) Caucasian, 9 (12%) other (not further specified)	Substance misuse (mainly heroin)	152	Home visiting by research midwife; antenatal and postnatal; eight contacts; face to face; also included mental health and stress management support, and immunisation discussion	A telephone contact at 2 months and a home visit at 6 months
Steube *et al.*[160,188,274,275]	USA	Mean age (SD) SG 30.3 (6.6) years Mean age (SD) CG 30.0 (6.0) years Ethnicity SG: Hispanic 5 (10%); non- Hispanic 45 (90%); Black/African American 22 (44%). Ethnicity CG: Hispanic 6 (12%); non- Hispanic 44 (88%); Black/African American 30 (60%)	GDM (excluding women with overt diabetes, indexed by a baseline A1c of ≥ 6.5 mg/dl)	100	Group sessions which included some breastfeeding support by IBCLC; 13 contacts but IBCLC was only available at four; antenatal and postnatal; face to face; telephone, SMS; also included nutritional advice and exercise classes to control GDM	Usual care, which included access to breastfeeding peer counsellors and inpatient consultation with IBCLC
Carlsen *et al.*[179,276]	Denmark	Mean age SG 31.3 (SD 4.5) years Mean age SG 31.8 (SD 4.1) years Ethnicity not reported	Obesity. Women had a pre-pregnancy BMI of at least 30 kg/m^2	226	Phone-based advisory support by a IBCLC; at least nine contacts; postnatal only; telephone	Standard care which included support in hospital and a contact with a health visitor or midwife within first week after birth
Chapman *et al.*[174,277–280]	USA	Median age SG 23 years (IQR 21–28 years) Median age CG 25 years (IQR 22–31 years) Ethnicity SG: Hispanic 80.3%; African American 13.2%; white 5.3%; other 1.3% Ethnicity CG: Hispanic 83.3%; African American 7.7%; white 5.1%; other 3.8%; Hispanic 83.3%; African American 7.7%; white 5.1%; other 3.8%	Low-income, overweight/obese women with a BMI of ≥ 27.0 kg/m^2	206	Specialised peer counsellors by peers who received additional training on breastfeeding and obesity; at least 15 contacts; antenatal and postnatal; face to face and telephone; women also received breast pumps and a sling	BFHI hospital. Routine care included prenatal education, assistance during hospital from nurses and IBCLC. Post-discharge access to a 'warm line' for advice

TABLE 17 Characteristics of included studies for breastfeeding support interventions for women with LTCs (see *Chapter 6*) (*continued*)

Study	Country	Participant characteristics	Participants' condition	Total sample (*n*)	Intervention	Comparator
Ehrlich *et al.*[175,189]	USA	Age SG: 21–24 years 3.1%; 25–29 years 18.8%; ≥ 30 years 78.1% Age CG: 21–24 years 4.0%; 25–29 years 20.8%; ≥ 30 years 75.3% Ethnicity SG: non-Hispanic white 19.8%; Black/African American 5.2%; Asian or Pacific Islander 49.0%; Hispanic origin 18.8%; other 4.2%; missing 3.1% Ethnicity CG: non-Hispanic white 18.8%; Black/African American 4.0%; Asian or Pacific Islander 54.5%; Hispanic origin 18.8%; other 2.0%; missing 2.0%	GDM	197	Diet, breastfeeding and exercise support by dieticians and IBCLCs; 15–26 contacts antenatal and postnatal; face to face and telephone; also provided advice and support to lose weight via diet and exercise	Usual care including printed material on GDM and infant safety
O'Brien *et al.*[180,281] (also includes unpublished data provided by author)	Ireland	Not reported	Overweight and obesity defined as BMI of ≥ 25 kg/m^2	224	Multicomponent intervention that targets prospective mothers and their support partner. Included antenatal education class; postnatal group clinics and video calls all by an IBCLC; at least eight contacts antenatal and postnatal	Oral and written information on antenatal and postnatal support for breastfeeding that is available in the study site hospital and community and receive routine antenatal care
Fan *et al.*[167]	Australia	Not reported	Not specifically targeted intervention for LTC but includes data for obese mothers and mothers with depression	765	Weekly lactation consultant telephone call; four contacts; postnatal	Standard postnatal care (no details)
Fiks *et al.*[176]	USA	Mean age SG 25.8 (SD 5.2) years Mean age SG 27.3 (SD 5.6) years Ethnicity SG: Hispanic/Latina 5%; Black/African; American 84%; white 7%; other 7% Ethnicity CG: Black/African American 93%; Hispanic/Latina 0%; white 5%; other 7%	Low-income women with obesity at start of pregnancy (defined as BMI of > 25 kg/m^2)	87	Private peer Facebook group facilitated by a psychologist with two face-to-face group sessions; antenatal and postnatal; also considered sleep obesity, wellbeing and wider infant-feeding topics	Text message reminders for recommended infant primary care visits

continued

TABLE 17 Characteristics of included studies for breastfeeding support interventions for women with LTCs (see *Chapter 6*) (*continued*)

Study	Country	Participant characteristics	Participants' condition	Total sample (*n*)	Intervention	Comparator
You *et al.*[184]	China	Median age SG 33.0 (30.0–37.0) years Median age CG 34.0 (31.0–37.0) years Ethnicity SG: Han 95.3%; minority 4.7% Ethnicity CG: Han 96.2%; minority 3.8%	GDM (women with type 2 diabetes were excluded)	226	Education and counselling from an IBCLC, written materials and WeChat peer support group; at least six contacts; antenatal and postnatal; face to face, telephone and digital	Usual care for lactation support during the antenatal and postnatal period (no details)
Ijumba *et al.*[168]	South Africa	Not reported by HIV status. Overall median age 23 years Ethnicity not reported	HIV	At least 3957 but not all were HIV positive	CHW who visited women to support infant feeding and other aspects of antenatal and newborn care; 7–9 visits; face to face; access to social welfare grants	CHWs who visited women to provide information on obtaining social welfare grants and not breastfeeding
Lewkowitz *et al.*[169]	USA	Age SG: aged 18–34 years 93%; aged ≥ 35 years 7% Age CG: aged 18–34 years 91.5%; aged ≥ 35 years 8.5% Women had to be African American to take part	Socioeconomically disadvantaged African American women with overweight or obesity defined as BMI of 25.0–45.0 kg/m^2	118	Home-based visits by parent educators with additional breastfeeding training, support and development of breastfeeding plan; bi-weekly antenatal only; also provided general parenting support and education	Standard home-based visits by parent educators who had one session on breastfeeding. Additional breastfeeding support was available on request
MacVicar *et al.*[181]	UK	Age SG: 20–35 years, 5 (71%); > 35 years, 2 (29%) Age CG: 20–35 years, 4 (57%); > 35 years, 3 (43%) All participants were Caucasian	Substance misuse	14	Support worker trained in BF in neonatal abstinence syndrome provided daily support during first 5 days of hospital stay; postnatal only; five contacts; face to face; also had a low-stimuli environment	Standard postnatal care of the newborn at risk of abstinence syndrome. Feeding advice was provided by ward staff and underpinned by the UNICEF ten steps to successful breastfeeding
Martin *et al.*[170]	Australia	Mean age SG 31.6 (SD 5.1) years Mean age SG 29.5 (SD 7.8) years Ethnicity SG: born in Australia 100% Control SG: born in Australia 91%	Overweight and obese mothers with a BMI of 25–35 kg/m^2	24	Lactation support from IBCLC; at least three contacts; antenatal and postnatal; telephone and face to face; dietary intervention included antenatal sessions by a dietitian	Dietary intervention and standard antenatal care (no details)
Reifsnider *et al.*[172,260,282]	USA	Age was not reported All women were Hispanic. SG mother's nation of birth: Mexico 57.4%; USA 42.6%; other 0%. CG mother's nation of birth: Mexico 56.9%; USA 39.7%; other 3.5%	Low-income Hispanic women with obesity: pre pregnant BMI of > 25 kg/m^2	174	Home visiting from promotors and support from lactation consultant if needed; antenatal and postnatal; at least seven contacts; also included infant growth and development; sleep; and play/exercise	Standard WIC services

TABLE 17 Characteristics of included studies for breastfeeding support interventions for women with LTCs (see *Chapter 6*) (*continued*)

Study	Country	Participant characteristics	Participants' condition	Total sample (*n*)	Intervention	Comparator
Namale-Matovu *et al.*[171]	Uganda	All groups had a mean age of 34 years Ethnicity not reported	HIV positive and undergoing appropriate antiretroviral treatment	218	Arm B: enhanced peer support. Family members and a hospital-based peer supported women to EBF; postnatal; five training sessions plus peer support as needed; also considered wider PMTCT Arm C: enhanced peer support + clinic-based coaching by an infant-feeding counsellor; face to face; postnatal; five sessions; also considered wider PMTCT and suitable foods for infants	Standard PMTCT messages on HIV and infant feeding with counselling and support from PMTCT counsellors face to face; postnatal; five sessions
Pezley *et al.*[177]	USA	Mean age SG 30.9 (3.3) years Mean age SG 29.7 (4.7) years Ethnicity SG: non-Hispanic 100% Ethnicity SG: non-Hispanic 89%	Mild-moderate depression (as defined with PHQ score of 5–14) but not medicated	22	Sunnyside Plus, which was web-based lesson, text support and video calls with a lactation consultant; antenatal and postnatal; six lessons and at least two video calls; also received Sunnyside for anxiety and depression	Sunnyside web-based programme to manage mood before and after pregnancy; web-based; antenatal and postnatal; nine sessions; no breastfeeding support
Rasmussen *et al.*[173]	USA	Mean age SG 27.3 (8.6) years Mean age CG 26.6 (9.1) years Ethnicity not reported	Obesity (defined as BMI of > 29 kg/m^2 pre-pregnancy)	50	Breastfeeding support from nurses in hospital plus pre- and postpartum calls with lactation consultant; visiting restrictions in hospital; at least four contacts; face to face and telephone; women also encouraged to move about after delivery	Routine care where women room-in with their infants and are observed using the Mother-Baby Assessment tool during at least one breastfeeding episode session. One prepartum call from a lactation consultant
Reimers *et al.*[182,283]	South Africa	Median age SG 28.4 (27.5–29.2) years Median age CG 28.8 (27.5–30.0) years Ethnicity not reported	HIV positive	619	Feeding buddy to help with adherence to PMTCT guidelines. Mothers selected the buddy and they were trained together including in EBF; face to face; antenatal and postnatal; four training sessions and ongoing buddy support; also considered compliance with treatment, immunisations and baby monitoring	No details provided

continued

TABLE 17 Characteristics of included studies for breastfeeding support interventions for women with LTCs (see *Chapter 6*) (*continued*)

Study	Country	Participant characteristics	Participants' condition	Total sample (*n*)	Intervention	Comparator
Rotheram-Borus *et al.*[183]	South Africa	Mean age SG 26.5 (5.5) years Mean age CG 26.5 (5.5) years Ethnicity not reported	HIV positive	1200	Peer mentor meetings, which included CBT, PMTCT, wider child support and breastfeeding; face to face; antenatal and postnatal; eight contacts	Standard clinic care of PMTCT services (does not seem to include breastfeeding)
Samburu *et al.*[186]	Kenya	Mean age SG 22.5 (0.5) years Mean age CG 22.4 (0.5) years Ethnicity not reported	HIV positive	52 (NB this is a subsample from a larger cluster-RCT that also included HIV-negative women)	Home-based counselling from community health visitors based on Baby Friendly Community Initiative. Included EBF and PMTCT; face to face; antenatal and postnatal (no. of contacts not defined). Also mother support groups, community gatherings, breastfeeding rooms at the primary care centre	Routine services including antenatal and postnatal care, delivery, general nutrition, hygiene and nutrition. Routine visits by community health workers
Suryavanshi *et al.*[187]	India	Median age SG 25 (IQR 22–29) years Median age CG 25 (IQR 22–29) years Ethnicity not reported	HIV positive	1191	COMBIND. Counselling based on scripts by outreach workers on breastfeeding and PMTCT; face to face; antenatal and postnatal; no. of contacts not specified; also includes HIV testing and treatment	India's national PMTCT programme that includes promotion of EBF, HIV testing and treatment

CG, control group; CHW, community health workers; EBF, exclusive breastfeeding; IBCLC, international board-certified lactation consultant; IQR, interquartile range; PMTCT, prevention of mother-to-child transmission; SD, standard deviation; SG, support group; WIC, special supplemental nutrition programme for women, infants and children.

Risk-of-bias assessments

TABLE 18 Risk-of-bias assessments of included studies for breastfeeding support interventions for women with LTCs (see *Chapter 6*)

	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective outcome reporting	Other bias
Fiks *et al.*[176]	Low	Low	High	High	Low	Unsure	High
Stuebe *et al.*[160]	Low	Unsure	High	Unsure	High	Unsure	High
Suryavanshi *et al.*[187]	Low	Unsure	High	Unsure	High	Unsure	High
Samburu *et al.*[186]	Low	Unsure	High	High	High	High	Low
Rotheram-Borus *et al.*[183]	Low	Unsure	High	High	Low	Unsure	High
Reimers *et al.*[182]	Unsure	Unsure	High	High	High	High	High
Rasmussen *et al.*[173]	Low	Unsure	High	High	High	High	High
O'Brien *et al.*[180]	Unsure	Unsure	High	High	Low	Unsure	High
Pezley *et al.*[177]	Low	Low	High	High	High	Unsure	Unsure
Namale-Matovu *et al.*[171]	Low	Unsure	High	High	High	Unsure	High
Reifsnider *et al.*[172]	Low	Unsure	High	High	Low	Unsure	High
Martin *et al.*[170]	Low	Low	High	High	High	High	High
MacVicar *et al.*[181]	Low	Low	High	High	High	Unsure	Unsure
Lewkowitz *et al.*[169]	Low	High	High	High	High	Unsure	Unsure
Ijumba *et al.*[168]	Low	Unsure	High	High	Low	High	Unsure
You *et al.*[184]	Low	Unsure	High	High	Low	Unsure	High
Fan *et al.*[167]	Low	Low	High	High	Low	Unsure	Unsure
Ehrlich *et al.*[175]	Unsure	Unsure	High	High	Unsure	Unsure	Unsure
Chapman *et al.*[174]	Low	Unsure	High	High	Low	High	Low
Carlsen *et al.*[179]	Low	Unsure	High	High	High	High	Unsure
Bartu *et al.*[178]	Low	Low	High	High	Low	High	Unsure
Aldana-Parra *et al.*[273]	Unsure	Low	High	High	Unsure	Unsure	Unsure

Appendix 5 Data and analysis for breastfeeding support interventions for women with long-term conditions (see *Chapter 6*)

Forest plots for interventions examining effectiveness of breastfeeding support for women with long-term conditions

Primary outcomes

Study or subgroup	Support Events	Support Total	Control Events	Control Total	Weight (%)	Risk ratio M–H, random, 95% CI
Bartu 2006	45	76	48	76	24.9	0.94 (0.73 to 1.21)
Carlsen 2013	22	108	31	118	9.6	0.78 (0.48 to 1.25)
Ehrlich 2014	17	96	12	101	5.1	1.49 (0.75 to 2.95)
MacVicar 2018	4	7	4	7	3.0	1.00 (0.40 to 2.48)
O'Brien 2019	36	112	46	112	16.1	0.78 (0.55 to 1.11)
Pezley 2022	2	13	3	9	1.0	0.46 (0.10 to 2.23)
Rasmussen 2011 BIBS 1	12	25	7	25	4.3	1.71 (0.81 to 3.63)
Reifsnider 2018	51	91	46	83	23.5	1.01 (0.78 to 1.32)
Steube 2016	16	50	25	50	9.3	0.64 (0.39 to 1.04)
You 2020	7	113	13	113	3.2	0.54 (0.22 to 1.30)
Total (95% CI)		**691**		**694**	**100.0**	0.90 (0.77 to 1.06)
Total events	212		235			

Heterogeneity: $\tau^2 = 0.01$; $\chi^2 = 10.71$, df = 9 ($p = 0.30$); $I^2 = 16\%$

Test for overall effect: z = 1.25 ($p = 0.21$)

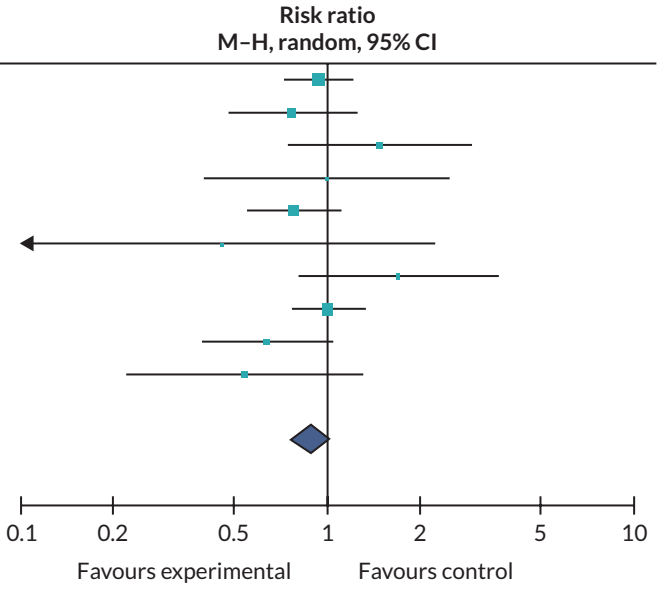

FIGURE 9 Breastfeeding support vs. usual care, outcome: not any breastfeeding at 4–8 weeks.

Study or subgroup	Support Events	Total	Control Events	Total	Weight (%)	Risk ratio M–H, random, 95% CI
Carlsen 2013	37	108	46	118	6.8	0.88 (0.62 to 1.24)
Chapman 2013	81	103	84	103	17.8	0.96 (0.84 to 1.11)
O'Brien 2019	68	112	71	112	12.9	0.96 (0.78 to 1.18)
Pezley 2022	3	13	5	9	0.8	0.42 (0.13 to 1.31)
Rasmussen 2011 BIBS1	17	25	13	25	4.3	1.31 (0.82 to 2.08)
Reifsnider 2018	71	81	65	83	17.5	1.12 (0.97 to 1.29)
Samburu 2020	2	8	2	9	0.4	1.13 (0.20 to 6.24)
Steube 2016	32	50	41	50	10.7	0.78 (0.61 to 1.00)
Suryavanshi 2020	347	500	343	430	22.4	0.87 (0.81 to 0.94)
You 2020	33	113	48	113	6.4	0.69 (0.48 to 0.98)
Total (95% CI)		**1113**		**1052**	**100.0**	0.92 (0.83 to 1.03)
Total events	691		718			

Heterogeneity: $\tau^2 = 0.01$; $\chi^2 = 19.32$, df = 9 ($p = 0.02$); $I^2 = 53\%$

Test for overall effect: z = 1.45 ($p = 0.15$)

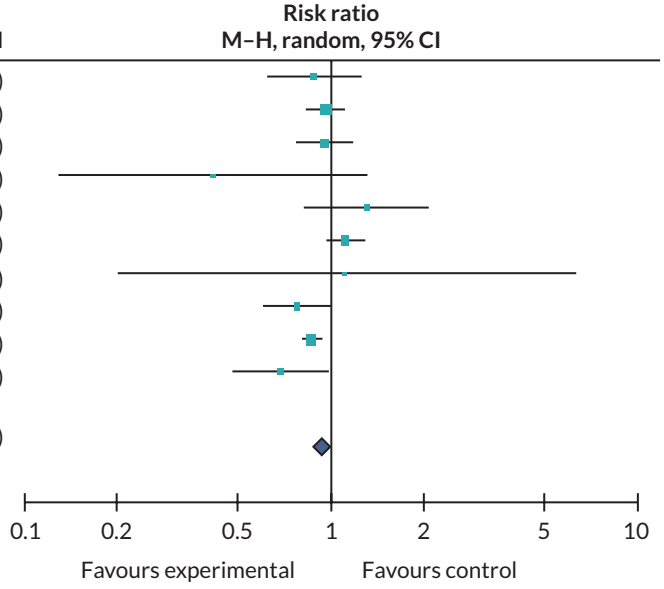

FIGURE 10 Breastfeeding support vs. usual care, outcome: not exclusive breastfeeding at 4–8 weeks.

Study or subgroup	Support Events	Total	Control Events	Total	Weight (%)	Risk ratio M–H, random, 95% CI
Bartu 2006	57	76	63	76	30.9	0.90 (0.77 to 1.07)
Ehrlich 2014	49	96	60	101	24.2	0.86 (0.67 to 1.11)
Namale-Matovu 2018 Nutrition education	9	73	3	37	2.5	0.52 (0.44 to 5.28)
Namale-Matovu 2018 Peer support	6	72	3	37	2.2	1.03 (0.27 to 3.88)
O'Brien 2019	62	112	68	112	26.5	0.91 (0.73 to 1.14)
You 2020	21	113	47	113	13.6	0.45 (0.29 to 0.70)
Total (95% CI)		**542**		**476**	**100.0**	0.83 (0.67 to 1.01)
Total events	204		244			

Heterogeneity: $\tau^2 = 0.03$; $\chi^2 = 10.62$, df = 5 ($p = 0.06$); $I^2 = 53\%$

Test for overall effect: z = 1.84 ($p = 0.07$)

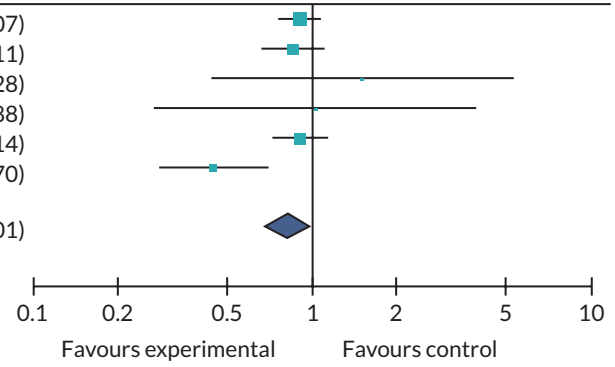

FIGURE 11 Breastfeeding support vs. usual care, outcome: not any breastfeeding at 6 months.

Study or subgroup	Support Events	Support Total	Control Events	Control Total	Weight (%)	Risk ratio M–H, random, 95% CI
Bartu 2006	73	76	76	76	14.8	0.96 (0.91 to 1.01)
Carlsen 2013	108	108	118	118	16.6	1.00 (0.98 to 1.02)
Chapman 2013	100	103	103	103	15.7	0.97 (0.93 to 1.01)
Fiks 2017	39	43	42	44	10.0	0.95 (0.85 to 1.07)
Namale-Matovu 2018 Nutrition education	10	73	6	37	0.4	0.84 (0.33 to 2.14)
Namale-Matovu 2018 Peer support	12	72	6	37	0.4	1.03 (0.42 to 2.52)
O'Brien 2019	79	112	86	112	7.4	0.92 (0.79 to 1.07)
Reimers 2018	17	27	20	29	2.0	0.91 (0.63 to 1.33)
Rotheram-Borus 2014	350	391	436	472	15.4	0.97 (0.93 to 1.01)
Samburu 2020	2	8	4	9	0.2	0.56 (0.14 to 2.29)
Suryavanshi 2020	337	500	317	430	12.5	0.91 (0.84 to 0.99)
You 2020	55	113	75	113	4.5	0.73 (0.58 to 0.92)
Total (95% CI)		**1626**		**1580**	**100.0**	**0.95 (0.89 to 1.00)**
Total events	1182		1289			

Heterogeneity: $\tau^2 = 0.01$; $\chi^2 = 67.87$, df = 11 ($p < 0.00001$); $I^2 = 84\%$

Test for overall effect: z = 1.89 ($p = 0.06$)

FIGURE 12 Breastfeeding support vs. usual care, outcome: not exclusive breastfeeding at 6 months.

Additional outcomes

Study or subgroup	Support Events	Support Total	Control Events	Control Total	Weight (%)	Risk ratio M–H, random, 95% CI
O'Brien 2019	44	112	53	112	35.4	0.83 (0.61 to 1.12)
Pezley 2022	3	13	3	9	9.5	0.69 (0.18 to 2.69)
Rasmussen 2011 BIBS 1	19	25	13	25	30.6	1.46 (0.94 to 2.26)
You 2020	13	113	26	113	24.5	0.50 (0.27 to 0.92)
Total (95% CI)		**263**		**259**	**100.0**	**0.86 (0.53 to 1.38)**
Total events	79		95			

Heterogeneity: $\tau^2 = 0.14$; $\chi^2 = 9.29$, df = 3 ($p = 0.03$); $I^2 = 68\%$

Test for overall effect: z = 0.64 ($p = 0.53$)

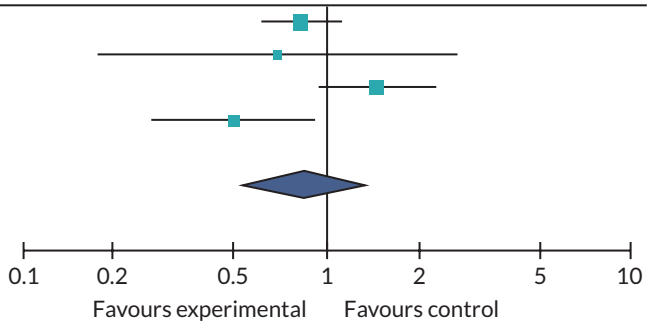

FIGURE 13 Breastfeeding support vs. usual care, outcome: not any breastfeeding at 3–4 months.

Study or subgroup	Support Events	Support Total	Control Events	Control Total	Weight (%)	Risk ratio M–H, random, 95% CI
Aldana-Parry 2022	19	43	36	47	18.1	0.58 (0.40 to 0.84)
Chapman 2013	88	103	91	103	27.5	0.97 (0.87 to 1.08)
O'Brien 2019	68	112	71	112	24.4	0.96 (0.78 to 1.18)
Pezley 2022	5	13	5	9	6.4	0.69 (0.28 to 1.71)
Samburu 2020	2	8	3	9	2.6	0.75 (0.16 to 3.41)
You 2020	40	113	68	113	21.1	0.59 (0.44 to 0.79)
Total (95% CI)		**392**		**393**	**100.0**	**0.77 (0.59 to 1.00)**
Total events	222		274			

Heterogeneity: $\tau^2 = 0.06$; $\chi^2 = 20.89$, df = 5 ($p = 0.0009$); $I^2 = 76\%$

Test for overall effect: z = 1.99 ($p = 0.05$)

FIGURE 14 Breastfeeding support vs. usual care, outcome: not exclusive breastfeeding at 3–4 months.

Sensitivity analysis

Primary outcomes

TABLE 19 Sensitivity analyses for stopping any breastfeeding at 4–8 weeks

Outcome	Risk ratio	95% CI
Studies excluded due to high risk of bias for allocation concealment	0.90	0.77 to 1.04
Studies excluded with > 20% loss to follow-up	1.02	0.62 to 1.67
Cluster-RCTs for which a design effect could not be calculated excluded	0.94	0.80 to 1.09
Studies for women with HIV excluded	N/A	N/A
Results of primary analysis	0.90	0.77 to 1.06

TABLE 20 Sensitivity analyses for stopping exclusive breastfeeding at 4–8 weeks

Outcome	Risk ratio	95% CI
Studies excluded due to high risk of bias for allocation concealment	0.93	0.75 to 1.16
Studies excluded with > 20% loss to follow-up	0.90	0.67 to 1.20
Cluster-RCTs for which a design effect could not be calculated excluded	0.94	0.84 to 1.06
Studies for women with HIV excluded	0.97	0.85 to 1.10
Results of primary analysis	0.92	0.83 to 1.03

TABLE 21 Sensitivity analyses for stopping any breastfeeding at 6 months

Outcome	Risk ratio	95% CI
Studies excluded due to high risk of bias for allocation concealment	0.76	0.54 to 1.07
Studies excluded with > 20% loss to follow-up	0.75	0.45 to 1.23
Cluster-RCTs for which a design effect could not be calculated excluded	N/A	N/A
Studies for women with HIV excluded	0.80	0.64 to 1.01
Results of primary analysis	0.83	0.67 to 1.01

TABLE 22 Sensitivity analyses for stopping exclusive breastfeeding at 6 months

Outcome	Risk ratio	95% CI
Studies excluded due to high risk of bias for allocation concealment	0.92	0.79 to 1.08
Studies excluded with > 20% loss to follow-up	0.84	0.54 to 1.32
Cluster-RCTs for which a design effect could not be calculated excluded	N/A	N/A
Studies for women with HIV excluded	0.94	0.86 to 1.03
Results of primary analysis	0.95	0.89 to 1.00

Additional outcomes

TABLE 23 Sensitivity analyses for stopping any breastfeeding at 3–4 months

Outcome	Risk ratio	95% CI
Studies excluded due to high risk of bias for allocation concealment	0.69	0.42 to 1.13
Studies excluded with > 20% loss to follow-up	0.87	0.28 to 2.73
Cluster-RCTs for which a design effect could not be calculated excluded	N/A	N/A
Studies for women with HIV excluded	N/A	N/A
Results of primary analysis	0.86	0.53 to 1.38

TABLE 24 Sensitivity analyses for stopping exclusive breastfeeding at 3–4 months

Outcome	Risk ratio	95% CI
Studies excluded due to high risk of bias for allocation concealment	0.70	0.48 to 1.02
Studies excluded with > 20% loss to follow-up	0.60	0.46 to 0.80
Cluster-RCTs for which a design effect could not be calculated excluded	N/A	N/A
Studies for women with HIV excluded	0.77	0.59 to 1.01
Results of primary analysis	0.77	0.59 to 1.00

Funnel plots

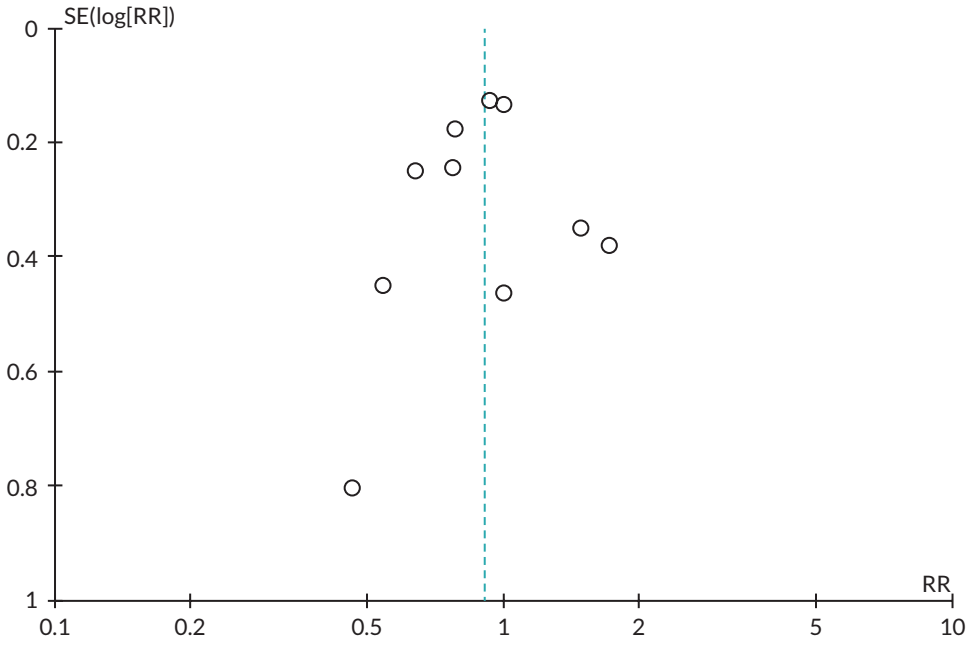

FIGURE 15 Funnel plot of comparison: 1 Breastfeeding support vs. usual care, outcome: not any breastfeeding at 4–8 weeks.

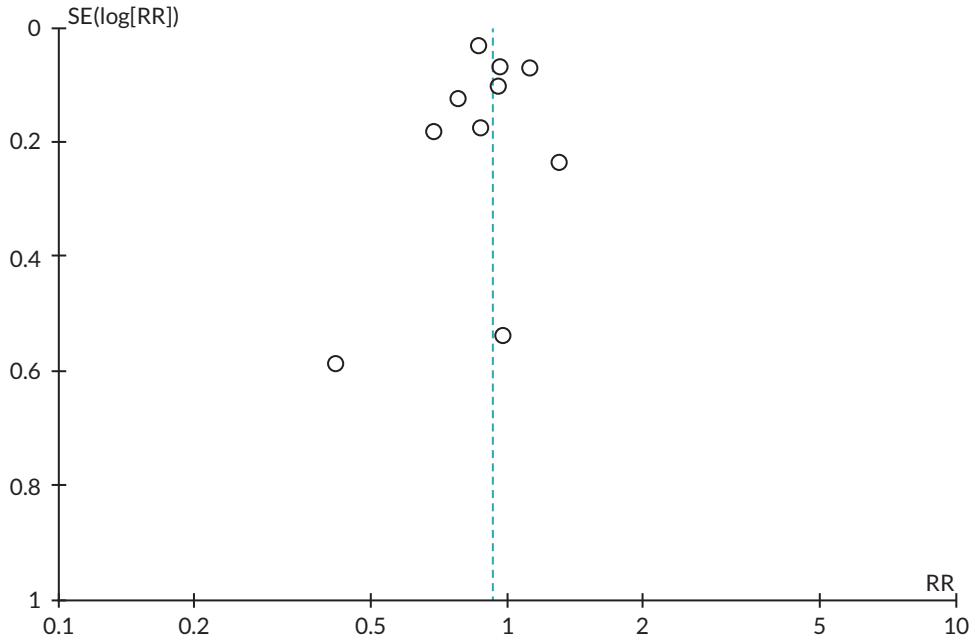

FIGURE 16 Funnel plot of comparison: 1 Breastfeeding support vs. usual care, outcome: not exclusive breastfeeding at 4–8 weeks.

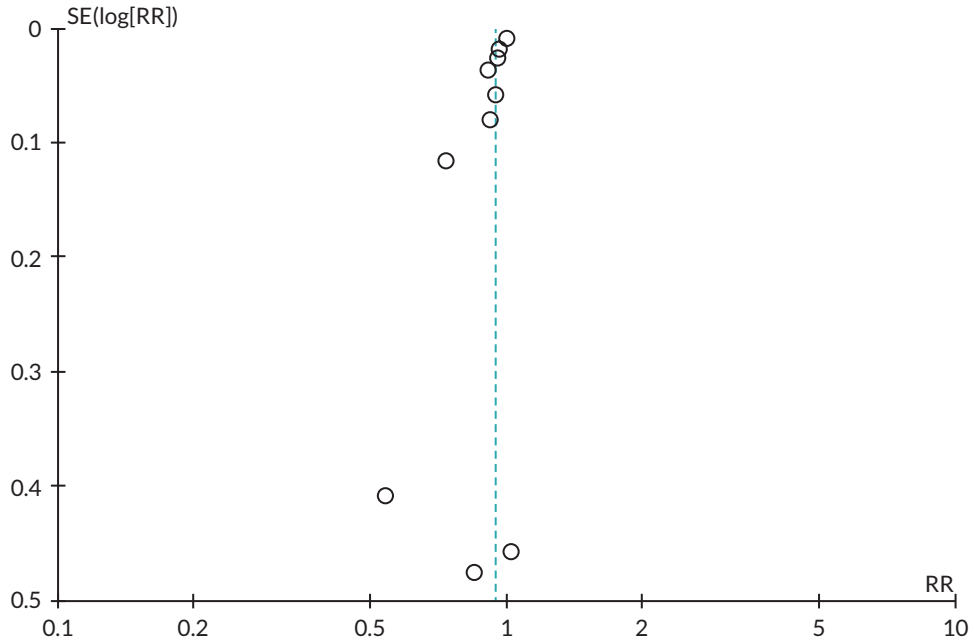

FIGURE 17 Funnel plot of comparison: 1 Breastfeeding support vs. usual care, outcome: not exclusive breastfeeding at 6 months.

Appendix 6 Study characteristics and risk-of-bias assessments of long-term conditions mixed-methods synthesis (see *Chapter 7*)

Study characteristics for long-term conditions mixed-methods synthesis (see *Chapter 7*)

TABLE 25 Characteristics of studies for mixed-methods synthesis for LTCs (see *Chapter 7*)

Study ID, country, setting	Aims	Study design, data collection and analysis method(s)	Sample size, population description	Main study conclusions
Acheampong *et al.* 2018[192] Ghana, hospital based	To describe HIV-positive, lactating women's perceptions of the role that social persuasion plays in their breastfeeding decisions and practices	Qualitative research In-depth, one-on-one interviews were conducted using a semi-structured interview guide Thematic content analysis	13 Breastfeeding mothers living with HIV, receiving ART in the public referral hospital, with infants younger than 1 year	Influential people in the lives of breastfeeding mothers with HIV should be involved during interventions by HIV counsellors to promote breastfeeding practices
Andrews *et al.* 2021[193] USA, population based	To qualitatively explore the lived experiences of disabled women related to breastfeeding	Qualitative research Semi structured interview Descriptive content analysis	24 Mothers with a disability who have at least one child under the age of 18 years	Our findings suggest that disabled women should be better supported in their breastfeeding decisions and require greater access to disability-affirmative and informative clinical resources and accessible communication
Demirci *et al.* 2015[194] USA, hospital based	Describe the experiences and perceptions impacting breastfeeding decisions among pregnant and postpartum women taking methadone	Qualitative research Interviews and focus groups following semi structured interview guides Content analysis	11 Pregnant and postpartum women expressing an interest in breastfeeding their child while taking methadone	Interventions to increase the prevalence of breastfeeding among women taking methadone should address identified logistical, educational and psychological barriers and consider inclusion of women themselves, partners, peers and clinicians. Clinicians who care for methadone-exposed mothers and infants should be educated on therapeutic communication, up-to-date breastfeeding contraindications and the health benefits of breastfeeding in this population
Dieterich *et al.* 2022[195] USA, clinic	To solicit experiences, perspectives and concerns from postpartum individuals with overweight and obesity who intended to breast-feed and explore if and how they perceived weight stigma impacted their breastfeeding counselling, decisions and experiences	Qualitative research Interview following semi structured guide Content analysis	18 Pregnant women 28–40+ weeks who had a pre-pregnancy BMI of ≥ 25 kg/m^2 that were planning to breastfeed or express milk for their infant	While participants in this sample recognised the existence of weight stigma in other settings, they did not perceive it during encounters with perinatal healthcare professionals. Additionally, individuals did not perceive weight stigma in any setting as influential on their breastfeeding experiences or practices

TABLE 25 Characteristics of studies for mixed-methods synthesis for LTCs (see *Chapter 7*) (*continued*)

Study ID, country, setting	Aims	Study design, data collection and analysis method(s)	Sample size, population description	Main study conclusions
Fadnes *et al.* 2010[212] Uganda, various study settings, hospitals, community and population setting	To assess how infant-feeding counselling was done and experienced among counsellors and mothers in eastern Uganda in the context of previous guidelines	Mixed-methods research Interviews and focus group discussions Cross-sectional surveys Inductive thematic analysis	Sample size not reported Key informant health workers who work with child health and infant-feeding guidance; health workers in the public hospital, health clinics and non-governmental organisations working with people living with HIV; mothers from general population and HIV-positive mothers	Health workers were faced with challenges related to workload, resources, scientific updating, and also a need to adjust to frequent changes in programs, recommendations and guidelines. The clients were faced with difficult choices, poverty, lack of education and stigma. Feasibility of the recommendations was a major concern. Systematic approaches to update health workers should be a priority
Flax *et al.* 2016[213] Malawi, community based	Study aims were to (1) document the type and frequency of IYCF counselling offered to HIV-infected women during postnatal PMTCT visits; (2) examine IYCF knowledge and practices of HIV-infected mothers in Option B+ with children ranging from 0 to 23 months; and (3) study HIV-infected women's IYCF decision-making and their perceptions of factors related to their IYCF practices	Mixed-methods research Survey In-depth interviews and observations Descriptive statistics Thematic analysis	224 (160 survey; 32 in-depth interviews; 32 observations) HIV-infected women participating in PMTCT Option B+, aged ≥ 18 years who had a child aged < 24 months	This represents a missed opportunity for health workers to support optimal IYCF practices within Option B+
Garner *et al.* 2014[196] USA, community based	To describe health professionals' experiences providing breastfeeding care for obese women during the prenatal, peripartum and postpartum periods	Qualitative research Semi structured in-depth interviews using interview guide Content analysis	34 Health professionals who provide care for obese women during pre-, peri- and postnatal periods	Health professionals identified multiple challenges that obese women encounter with breastfeeding, as well as their own challenges with providing care
Hazemba *et al.* 2016[197] Zambia, health facilities	The aim of this study was to explore factors that influence the decision to exclusively breast-feed in the context of preventing mother-to-child transmission of HIV	Qualitative research Semi structured interviews Participant observation Framework analysis guided by social constructivism theory	36 HIV-positive mothers on treatment regimen and have attended health promotion talks on infant feeding and who opted to exclusively breastfeed. Key informants from the prevention of mother-to-child transmission programme, including nurses, nutritionists and clinical officers	In order to enhance feeding practices for HIV-exposed infants, our study suggests a broader health campaign supporting all mothers to exclusively breastfeed

continued

TABLE 25 Characteristics of studies for mixed-methods synthesis for LTCs (see *Chapter 7*) (*continued*)

Study ID, country, setting	Aims	Study design, data collection and analysis method(s)	Sample size, population description	Main study conclusions
Hicks *et al.* 2018[207] USA, hospital based	This study aimed to capture the infant-feeding practices and barriers to exclusive breastfeeding for women in methadone maintenance therapy	Mixed-methods research A qualitative and quantitative interview-based survey – 47-item instrument incorporated questions from Infant Feeding Survey and adapted questions anchored by Bandura's triadic reciprocal causation model Content analysis Descriptive statistics	30 Women who delivered their baby while in treatment at an opioid dependence treatment centre	Women in treatment for opioid dependence both desire and attempt to establish breastfeeding, but encounter significant challenges, including long NICU stays and lack of support and education, that compromise their success. These findings should inform the development of future programs or interventions geared toward increasing breastfeeding initiation, support and duration among women who give birth to babies while in treatment for opioid addiction
Howard *et al.* 2018[198] USA, hospital based	To investigate perspectives of mothers with opioid use disorder regarding breastfeeding and rooming-in during the birth hospitalisation and identify facilitators and barriers	Qualitative research In-depth semistructured interviews utilising interview guide Grounded theory analysis	25 Mothers with opioid use disorder enrolled in a treatment programme	Future interventions aimed at increasing breastfeeding and rooming-in during the birth hospitalisation should focus on education regarding the benefits of breastfeeding and rooming-in, supporting mothers' autonomy in caring for their infants, minimising stigma and maximising resilience
Israel-Ballard *et al.* 2014[199] Kenya, community based	To assess how counsellors, who provide infant-feeding counselling to HIV-positive women, deal with challenges they face in two Kenyan provinces	Qualitative research Post-counselling exit interviews Observations and key informant interviews Analysis not reported	Unclear 80 post-counselling interviews; 22 counselling session observations; 11 key informant interviews HIV-positive women pregnant or with child 3, 6, 9 or 12 months of age Local stakeholders, including district and provincial nutritionists and nursing officers	Implementing the new WHO guidance will reduce the need for AFASS assessments, greatly simplifying both the government's and counsellor's tasks
Jagiello and Azulay Chertok 2015[200] USA, hospital based	The purpose of the study was to gain insight into the breastfeeding challenges that women with GDM face in the early postpartum period	Qualitative research Phenomenological approach using focus groups and interviews Thematic analysis	27 Women with GDM and had initiated breastfeeding following birth	Participants identified breastfeeding facilitators and barriers, many of which could have been modified. The women expressed a need for consistent lactation advice, education, assistance and strategies to address breastfeeding challenges and milk supply issues

TABLE 25 Characteristics of studies for mixed-methods synthesis for LTCs (see *Chapter 7*) (*continued*)

Study ID, country, setting	Aims	Study design, data collection and analysis method(s)	Sample size, population description	Main study conclusions
Keely *et al.* 2015[201] UK, population based	To explore the views and experiences of obese women who initiated breast-feeding when their babies were born and intended to continue exclusively breastfeeding until at least 16 weeks later, but who were no longer exclusively breastfeeding, or had stopped breast-feeding 6–10 weeks later	Qualitative research Semistructured face-to-face interviews Thematic analysis	28 Women who had given birth to a single baby at > 37 weeks' gestation, breastfeeding at first feed but no longer exclusively breast-feeding at 6–8 weeks postnatal, and BMI at the start of pregnancy of > 30 kg/m^2	Midwives should be mindful of the presence of additional factors alongside maternal obesity, such as caesarean delivery, physical difficulties when breastfeeding, poor body image and lack of confidence about sufficient milk supply. Scope for innovation within hospital policies with regard to both the facilitation of early skin-to-skin contact and privacy in postnatal accommodation could be explored in future research. Women should be provided with information about the provision and specific purpose of breastfeeding support groups and services and encouraged to access these services when appropriate
Laws *et al.* 2016[211] Australia, population based	The aim of the study was to report on the experiences of some mothers attempting to breastfeed when they or their infant have the rare genetic disorder ectodermal dysplasia	Mixed-methods research Focus group discussions Survey questionnaires Content analysis	149 (23 included in focus groups, 126 survey unclear) Parents caring for a child with ectodermal dysplasia. Also includes parents who had themselves been diagnosed with ectodermal dysplasia	While genetic screening is offered to pregnant women who have a known family history of a genetic disorder, many genetic orders are rare and go undetected. Newly birthed mothers with a genetic disorder may encounter difficulties when attempting to establish breastfeeding. More genetic education is needed to assist midwives in gaining a better understanding of how physiological problems, associated with a genetic disorder, may be a root cause of breast-feeding difficulties
MacVicar *et al.* 2017[202] UK, hospital based	The aim of this, study was to explore the views of women with opiate dependence on, proposed elements for inclusion in a breastfeeding support intervention	Qualitative research Qualitative think aloud interviews with contextual notes Stepwise approach particular to the think aloud technique Framework analysis	6 Opiate-dependent women within 6 months of giving birth; were enrolled on opiate medication treatment during their pregnancy; had initiated breastfeeding and accessed in-hospital breastfeeding support	There are distinct facilitators of, modifiers of and barriers to breastfeeding within the context of opiate exposure. Using this awareness to underpin the key features of the design should enhance maternal receptiveness, acceptability and usability of the support intervention

continued

TABLE 25 Characteristics of studies for mixed-methods synthesis for LTCs (see *Chapter 7*) (*continued*)

Study ID, country, setting	Aims	Study design, data collection and analysis method(s)	Sample size, population description	Main study conclusions
MacVicar *et al.* 2018[181] UK, hospital based	This study explored the feasibility of in-hospital, tailored breastfeeding support for the substance exposed mother and baby	Mixed-methods research A RCT and maternal questionnaire Descriptive statistics	14 Mothers who were on opioid substitution medication therapy during pregnancy, had an intention to breastfeed, were > 36 weeks' gestation and > 16 years of age	The findings highlight the feasibility of tailored breastfeeding support for the substance exposed mother and baby and endorse the promotion and support of breastfeeding for this group. Future research of a statistically powered RCT to evaluate clinical efficacy is recommended
Matsunaga *et al.* 2021[208] Japan, hospital based	This study aimed to examine the current levels of implementation of breastfeeding support to women with GDM in Japan and to clarify barriers to promoting breastfeeding among this population	Quantitative, cross-sectional study 25-item questionnaire Descriptive statistics Content analysis	296 Senior midwife or nurse, who was familiar with the hospital's practices and services for women with GDM	In Japan, most hospitals that responded provided general breastfeeding support from the antenatal to postpartum periods. However, the benefits of breastfeeding in terms of preventing the incidence of type 2 diabetes following GDM were insufficiently communicated to women with GDM. Furthermore, there were numerous barriers to promoting breastfeeding among women with GDM
Misita *et al.* 2021[214] Canada	(1) To determine the likelihood of full breastfeeding at 3 months postpartum in women with and without DiP; (2) to explore associations between diabetes management practices and infant-feeding practices in those who had DiP; and (3) to examine women's experiences of feeding their infants after having DiP	Mixed-methods research Infant feeding questionnaires, prospective breastfeeding diaries and medical chart data Semistructured interviews Chi-squared tests, two-sample *t*-tests Thematic analysis	261 (62 quantitative cohort matched to 175 participants without diabetes, 24 qualitative interviews) Women who had diagnosis of diabetes in pregnancy 8 months postpartum, > 18 years of age	Women with diabetes in pregnancy may require additional prenatal and postnatal infant feeding support to be better prepared to overcome feeding challenges they may face

TABLE 25 Characteristics of studies for mixed-methods synthesis for LTCs (see *Chapter 7*) (*continued*)

Study ID, country, setting	Aims	Study design, data collection and analysis method(s)	Sample size, population description	Main study conclusions
Nieuwoudt *et al.* 2018[203] South Africa, community based	To explore how health workers attached to community health clinics understood and were implementing the new infant-feeding guidelines. The study explored (1) health workers' knowledge of the declaration; (2) how formula removal and training influenced their counselling; and (3) their impressions about changes in breastfeeding practices. Drawing on health workers to share and reflect on their upbringing, experiences of infant feeding, and values as these related to their experiences	Qualitative research Semistructured interviews using interview guide Thematic content analysis	11 Health workers from four community health clinics, who had counselled mothers on infant feeding before and after the policy change	Some participants believed that breast-feeding practices were driven by finance or family pressures rather than the health information they provided. Health workers generally lacked training on the policy's evidence base, particularly the health benefits of exclusive breastfeeding for non-exposed infants. They wanted clarity on their counselling role, based on individual risk or to promote exclusive breastfeeding as a single option. If the latter, they needed training on how to assist mothers with community-based barriers. Infant feeding messages from health workers are likely to remain confusing until their uncertainties are addressed. Their insights should inform future guideline development as key actors
Nor *et al.* 2009[205] South Africa, community based	The aim of the study was to explore the perceptions and experiences of infant-feeding peer counselling in three diverse settings in South Africa	Qualitative research Individual interviews Participant observations Review of records Informal interviews taken during observations Thematic analysis using interpretative description framework	27 Women, both HIV-infected and uninfected, enrolled in an exclusive breastfeeding intervention study who had been offered peer counselling	The findings underline the contextual barriers facing peer counsellors and show that these challenges could have important implications for the effectiveness of infant-feeding counselling in high HIV prevalence countries
Nor *et al.* 2012[204] South Africa, community based	To explore mothers' perceptions and experiences of infant feeding within a community-based peer counselling intervention promoting exclusive breast or formula feeding. Of particular interest was whether peer counselling on infant feeding helped the mothers to negotiate existing systems of beliefs and traditions	Qualitative research Semistructured interviews using interview guide Qualitative interpretative description	17 HIV-positive and negative mothers who were participating in the PROMISE-EBF peer counselling intervention cluster	Efforts to reduce barriers to EBF need to be intensified and further take into account the strong cultural beliefs that promote mixed feeding

continued

TABLE 25 Characteristics of studies for mixed-methods synthesis for LTCs (see *Chapter 7*) (*continued*)

Study ID, country, setting	Aims	Study design, data collection and analysis method(s)	Sample size, population description	Main study conclusions
O'Reilly *et al.* 2022[206] Ireland, population and hospital based	This study aimed to (a) explore the barriers and enablers to breastfeeding in women with high BMIs, and (b) map specific behaviours suitable for intervention across the antenatal to postpartum periods	Qualitative research Semistructured interviews Reflexive thematic analysis	61 Women with a BMI of > 25kg/m^2 who had exclusively breastfed for ≥ 6 months within the previous 2 years Partners who were main support for a woman who had breastfed successfully for 6 months or more within the previous 2 years; healthcare professionals involved in providing breastfeeding support	The barriers and enablers identified for participants with high BMIs were similar to those for the broader population; however, the physicality and associated social bias of high BMIs mean that additional support is warranted. Antenatal and postpartum breastfeeding services need a multifaceted, inclusive and high-quality program to provide the necessary support to women with higher BMIs
Powell *et al.* 2018[209] USA, population based	This study aimed to explore the facilitators of and barriers to breastfeeding among women with physical disabilities	Qualitative research Semistructured telephone interviews Content analysis	25 Women who had a physical disability or condition that affected their ability to walk or use of arms or hands at the time of pregnancy, and had delivered a child within the past 10 years	The need for greater supports for women with physical disabilities who desire to breastfeed as well as information for women and their clinicians about facilitating breastfeeding
Rasmussen *et al.* 2006[210] USA, population based	The purpose of this study was to describe the experience and attitudes about BF of those who provide care to lactating women about BF and to evaluate how they counsel obese mothers about breastfeeding	Quantitative, cross-sectional study Questionnaire survey conducted via e-mail or telephone interview Chi-squared tests	120 Healthcare providers (including lactation consultants, physicians, midwives, nurses) who counsel mothers about breastfeeding	Given the excess risk for premature lactation failure among obese women, these findings suggest that those who care for such women need to be made aware of this risk so that they can develop and provide appropriate services

AFASS, acceptable, feasible, affordable, sustainable, safe; DiP, diabetes in pregnancy; EBF, exclusive breastfeeding; IYCF, infant and young child feeding; NICU, neonatal intensive care unit; PMTCT, prevention of mother-to-child transmission.

Critical Appraisal Skills Programme qualitative summary

TABLE 26 Critical Appraisal Skills Programme qualitative summary for mixed-methods synthesis (see *Chapter 7*)

Study	1. Was there a clear statement of the aims of the research?	2. Is a qualitative methodology appropriate?	3. Was the research design appropriate to address the aims of the research?	4. Was the recruitment strategy appropriate to the aims of the research?	5. Was the data collected in a way that addressed the research issue?	6. Has the relationship between researcher and participants been adequately considered?	7. Have ethical issues been taken into consideration?	8. Was the data analysis sufficiently rigorous?	9. Is there a clear statement of findings?	10. How valuable is the research?
Acheampong *et al.*[192]	Yes	Yes	Yes	Yes	Yes	Partial	Yes	Yes	Yes	Partial
Andrews *et al.*[193]	Yes	Yes	Partial	Yes	Partial	Partial	No	Yes	Yes	Yes
Dieterich *et al.*[195]	Yes	Yes	Yes	Yes	Yes	Partial	Yes	Partial	Partial	Yes
Demirci *et al.*[194]	Yes	Yes	Can't answer	Partial	Partial	Partial	Partial	Yes	Partial	Yes
Fadnes *et al.*[212]	Yes	Yes	Yes	Yes	Can't answer	No	Yes	Yes	Yes	Yes
Flax *et al.*[213]	Yes	Yes	Yes	Yes	Yes	No	Partial	Yes	Yes	Yes
Garner *et al.*[196]	Yes	Yes	Partial	Yes	Yes	Partial	Partial	Yes	Yes	Partial
Hazemba *et al.*[197]	Yes	Yes	Partial	Yes	Partial	No	Yes	Yes	Partial	Partial
Howard *et al.*[198]	Yes	Yes	No	Yes	Yes	No	No	Partial	Yes	Partial
Israel-Ballard *et al.*[199]	Yes	Yes	Can't answer	Yes	Partial	No	Partial	No	No	No
Jagiello and Azulay Chertok[200]	Yes	Yes	Yes	Yes	Partial	No	Yes	Yes	Yes	Yes
Keely *et al.*[201]	Yes	Yes	Yes	Yes	Yes	No	Partial	Partial	Partial	Yes

continued

TABLE 26 Critical Appraisal Skills Programme qualitative summary for mixed-methods synthesis (see *Chapter 7*) (*continued*)

Study	1. Was there a clear statement of the aims of the research?	2. Is a qualitative methodology appropriate?	3. Was the research design appropriate to address the aims of the research?	4. Was the recruitment strategy appropriate to the aims of the research?	5. Was the data collected in a way that addressed the research issue?	6. Has the relationship between researcher and participants been adequately considered?	7. Have ethical issues been taken into consideration?	8. Was the data analysis sufficiently rigorous?	9. Is there a clear statement of findings?	10. How valuable is the research?
Laws *et al.*[211]	Yes	Yes	Partial	Partial	Partial	No	Partial	No	Partial	Partial
MacVicar *et al.*[202]	Yes	Yes	Yes	Yes	Partial	Partial	Yes	Partial	Partial	Yes
MacVicar *et al.*[181]	Yes	Yes	Yes	Partial	Yes	No	Partial	Partial	Partial	Yes
Misita *et al.*[214]	Yes	Yes	Yes	Yes	Yes	No	Partial	Partial	Partial	Partial
Nieuwoudt and Manderson[203]	Yes	Yes	Partial	Partial	Yes	Partial	Yes	Partial	Partial	Yes
Nor *et al.*[205]	Yes	Yes	Partial	Partial	Partial	Partial	Partial	Yes	Partial	Yes
Nor *et al.*[204]	Partial	Yes	Partial	Partial	Partial	No	Partial	Yes	Partial	Partial
O'Reilly *et al.*[206]	Yes	Yes	Partial	Partial	Yes	Yes	Yes	Yes	Partial	Yes
Powell *et al.*[209]	Yes	Yes	Partial	Partial	Yes	No	Yes	Yes	Yes	Yes

AXIS summary

TABLE 27 AXIS summary for mixed-methods synthesis (see *Chapter 7*)

		Hicks *et al.*[207]	Laws *et al.*[211]	Matsunaga *et al.*[208]	Rasmussen *et al.*[210]
1	Were the aims/objectives of the study clear?	Yes	No	Yes	Yes
2	Was the study design appropriate for the stated aim(s)?	Yes	No	Yes	Yes
3	Was the sample size justified?	No	No	Yes	No
4	Was the target/reference population clearly defined? (Is it clear who the research was about?	Yes	No	Yes	Yes
5	Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	No	Don't know	Yes	Don't know
6	Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	No	Don't know	N/A	Don't know
7	Were measures undertaken to address and categorise non-responders?	No	No	No	No
8	Were the risk factor and outcome variables measured appropriate to the aims of the study?	Yes	Don't know	Yes	Don't know
9	Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	Don't know	No	Don't know	No
10	Is it clear what was used to determined statistical significance and/or precision estimates? (e.g. *p*-values, CIs)	Yes	No	Don't know	Yes
11	Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	No	No	Yes	No
12	Were the basic data adequately described?	Yes	No	Yes	No
13	Does the response rate raise concerns about non-response bias?	Don't know	Don't know	Yes	Yes
14	If appropriate, was information about non-responders described?	No	No	No	No
15	Were the results internally consistent?	N/A	Don't know	Don't know	Don't know
16	Were the results presented for all the analyses described in the methods?	Yes	Don't know	Yes	Don't know
17	Were the authors' discussions and conclusions justified by the results?	No	No	Yes	No
18	Were the limitations of the study discussed?	Yes	Partial	Yes	Don't know
19	Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	No	Don't know	No	No
20	Was ethical approval or consent of participants attained?	Yes	Yes	Yes	No

Primary studies underpinning synthesis themes

TABLE 28 Primary studies underpinning synthesis themes

Included studies (*n* = 24)	Additional breastfeeding support needs for mothers with LTCs	Availability of breastfeeding support for mothers with LTCs	The role and practice of breastfeeding support for mothers with LTCs	Suggested strategies to improve breastfeeding support for mothers with LTCs
Acheampong 2018			•	•
Andrews 2021	•		•	
Demirci 2015	•	•	•	•
Dieterich 2022			•	•
Fadnes 2010	•		•	
Flax 2016		•	•	•
Garner 2014	•		•	•
Hazemba 2016	•		•	•
Hicks 2018	•	•	•	
Howard 2018	•	•	•	
Israel-Ballard 2014			•	•
Jagiello 2015	•	•	•	•
Keely 2015	•	•	•	•
Laws 2016	•	•	•	•
MacVicar 2017			•	•
MacVicar 2018		•	•	•
Matsunaga 2021	•	•	•	
Misita 2021	•		•	•
Nieuwoudt 2018	•	•	•	
Nor 2009	•		•	•
Nor 2012	•		•	
O'Reilly 2022		•	•	•
Powell 2018	•	•	•	•
Rasmussen 2006		•	•	•

Appendix 7 Characteristics of included economic evaluation studies

TABLE 29 Characteristics of included economic evaluation studies (see *Chapter 8*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Avram 2020[216] USA Nationwide Hospital setting	**Rooming-in + usual care** **Support**: Breastfeeding only **Description**: Rooming-in newborns with families encourages parental involvement and promotes breastfeeding, thereby decreasing the need for opioid replacement and shortening hospitalisation **Provider**: Professional **Mode of delivery**: Face to face **Intensity**: Not reported **Duration**: Hospital stay after birth	**Usual care** **Description**: Not reported	**Inclusion criteria**: Women/infant dyads with prenatal use of opioids and infants with neonatal opioid withdrawal **Exclusion criteria**: Not reported **Sample size**: Not applicable, as model-based **Baseline characteristics**: Not applicable	**Type of economic evaluation**: CUA (model-based) **Perspective**: Societal **Currency, price year**: USD, 2018 **Time horizon**: Lifetime **Discount rate**: 3% **Primary outcome**: Cost per QALY gained **Secondary outcomes**: **N/A** **Data sources**: *Outcome of effect*: Literature-based (systematic reviews and retrospective cohort studies *Resource use*: Literature-based costs *Unit costs*: Not reported **Measurement of uncertainty**: Not reported **Consideration of heterogeneity**: Not reported **Sensitivity analyses**: Univariate sensitivity analyses conducted on model inputs across a range of parameters	**Base-case results**: Rooming-in resulted in cost savings of US$509,652,728 and 12,333 additional QALYs per annual cohort **Findings from sensitivity analyses**: The largest driver of the model was the risk ratio of pharmacotherapy associated with rooming-in compared with not rooming-in. The model was also sensitive to the probability of developing severe neurological impairment in neonates whose withdrawal symptoms did not warrant pharmacotherapy	**Not applicable**: OECD settings, societal perspective, cost savings and additional QALYs reported, time horizon from birth up to lifetime
Bick 2020[219] UK Inner-city unit, south England Community healthcare setting	**Slimming World + usual care** **Support**: Breastfeeding plus **Description**: Programme of weight management **Provider**: Lay person **Mode of delivery**: Face to face **Intensity**: High (12 weekly sessions) **Duration**: From 8 to 16 weeks postpartum until infants are 12 months old	**Usual care** **Description**: Standard NHS maternity care to 6–8 weeks postpartum, including routine midwife, health visitor and GP contacts	**Inclusion criteria**: Women 18 years +, able to speak/read English, singleton pregnancy, BMI of > 25 kg/m^2 at pregnancy booking or normal BMIs (18.5–24.9 kg/m^2) with excessive gestational weight gain **Exclusion criteria**: Not stated **Sample size**: Total, *N* = 193 (intervention, *n* = 98; control, *n* = 95) **Baseline characteristics**: Baseline characteristics appear balanced	**Type of economic evaluation**: Cost–outcome description (alongside a feasibility study) **Perspective**: Provider **Currency, price year**: GBP, 2000 **Time horizon**: Within feasibility trial **Discount rate**: N/A **Primary outcome**: Feasibility of collecting economic data **Secondary outcomes**: Not reported **Data sources**: *Outcome of effect*: Within study *Resource use*: Within study *Unit costs*: National sources **Measurement of uncertainty**: N/A **Consideration of heterogeneity**: N/A **Sensitivity analyses**: N/A	**Base-case results**: Data collection tools were suitable	**Not applicable**: minimal economic data reported; UK setting, provider perspective, time horizon up to infant age 1 year

TABLE 29 Characteristics of included economic evaluation studies (see *Chapter 8*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Desmond 2008[217] South Africa KwaZulu-Natal province Community healthcare setting	**Vertical Transmission Study (VTS) + usual care** **Support**: Breastfeeding only **Description**: A breastfeeding intervention strategy, designed to promote exclusive breastfeeding from birth to 6 months **Provider**: Lay breastfeeding counsellor **Mode of delivery**: Face to face **Intensity**: High (minimum 14 visits) **Duration**: From late pregnancy to 6 months postpartum	**Usual care** **Description**: Not reported	**Inclusion criteria**: Women living with HIV **Exclusion criteria**: Not reported **Sample size**: not reported, suggested hypothetical sample **Baseline characteristics**: Not reported	**Type of economic evaluation**: CEA (within trial and model-based) **Perspective**: Provider **Currency, price year**: USD, 2000 **Time horizon**: 7 months **Discount rate**: N/A **Primary outcome**: Cost per increased month of EBF **Secondary outcomes**: Not reported **Data sources**: *Outcome of effect*: Within-trial *Resource use*: Within-trial *Unit costs*: Local and national sources **Measurement of uncertainty**: N/A **Consideration of heterogeneity**: N/A **Sensitivity analyses**: Scenario analyses reported for different levels of intervention	**Base-case results**: ICER = US$88 per increased month of EBF **Findings from scenario analyses**: Simplified scenario US$29 per increased month of EBF, full scenario US$48 per increased month of EBF	**Not applicable**: Non-OECD setting; provider perspective, cost per DALY averted reported, time horizon from birth up to 7 months
Mottl-Santiago 2020[125] USA Community healthcare and hospital setting	**Birth Sisters Best Beginnings for Babies program (doula support) + usual care** **Support:** Breastfeeding plus **Description:** Birth Sisters Best Beginnings for Babies provided community doula services with consultation from the Medical Legal Partnership when indicated **Provider:** Lay (doula peer support) **Mode of delivery:** Face-to-face **Intensity:** High – Participants receive up to eight 2-hour prenatal home visits; continuous support through labour and birth, and up to four 2-hour postpartum home visits through 6–8 weeks postpartum **Duration**: From 24 weeks gestation up to 8 weeks postpartum	**Usual care** **Description**: Usual prenatal, intrapartum and postpartum maternity care	**Inclusion criteria**: Subgroup of medically high-risk women (hypertension or diabetes in pregnancy) **Exclusion criteria:** < 18 years of age, high-risk pregnancy defined by care in the high-risk prenatal clinic **Sample size:** Total, *N* = 411 (intervention, *n* = 207; control, *n* = 204) **Baseline characteristics:** No group differences observed at baseline	**Type of economic evaluation:** CBA (study-based) **Perspective:** Payer **Currency, price year:** USD, 2018 **Time horizon:** From mid-pregnancy to 6–8 weeks postpartum **Discount rate:** N/A **Primary outcome:** Return on investment **Secondary outcomes:** N/A **Data sources:** *Outcome of effect:* Within trial *Resource use:* Within trial *Unit costs:* Local sources **Measurement of uncertainty:** Payments were winsorised to address outliers **Consideration of heterogeneity:** Variations in impact for different populations, with the focus here on medically high-risk mothers **Sensitivity analyses:** N/A	**Base-case results:** ROI 276%	**Not applicable**: OECD setting, payer perspective, time horizon from mid-pregnancy up to 8 weeks postpartum

continued

TABLE 29 Characteristics of included economic evaluation studies (see *Chapter 8*) (*continued*)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Maredza 2013[218] South Africa Rural and urban settings Community healthcare setting	**Infant feeding strategies + usual care** **Support**: Breastfeeding only **Description**: Strategy of actively supporting breastfeeding with extended nevirapine prophylaxis for 12 months **Provider**: Paraprofessional (skilled care workers and community health workers) **Mode of delivery**: Face-to-face **Intensity**: Unclear **Duration**: From first trimester of pregnancy until infants are 12 months old	**Usual care** **Description**: Not reported	**Inclusion criteria**: Women living with HIV **Exclusion criteria**: Not reported **Sample size**: Not reported **Baseline characteristics**: Not reported	**Type of economic evaluation**: CUA (model-based) **Perspective**: Health provider **Currency, price year**: USD, 2000 **Time horizon**: **Discount rate**: Annual rate of 3% **Primary outcome**: Incremental cost per DALY averted **Secondary outcomes**: N/A **Data sources**: *Outcome of effect*: Literature and expert opinion *Resource use*: Literature *Unit costs*: Local and national sources **Measurement of uncertainty**: 95% CI estimated **Consideration of heterogeneity**: Not reported **Sensitivity analyses**: Univariate sensitivity analyses conducted in certain urban settings	**Base-case results**: ICER = Cost per DALY averted dominant with a 95% CI of dominant, 13,000 **Findings from sensitivity analyses**: ICER for actively supporting breastfeeding was less costly and less effectively for all one-way SA, with the exception of proportion of HIV-diagnosed breastfeeding women on HAART, where the ICER was dominant	**Not applicable**: Non-OECD settings Provider perspective, cost per DALY averted reported, time horizon from birth up to lifetime

CBA, cost–benefit analysis; CEA, cost-effectiveness analysis; CUA, cost–utility analysis; DALY, disability-adjusted life-year; EBF, exclusive breastfeeding; HAART, highly active antiretroviral therapy.

Appendix 8 Draft toolkit

Introduction

This draft toolkit outlines the proposed toolkit structure and contents resulting from the co-development process described in *Chapter 9*. Further co-development work, write-up and refinement of the toolkit output is ongoing.

Section 1 of the toolkit describes a proposed set of evidence-based intervention components recommended for breastfeeding support services. Section 2 summarises the key criteria for those considering adopting and adapting the proposed intervention components for delivery in UK settings and/or to meet the needs of breastfeeding women with MLTC. Section 3 provides recommendations to support the planning of the implementation and roll-out stages of the proposed intervention components in UK settings. Finally, section 4 sets out recommendations for the evaluation of breastfeeding support interventions in UK settings, including a range of suggested outcomes and practical considerations.

1. Evidence-based recommendations for breastfeeding support services.

Based on the most recently available high-quality evidence on effectiveness of breastfeeding support interventions, the most effective intervention components have been identified and used to develop a comprehensive breastfeeding support programme prototype. These components were selected from interventions in the Cochrane review[83] meeting two key criteria: (1) identified as effective in reducing the number of women stopping breastfeeding; and (2) judged to be at low risk of bias, using allocation concealment as a proxy indicator. Thus, the proposed set of intervention components is underpinned by seven interventions[103,221–226] and together they provide a range of ways most likely to effectively support breastfeeding women.

The proposed programme involves the following components and activities.

The breastfeeding support package will be delivered one to one by infant-feeding advisors. It consists of one 30-minute antenatal appointment, one 30-minute hospital visit, one 30-minute home visit within 48 hours of discharge and regular telephone calls. The antenatal session will focus on building rapport, providing education and identifying any concerns regarding breastfeeding. The hospital and discharge visits will involve checking latch, helping with positioning and observing a feed if requested by the mother. Infant-feeding advisors will also provide encouragement, praise and reassurance during visits. Women will be given the chance to ask questions and raise any concerns.

Following the initial three contacts, support will be provided remotely unless a face-to-face visit is required. For the first 4 weeks there will be a weekly proactive telephone call and beyond that support will be provided monthly until 3 months or when breastfeeding ceases. Women can also contact infant-feeding advisors as needed by telephone or SMS during this 3-month period and beyond as new issues arise.

The infant-feeding advisor will also signpost women to the local breastfeeding peer support group, which provides support via WhatsApp and weekly face-to-face support groups. Infant-feeding advisors will receive training on the intervention delivery.

2. Adapting the evidence-based recommendations to your local services.
   - Prioritised criteria to consider to the adoption and adaptation of the proposed intervention in UK settings.

These criteria were developed in collaboration with our stakeholders and PPI members through interactive exercises to facilitate the discussion, tailoring and prioritisation of a readily available set of general criteria to evaluate the transferability of health interventions.[81]

The resulting set of prioritised criteria were:

1. population's acceptability of the intervention
2. the quality of the primary evidence available
3. sustainability of the intervention
4. service providers' perception and support of the intervention
5. conditions of health service provision
6. existence of a knowledge translation process for the intervention
7. quality of communication in multidisciplinary work and teams
8. the utility/usefulness of the primary evidence available
9. the structure of the healthcare system and relevant services
10. co-operation between intervention providers and recipients
11. sociodemographic characteristics of the population
12. the conception of the intervention.

- Adaptations to meet needs of breastfeeding women with MLTC.

These criteria were developed in collaboration with our stakeholders and PPI members, based on the experiences of those who took part in our PPI meetings and in our stakeholder engagement workshops. The suggested adaptations to the proposed intervention components to meet the needs of breastfeeding women with MLTC are the following:

- The antenatal appointment should be longer than 30 minutes.
- Continuity is needed with the same person delivering the intervention antenatally and postnatally so that women do not have to repeat their stories.
- Infant-feeding advisors should be included in joint obstetric and medical clinics.

Other adaptations to consider:

- The person delivering the intervention should have expertise in medications and breastfeeding, as well as in breastfeeding support.
- Antenatal appointments of 90 minutes would be more realistic, or several shorter appointments could be helpful.
- Starting discussions early in pregnancy could be beneficial to take account of the higher risk of preterm birth for women with multimorbidities and to give practitioners more time to find accurate information.
- Women require a medication review in early pregnancy, and this should involve a pharmacist who is knowledgeable about medications and breastfeeding.
- Women should be able to see all their healthcare providers (e.g. midwife, obstetrician, physician, pharmacist) at one appointment to minimise the woman's time, effort and costs. Ideally the appointment would include key members of the women's support network (e.g. partner, family).
- The antenatal appointment should focus on practical tips for managing varying levels of fatigue and pain, such as how to find comfortable positions for breastfeeding. Content should also be flexible to meet the women's needs, adaptable to changing circumstances and consistent across different healthcare providers.
- 30-minute postnatal appointments are too short.

- For the 3-month follow-up support, women should have the option of telephone or face-to-face contacts, and 24-hour telephone support should be available.
- Peer support could be offered antenatally, and group antenatal peer support could help normalise breastfeeding for women with LTCs. Women could be offered the choice of one-to-one or group peer support.
- Third-sector organisations could help with provision of breastfeeding and emotional support.
- To be sustainable, peer supporters should be paid.
- Training is needed to increase knowledge of breastfeeding and multimorbidities in the multidisciplinary team including GPs. Supporting women with multimorbidities to breastfeed should be included in routine breastfeeding training updates.
- Services should be co-ordinated with the infant-feeding advisor as the key point of contact for the multidisciplinary team.

3. Implementing your new breastfeeding support service.

These recommendations to support the planning of the implementation (part 1) and roll-out (part 2) of the proposed intervention components were developed in collaboration with our stakeholders and PPI members through a range of meetings and engagement activities with the research team. Sessions were informed by the barriers to/enablers of implementing breastfeeding support interventions derived from synthesising process evaluations of effective interventions (see *Chapter 4*) that were discussed, validated and/or refined and adapted based on the views and experiences of participating stakeholders.

The combined recommendations resulting from this process are:

3.1. Part 1: considering the barriers to and enablers of implementing your new service.

- Key enablers to address:
  - Training – counselling skills and technical competence, practical expectations of undertaking the breastfeeding supporter role (e.g. uncertainties about safety, transport and reimbursement while delivering support, managing difficult scenarios, interplay of cultural beliefs and breastfeeding practice).
  - Effective management and supervision.
  - Ongoing emotional support, including mentoring and motivation for peer, lay or volunteer supporters.
  - Offering women the opportunity to ask questions and being allowed to spend enough time to address any issues.
  - Provide support flexibly as needed, rather than having to fit support around fixed working hours or at times which might not be convenient for women.

- Key barriers to address:

Intervention

  - Schedule and length of appointments lack flexibility and would need to be tailored to individual women's needs and circumstances.
  - The intervention does not include the women's partner and/or other family members who could be important sources of breastfeeding support.
  - Lack of continuity across the intervention.
  - Lack of intensity in the first 2 weeks postnatally.
  - Costs to the service.
  - Multiple appointments may not be convenient for women.
  - Intervention may not be perceived to be better than existing or alternative approaches to breastfeeding support.

External barriers

- Negative societal attitudes to breastfeeding/bottle-feeding culture.
- Pressure from families/social networks.
- Impact of formula marketing.
- Challenges to developing partnerships between health services and other sectors (local authorities, third-sector organisations).
- Socioeconomic and structural factors, for example lack of transport, lack of childcare, digital poverty, cost-of-living crisis.
- Lack of external financing.

Health system barriers

- Workforce challenges – staff shortages, high staff turnover, lack of staff time, lack of right skill mix.
- Overdependency on individuals or small groups of staff.
- Poor communication within the multidisciplinary team.
- Fragmented services.
- Lack of valuing peer support services and barriers to integrating professional and peer support.
- Reliance on unpaid volunteers to provide peer support.
- Lack of tailoring of services to diverse populations, for example lack of language support, lack of accessible venues, staff attitudes (stereotyping).
- Lack of feedback to staff, for example data sharing, sharing good practices.
- Lack of resources – appropriate venues to deliver the intervention considering space for women to breastfeed and accessible locations for groups to meet.
- Lack of compatibility of the innovation with existing policies and guidelines.
- Early postnatal discharge following birth.
- Overlap of the innovation with existing breastfeeding support services.

Individuals

- For those delivering the intervention – lack of knowledge, practical and interpersonal skills, lack of experience and training, lack of motivation, lack of confidence.
- For strategic and operational managers – lack of buy-in, lack of understanding of the value of breastfeeding, lack of commitment, lack of champions and skilled implementation leads and teams.
- For intervention recipients – inaccessible services, lack of awareness of services, lack of time.

Implementation process

- Lack of engagement of staff/resistance to change.
- Lack of management oversight to ensure innovation implemented as intended.
- Lack of feedback to staff concerning the quality of the intervention.

3.2. Part 2: Planning the implementation strategy to successfully roll out your new service.

- Overview of most relevant strategies linked to the key barriers they can address.

Implementation strategies	Barriers addressed
Deliver realistic, evidence-based information in multiple formats on how to deliver the breastfeeding support intervention and why it is important	Lack of staff training, knowledge and skills Lack of consistency of information Lack of continuity of care Challenges to accessing the intervention for women and families Lack of buy-in from senior managers
Assign a key practitioner to raise awareness about the intervention to ensure a consistent message	Challenges to working with sectors outside the health system Poor communication across the multidisciplinary team Lack of joined-up vision and working

Implementation strategies	Barriers addressed
New or existing funding for breastfeeding support should be a general health investment for local councils, and the government, and not just the NHS	Lack of funding in the health system Cost of the service to the NHS Lack of relationship between the health system and the community Lack of sustainability Cost of the intervention to women Reliance on non-paid peer supporters
Create an infant-feeding team in every NHS organisation to lead the intervention, working collaboratively with multidisciplinary practitioners and lay supporters	Lack of availability of good-quality training Time and capacity issues Professional boundaries – especially working with peer supporters Lack of confidence of those delivering the intervention Lack of integration across the continuum (antenatal/postnatal) and across the multidisciplinary team
Revise roles as needed to support the intervention, for example integrate peer supporters with NHS infant-feeding teams, and consider upskilling maternity staff to specialist lactation training levels	Barriers to integrating peer support with health services including lack of valuing peer support Lack of right skill mix Lack of knowledge and skills of staff delivering the intervention Infant-feeding specialists overloaded

4. Evaluating your new breastfeeding support service.

This section sets out recommendations for the evaluation of breastfeeding support interventions in UK settings, including a range of suggested outcomes and practical considerations, based on the views and experiences of those attending our PPI and stakeholder meetings and workshops.

- Practical considerations for evaluation strategies:
  - Collect data early to capture those who cease to engage with the intervention.
  - Gain feedback from those who declined the intervention.
  - Use digital options for data collection.
  - Collect data on participant characteristics.
  - Consider using quality improvement approaches or comparative studies.

- Recommended outcomes:
  - Parental feeding expectations and goals met.
  - Satisfaction with support and information received.
  - Confidence after the intervention (self-efficacy).
  - Views and experiences of intervention deliverers and recipients.
  - Intervention fidelity.
  - Breastfeeding rates – exclusive and any with clear definitions and consider further subdivisions at:

First feed within 1 hour after birth
Discharge from hospital
6–8 weeks
6 months
(consider adding to above 10–12 days, 3–4 months, 12 months)

- Number of infants admitted to hospital.
- Reasons for stopping breastfeeding.

Future plans

Further co-development work, write-up and refinement is ongoing, with a view to produce a user-friendly toolkit that will support NHS and third-sector organisations to implement evidence-based breastfeeding support for women in the UK.

Following this, the research team will seek further funding to undertake a robust evaluation of the implementation and effectiveness of our proposed, adapted composite intervention in UK settings.

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