

Title Page

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

Key words

Breastfeeding, infant feeding, evidence synthesis, multiple long-term conditions, stakeholder engagement

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Disclosure of interest statement: Louise Wallace was a panel member on the following: DH NIHR Health Services & Research Development panel (2012-13); NIHR HS &DR Researcher Lead Panel (2013-15); Member SDO Service Evaluations panel (2009-2011); and NIHR Health Services & Research Development panel (Seacole) (October 2020-2022). These received no payments other than expenses. Louise Wallace was also a paid scientific advisor for NIHR HS & DR Remit and Competitive committee (2015- 2019)

Abstract

Background

Breastfeeding impacts multiple health outcomes but less than 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 i) healthy women, and ii) 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. Cross-study synthesis integrated qualitative and quantitative findings.

Systematic reviews synthesised evidence on the incremental costs and cost-effectiveness of breastfeeding support following NICE guidance. All searches were conducted 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 attended the workshops.

Results

We found considerably more interventions that were designed for healthy women (Review 1) compared to those aimed at women with long-term conditions (Reviews 1 and 4, approximately half the studies were targeted at groups at higher risk of poor breastfeeding outcomes, and possibly 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 them in the provision of breastfeeding support for women with long-term conditions. 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.

Limitations

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

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 may reduce the number of women stopping exclusive breastfeeding at 4-6 weeks and 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, in particular 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

The reviews in this study are registered at PROSPERO: CRD42022337239; CRD42021229769; CRD42022374509. The protocols for the economic evaluation are available on request.

Funding

This project was funded by the National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Research programme and will be published in full in Health and Social Care Delivery Research; Vol. XX, No. XX. See the NIHR Journals Library website for further project information.

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List of supplementary material

Supplementary file 1: Ranked strategies and number of times selected

List of abbreviations

aOR	Adjusted odds ratio
BFHI	Baby friendly hospital initiative
BMI	Body mass index
CASP	Critical Appraisal Skills Programme
CBA	Cost-benefit analysis
CEA	Cost-effectiveness analysis
CFIR	Consolidated Framework for Implementation Research
CI	Confidence interval
CUA	Cost-utility analysis
DALY	Disability-adjusted life year
DCE	Discrete choice experiment
GBP	Great British Pound
GDM	Gestational diabetes mellitus
GP	General practitioner
GRADE	Grading of Recommendations, Assessment, Development, and Evaluations
HIC	High-income country
HIV	Human Immunodeficiency virus
IBCLC	International board-certified lactation consultant
ICER	Incremental cost-effectiveness ratio
LIC	Low-income country
LMIC	Low- and middle-income country
LTC	Long-term condition
MLTC	Multiple long-term condition
NCT	National Childbirth Trust
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICU	Neonatal intensive care unit
NIHR	National Institute for Health and Care Research
OECD	Organisation for economic cooperation and development

OR	Odds ratio
PPI	Patient and public involvement
PMTCT	Prevention of mother to child transmission
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSS	Personal social services
QALY	Quality-adjusted life year
RCT	Randomised controlled trial
RR	Relative risk
SROI	Social Return on Investment
UMIC	Upper and middle-income country
WHO	World Health Organization
WIC	Special supplemental nutrition program for women, infants and children
WTP	Willingness to pay

Plain English 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 wanted to. This is noticeable for women living in disadvantaged areas with 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 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 to usual care, but parents and providers saw the value in 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 within 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 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 two years. However, less 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, to co-create with stakeholders a framework to guide implementation and evaluation of cost-effective breastfeeding support interventions in the National Health Service (NHS).

1. Update the Cochrane review “Support for healthy breastfeeding mothers with healthy term babies”;
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;
5. Synthesise evidence of barriers to and facilitators of breastfeeding support for women with long-term conditions;
6. Conduct a systematic review of economic evaluations of breastfeeding support interventions;
7. Co-create an 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 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’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 are provided (e.g., vaccination, intrapartum care). 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 evidence of incremental costs and cost-effectiveness in comparison to a control. Eligibility criteria mirrored Review 1, with the addition of relevant economic outcomes, such as, incremental cost-effectiveness ratios. Quality assessment followed National Institute for Health 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 long-term conditions (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 long-term conditions. 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 that were designed for healthy women (Review 1) compared to those aimed at women with long-term conditions (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 long-term conditions probably have little or no effect on breastfeeding outcomes. In both reviews approximately half the studies were targeted at groups at higher risk of poor breastfeeding outcomes, and it is possible 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 suggestions from participants regarding potential strategies to improve breastfeeding support, with the most widely reported suggestion being the need to involve wider sources of support (e.g., partners, family, friends, peers, external professionals, web-based resources) in supporting women with long-term conditions 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 utilised 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 for 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 ten 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 (CFIR) 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 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 the intervention was unlikely to be cost-effective (£56,074.98 per quality adjusted life year (QALY) gained at 2022 Great British Pound (GBP) prices). There was evidence for the incremental cost per additional woman breastfeeding (any or exclusive) with incremental cost-effectiveness ratios (ICERs) ranging from £67-£112 from 2 weeks up to 8 weeks postpartum; and £2446-£4226 up to 6 months postpartum. Without willingness-to-pay thresholds, value for money is unclear. Evidence for breastfeeding plus support suggests they are 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 see changes in costing the intervention, which suggested costs were sensitive. Eight studies were deemed to have potentially to 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 infant pairs. The most common condition, with nine studies, was overweight and obesity. A further three studies were for women with gestational diabetes mellitus (GDM). Five studies included women with Human Immunodeficiency Virus (HIV). Two studies were for women with substance misuse problems, and one was for women with anxiety and depression. Interventions varied in terms of whether they provided breastfeeding support only or if they also provided support for the long-term condition.

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

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

Review 5

We included 24 studies. The health conditions covered were HIV, obesity and overweight, substance use, diabetes in pregnancy, women with disabilities and women with 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 long-term conditions; 2) variable or insufficient availability of breastfeeding support for mothers with long-term conditions; 3) experiences of breastfeeding support of mothers with long-term conditions suggested complex breastfeeding journeys; and 4) suggestions from participants regarding potential strategies to improve breastfeeding support.

Review 6

We included five economic evaluations. The conditions assessed were women living with HIV, obesity, prenatal opioid use, and women considered 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 are 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 groups discussions involving 23 participants from an area of high socio-economic disadvantage represented 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 multi-morbidities. They discussed adapting interventions identified in the main study to meet the needs of women with long-term conditions. 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, policymakers and academics. The output of the workshop was a toolkit to inform the implementation of 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, guidance on implementing new breastfeeding support services, planning the implementation strategy and evaluating the breastfeeding support service. 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 exclusive breastfeeding.

Conclusions

'Breastfeeding only' support can increase the duration and the exclusivity of breastfeeding in healthy women. For 'breastfeeding plus' and interventions for women with long-term conditions 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 long-term conditions 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 long-term conditions, stakeholder engagement suggested health services could integrate infant feeding specialists with the multi-disciplinary team to give infant-feeding 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 long-term conditions and multi-morbidities, particularly for mental health conditions, overweight/obesity and gestational diabetes,
2. Focus on understanding what components of breastfeeding support interventions make them effective including what components would be more effective in populations at risk of

- poorer breastfeeding outcomes (e.g., areas of high socio-economic 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

The reviews in this study are registered at PROSPERO: CRD42022337239; CRD42021229769; 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/>).

Funding

This project was funded by the National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Research programme and will be published in full in Health and Social Care Delivery Research; Vol. XX, No. XX. See the NIHR Journals Library website for further project information.

Chapter 1: Background

1.1 Importance of breastfeeding

Breastfeeding has significant impact on multiple health outcomes across the lifespan. In children, this includes fewer deaths and hospital admissions for infectious diseases¹⁻⁴ 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 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 to high-income countries (HICs) such as the UK. Globally, the scaling up of breastfeeding to near universal level could prevent 823,000 deaths in children under five years and 20,000 annual deaths 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 continued as part of a mixed diet until two years and beyond.^{15, 16}

Increased breastfeeding has potential to reduce health care 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 National Health Service (NHS) and environmental benefits. The cost to the global economy of not breastfeeding has been estimated at £242 billion and, in the UK, estimates were that £23.6 million 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 plastics and resources used by the dairy industry.^{20, 21} Therefore, there are significant health and societal and environmental gains to increasing breastfeeding duration and exclusivity.

1.2 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 is lacking. For England, the most recent data, reported by NHS Trusts (2020/21 data), were 72% initiation rate and 49% prevalence of breastfeeding at 6-8 weeks.²² The comparative figures for Wales (2016 data) were 60% initiation and 45% prevalence at 6-8 weeks²³ and for Scotland (2018/19 data) were 65% initiation and 43% prevalence at 6-8 weeks.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 socio-economically 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 to 28% in the most deprived quintile. The differences were starker by mother's age with breastfeeding prevalence at 6-8 weeks of 58% for mothers aged 40 years and 13% for mothers aged under 20 years.²⁴ In the UK, women from non-White ethnic groups had higher rates of breastfeeding initiation, prevalence and duration compared to White mothers, rates of exclusive breastfeeding after one 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 distress²⁶ 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 timepoints and for different years. Nevertheless, rates of breastfeeding in the UK are consistently reported to be lower than those of other European countries. For example, in 2015, a survey of European countries found breastfeeding initiation rates ranged from 80% in the Netherlands to 98% in Norway and breastfeeding prevalence at 2 months ranged from 64% in the Netherlands to 89% in

Norway (both outcomes were reported by six 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

1.3 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 support for breastfeeding 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 and the perception that they do not produce sufficient milk to meet their baby's needs,³⁴ embarrassment when 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 e.g., Bangladeshi women, include diverse cultural influences of their heritage and their areas of residence in the UK³⁷ and cultural stereotypes held by healthcare providers.³⁸ There is strong global evidence that for healthy women and babies, breastfeeding support is effective in increasing partial and exclusive breastfeeding.³⁹⁻⁴² However, these reviews combine evidence from high- middle- and low-income countries (HIC, LMIC), with most of the high-income country evidence coming from the USA. Interventions tested in trials are heterogeneous and generally under-theorised. 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.

1.4 Women with multi-morbidities

The prevalence of maternal chronic conditions is rising,⁴⁸ which is in part due to increasing maternal age and improved management of long-term conditions (LTCs).⁴⁹ For instance, UK data have shown that 2.3% of women have been diagnosed with diabetes either prior 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 method⁵⁴ and this increases the risk of development of type 2 diabetes 10-fold.⁵⁵

The prevalence of multiple long-term conditions (MLTCs) in the UK is also rising, particularly in working age adults.⁵⁶ Within a general adult population, the onset of MLTCs happens 10-15 years earlier in those living in the most deprived areas compared to more affluent areas.⁵⁷ The MuMPReDiCT study sought to identify the prevalence of multi-morbidity specifically during pregnancy and has reported that between 19.8% and 46.2% of pregnant women experience two or more LTCs.⁵⁸ LTCs were defined as conditions that had significant impact on patients and the specific 79 conditions included in the study were determined in consultation with stakeholders.⁵⁹ Unlike the general adult population, it is not currently clear if the prevalence of MLTCs is higher in women from areas of high socio-economic deprivation. The MuMPReDiCT study did not find higher odds of multi-morbidity in women from areas of high socio-economic deprivation or in any specific ethnic groups.

⁵⁸ Post-hoc analysis explored whether this was being impacted by the health conditions used to define multi-morbidity, 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 multi-morbidity after adjusting for maternal age and gravidity adjusted odds ratio (aOR) 1.30, 95% Confidence Interval (CI) 1.08, 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, 1.27). MLTCs were more common in maternal ages 45-49 years (aOR 1.8, 95% CI 1.0, 3.20) and this remained significant when adjusted for other characteristics.

Living with MLTC can have a significant impact on mental wellbeing and can make engaging in other activities difficult.⁶⁰ Within the context of maternal health, experiencing a long-term condition during pregnancy is associated with mental health conditions in the postpartum period such as posttraumatic stress.⁶¹ Mothers with long-term conditions 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 the single condition. However, there is a complete lack of evidence on MLTCs 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 MLTCs, as is evidenced in significantly lower breastfeeding rates in 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 compared to women without any conditions (25.6% vs 33.4%).⁶² However, rates of initiation were similar. Data from Canada found that while women with chronic diseases had similar odds of initiating breastfeeding, they were more likely to cease breastfeeding early compared to the general population (aOR 2.48, 95% CI 1.49-4.12).⁶⁸ Data from other countries also suggest that breastfeeding rates are lower in a range of specific conditions such as insulin dependent diabetes (aOR 0.49, 95% CI 0.27-0.89); epilepsy (aOR 0.42, 95% CI 0.26-0.68);⁶⁹ rheumatoid arthritis (any breastfeeding at 3 months in women with rheumatoid arthritis = 26% versus 46% of general population). There is currently a complete lack of evidence on breastfeeding rates in women with MLTCs.⁷⁰

There are several factors why women with LTCs may have additional difficulties breastfeeding, including a physiological delay to milk release 72 hours after birth, increased risk of early separation of the infant due to Caesarean section and/or requirement of neonatal intensive care unit (NICU) 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 being 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 be able provide effective support for all women, which is tailored to their individual needs.⁷¹

1.5 Economic impact

Breastfeeding in itself is considered a cost-effective intervention.^{17, 72} Increased breastfeeding has potential to reduce health care 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 US\$570 billion (£396 billion) each year, with estimates indicating that 0.75% of gross national income for high-income countries is lost from not breastfeeding.⁷³ With a gross national

income of £2, 505 billion in 2022,⁷⁴ this equated to a value of £18.8 billion to the UK economy. For the UK health system, estimates were that £23.6 million additional treatment costs each year could be saved by increased breastfeeding.¹⁷ This cost to the NHS was 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 800g tin specialised formula (Aptamil Pepti® 1 powder) prescribed for cow's milk allergy, which would feed a baby under 6-months for one 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 of carbon dioxide emissions equivalent to 50,000-77,500 cars on the road each year and a water footprint of 4,700 L/kg.^{20, 21} Therefore, there are significant health and societal and environmental gains to 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.

1.6 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 socio-economic status, those from marginalised groups, and those with multi-morbidities. 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

2.1 Aim and objectives

The aim was to synthesise global and UK evidence to co-create with stakeholders a framework to guide 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 (Chapter 3);
2. Conduct a theoretically-informed mixed methods synthesis of process evaluations of UK-relevant breastfeeding support interventions (Chapter 4);
3. Conduct an economic evaluation of interventions to enable women to breastfeed (Chapter 5);
4. Conduct a systematic review to identify effective interventions which provide breastfeeding support for women with long-term conditions (Chapter 6);
5. Conduct a mixed-methods synthesis of barriers and facilitators to breastfeeding support in women with long-term conditions (Chapter 7);
6. Conduct a systematic review of economic evaluations of breastfeeding support interventions for women with single long-term conditions (Chapter 8);
7. Co-create an NHS-tailored implementation and evaluation strategy framework to address contextual barriers and inform transferability of cost-effective interventions to increase breastfeeding rates for healthy women and those with long-term conditions in the UK (Chapter 9);
8. Contribute to methodological development on involving stakeholders in co-creation of systematic reviews and synthesising process evaluations to support transferability and applicability of global evidence to local health service contexts (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 multi-morbidities. The focus of objectives 4-6 is on single LTCs due to the lack of evidence relevant to multi-morbidities. 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 socio-economic groups. The work on multiple long-term conditions was an add-on. However, we were also interested in multi-morbidities 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.

2.2 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 study outputs were relevant to the NHS context. The main study included 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 two-years and the additional work over nine 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.

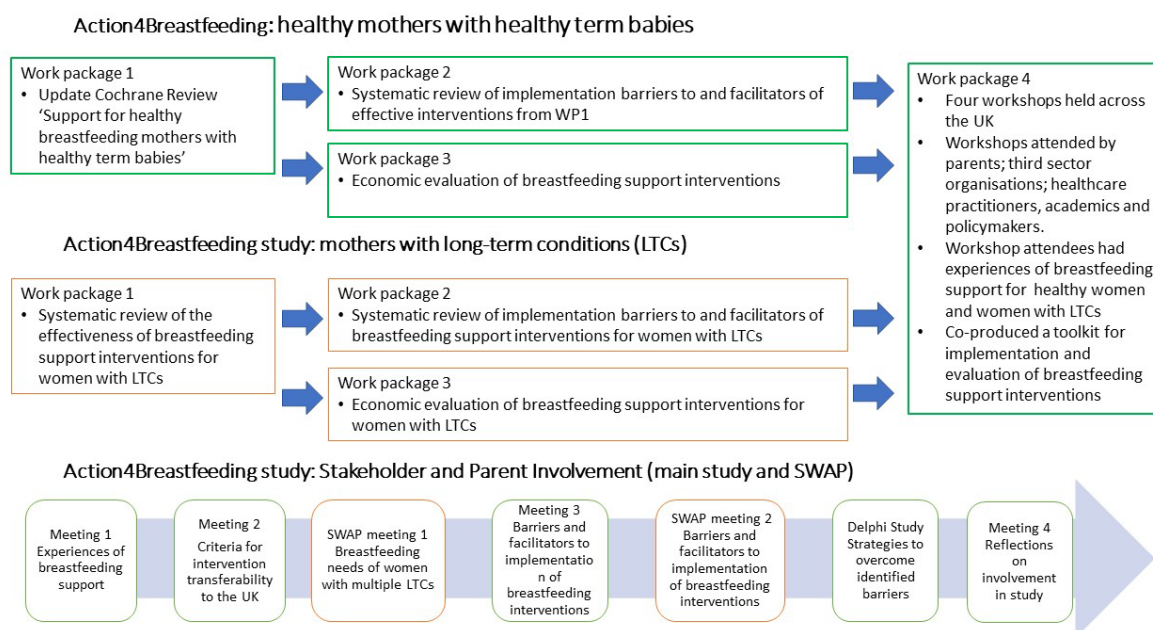


Figure 1. Study flow diagram

2.3 Ethics approval

The stakeholder engagement component of the study was approved by the University of Dundee School of Health Sciences research ethics committee (UOD-SHS-2021-010).

2.4 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: co-investigator (PB) from a breastfeeding support organisation represented service user views; the stakeholder working group, parents panel and focus group discussions ensured the experiences of breastfeeding women and service providers were involved 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.

2.4.1 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. 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 Northeast 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 recruiting parents who are 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 groups 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 that are least likely to breastfeed. The participants were recruited via a not-for profit organisation providing peer support (not specific to infant feeding) for parents living in economically-deprived, ethnically diverse populations in West Yorkshire. Fifteen women participated in the focus group discussions.

2.4.2 Activities and outcomes

The Stakeholder working group and parents panel each met four times as well as participating 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 timepoints 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. In between meetings, a newsletter was circulated to all members to update them on the progress of the study. In the fourth meetings, the stakeholder working group and parents panel reflected on their experiences of engaging with the study. Their views are included in *Chapter 10*.

2.5 Stakeholder and parent engagement (multiple long-term conditions)

2.5.1 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 HIV Association) and a wide range of healthcare professionals (consultant physician, consultant psychiatrist, GP, pharmacist, health visitor, specialist midwife, infant feeding coordinator and diabetes specialist nurse) involved with caring for women with MLTCs who may breastfeed. Stakeholder working group members were from England, Scotland and Wales and were selected due to 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 MLTCs parents panel comprised seven parents with MLTCs 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.

2.5.2 Activities and outcomes

The MLTCs stakeholder working group and parents panel met twice during the nine-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 focussed mainly on giving parents opportunities to tell their stories of breastfeeding alongside coping with multi-morbidities. The first meeting of the stakeholder working groups was focused on participants' experiences in providing breastfeeding support to women with MLTCs and the barriers and facilitators to providing support. In the second meeting, the stakeholder working group and parents panel discussed the same five

effective interventions as used in the main study, this time focussing on whether and how these interventions could be adapted to meet the needs of women with multi-morbidities. The findings from the MLTCs stakeholder engagement contributed to the workshop activities as described in *Chapter 9*.

2.6 Role of stakeholder engagement

The main purpose of the stakeholder working groups, the parents panel and the focus group discussion were to adapt the international evidence i.e., 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 timepoints and variables for the meta-regression for Review 1.

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 timepoints).
FGD 1 (8) 5 online 3 face-to-face	Topic guide covered personal experiences of breastfeeding support, 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 timepoints).
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 in to account when transferring interventions from another country to a UK setting.	Discussions of barriers and facilitators to 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 to findings from SWG, PP and workshops to illuminate considerations that might be needed when adapting for communities with low breastfeeding rates.

Key: SWG – Stakeholder working group; PP – parents panel; FGD – Focus group discussions; PIET-T- Population-Intervention-Environment-Transfer Model of Transferability

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

3.1 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, 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.

3.2 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:
 1. type of support (e.g., face-to-face, telephone, digital technologies, group or individual support, proactive or reactive);
 2. intensity of support (i.e., number of postnatal contacts);
 3. person delivering the intervention (e.g., healthcare professional, lay person);
 4. to examine whether the impact of support varied between high-, and low-, and middle-income countries.

3.3 Methods

3.3.1 Criteria for considering studies for this review

Inclusion criteria

Types of studies

All randomised or quasi-randomised controlled trials (RCT), with or without blinding were included. Cluster-randomised controlled trials 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 which is supplementary to the standard care offered in that setting. Interventions could be delivered as either 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 phone.

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 random allocation of participants was excluded (non-randomised controlled trials; quasi-experimental studies; one group before-and-after studies; cohort studies; case control studies; case reports; or qualitative studies).

Types of participants

Studies which focused specifically on women or infants with additional care needs were excluded. For mothers this could mean co-existing 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 to extract data. If they did not provide sufficient information, they were recorded as on-going studies.

3.3.2 Search methods for identification of studies

The Cochrane Pregnancy and Childbirth's Trials Register was searched by their information specialist in May 2021. This includes results of searches of CENTRAL, MEDLINE, Embase, CINAHL, ClinicalTrials.gov, 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 which met the new inclusion criteria.⁴¹

3.3.3 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 Evaluations (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 (SD)) 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 e.g., 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 being 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 in ‘awaiting classification’.

3.3.4 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 there was a sufficient number of studies included in the analyses (i.e., at least ten 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 versus lay person, or both).
2. By mode of support (face-to-face versus telephone support versus digital versus combination).
3. By intensity of support (low (<four) versus moderate (four to eight) versus high (nine or more)).
4. By income status of country (high-income country versus low and middle-income country).

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.

3.4 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, eight studies that were on-going in the last version of the review and six previously excluded studies that were re-assessed due to the change in inclusion criteria. Of these, 72 meet 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 studies, and for the new studies identified in this update, we required clarification for 43 studies. In total, we received satisfactory responses for 27 studies. In total 54 studies were re-classified 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 have been excluded with reasons (this includes 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 only focused on education and/or promotion and did not offer any support; interventions which

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 on the basis of not focusing on healthy mothers (e.g., co-existing 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 excluded studies.

3.4.1 Description of included studies

This updated review includes 116 trials of which 103 contribute data to the analyses. The 116 studies include 83 individually randomised trials and 33 cluster-randomised trials. Most are two-arm randomised control trials; however, 20 studies are either three- or four- arm randomised control trials. 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.

3.4.1.1 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 high-income countries (HICs), six in upper middle-income countries (UMICs), 16 in lower middle-income countries (LMICs), and five 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 within their country. Most of these were conducted in HICs (n=33). This included women defined as low-income or living in a disadvantaged area (n=18); women with non-white ethnic background (n=9); and young mothers (n=6).

3.4.1.2 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 multi-component 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 six 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 peer supporters), 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); high intensity (nine or more contacts). Twenty-one interventions

were specified as low intensity, 41 as moderate intensity, and 44 interventions were specified as high intensity. The remaining 19 did not specify the intensity of the intervention.

In 97 studies, the control groups were described to receive 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 either against an active control arm or a control group which 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.

3.4.2 Risk of bias assessments

We considered 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*.

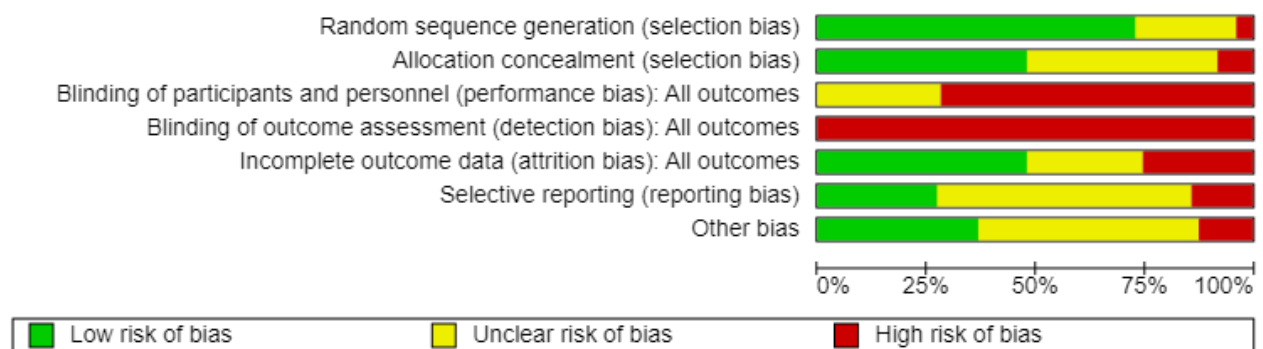


Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

(Gavine A, Shinwell SC, Buchanan P, Farre A, Wade A, Lynn F, Marshall J, Cumming SE, Dare S, McFadden A. Support for healthy breastfeeding mothers with healthy term babies. Cochrane Database of Systematic Reviews 2022, Issue 10. Art. No.: CD001141. DOI: 10.1002/14651858.CD001141.pub6. Accessed 14 February 2023).⁸³

3.4.3 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 please 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% 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). Sensitivity analyses excluding studies at high or unclear risk of bias for allocation concealment and incomplete outcome reporting found similar or more beneficial treatment effects.

Table 2. Summary of findings - breastfeeding support only compared to usual care

(Gavine A, Shinwell SC, Buchanan P, Farre A, Wade A, Lynn F, Marshall J, Cumming SE, Dare S, McFadden A. Support for healthy breastfeeding mothers with healthy term babies. Cochrane Database of Systematic Reviews 2022, Issue 10. Art. No.: CD001141. DOI: 10.1002/14651858.CD001141.pub6. Accessed 14 February 2023).⁸³

Outcomes	Anticipated absolute effects ^a (95% CI)		Relative effect (95% CI)	No 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)	14610 (30 RCTs)	⊕⊕⊕○ Moderate ^a
Stopping exclusive breastfeeding at 6 months	847 per 1000	763 per 1000 (746 to 788)	RR 0.90 (0.88 to 0.93)	16332 (40 RCTs)	⊕⊕⊕○ Moderate ^a
Stopping breastfeeding (any) at 4-6 weeks	308 per 1000	271 per 1000 (244 to 299)	RR 0.88 (0.79 to 0.97)	11413 (36 RCTs)	⊕⊕⊕○ Moderate ^a
Stopping exclusive breastfeeding at 4-6 weeks	518 per 1000	430 per 1000 (394 to 466)	RR 0.83 (0.76 to 0.90)	14544 (42 RCTs)	⊕⊕⊕○ Moderate ^a

Explanations

^aWe downgraded 1 level for serious concerns about inconsistency. Evidence of substantial unexplained heterogeneity.

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 may be 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 in low- and middle-income countries (LMICs) stopping exclusive breastfeeding at 6 months compared to women in high-income countries (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.

Table 3. Summary of findings - breastfeeding plus compared to usual care

(Gavine A, Shinwell SC, Buchanan P, Farre A, Wade A, Lynn F, Marshall J, Cumming SE, Dare S, McFadden A. Support for healthy breastfeeding mothers with healthy term babies. Cochrane Database of Systematic Reviews 2022, Issue 10. Art. No.: CD001141. DOI: 10.1002/14651858.CD001141.pub6. Accessed 14 February 2023).⁸³

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No 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 ^a
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 ^{a,b}
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 ^c
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 ^{b,d}

Explanations

^aWe downgraded 1 level for serious concerns on risk of bias. Studies at risk of selection bias due to unclear allocation concealment.

^bWe downgraded 1 level for serious concerns regarding inconsistency. Evidence of substantial unexplained heterogeneity.

^cWe downgraded 1 level for serious concerns in 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.

^dWe downgraded 2 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 which could not be adjusted for clustering changed the effect estimate to non-significant.

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, 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, 1.11) or 12 months (RR 0.87, 95% CI 0.90, 1.00).

'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, 1.03, *very low-certainty evidence*); any at 3-4 months (RR 0.97, 95% CI 0.81, 1.15, *low-certainty evidence*); exclusive at 3-4 months (RR 0.86, 95%

CI 0.75, 1.00, *low-certainty evidence*); or any at 12 months (RR 0.96, 95% CI 0.91, 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.

3.5 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 in particular, 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 compared to 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, phone, 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

4.1 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 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.

4.2 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.

4.3 Methods

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

4.3.1 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 (*Chapter 3*), included articles authors, as well forward and backward citation checking.

4.3.2 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 policymakers.

Qualitative and quantitative studies, either standalone or in mixed methods designs, were included. Studies reporting 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 based 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 which focused specifically on women or infants with additional care needs were excluded. For mothers this could mean co-existing 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 in nature.

4.3.3 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.

4.3.4 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 involvement of a third reviewer where necessary. See *Appendix 2, Table 14*.

4.3.5 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 methods⁹⁰ 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 synthesis⁹¹ 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 synthesis⁹¹ 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 which characterises contextual determinants of implementation and can be used to inform implementation theory development and verification of what works where and why across multiple contexts.

4.4 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 due to the studies not being linked to an intervention identified as effective in Review 1 (n=84), followed by standalone studies which 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, as well as 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 ten RCTs of effective interventions from Review 1.

4.4.1 Summary of included studies

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

Twelve studies contributed qualitative data to the synthesis, including eight qualitative⁹³⁻¹⁰⁰ and four mixed-methods¹⁰¹⁻¹⁰⁴ process evaluation studies; and eight studies contributed quantitative data to the final synthesis, including four quantitative¹⁰⁵⁻¹⁰⁸ 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). The studies from Uganda and South Africa were all 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 living in areas with low breastfeeding rates.

Study samples ranged from 26 – 130 mothers, 12 - 254 peer counsellors, 13 - 28 healthcare staff, and 2-409 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*).

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*.

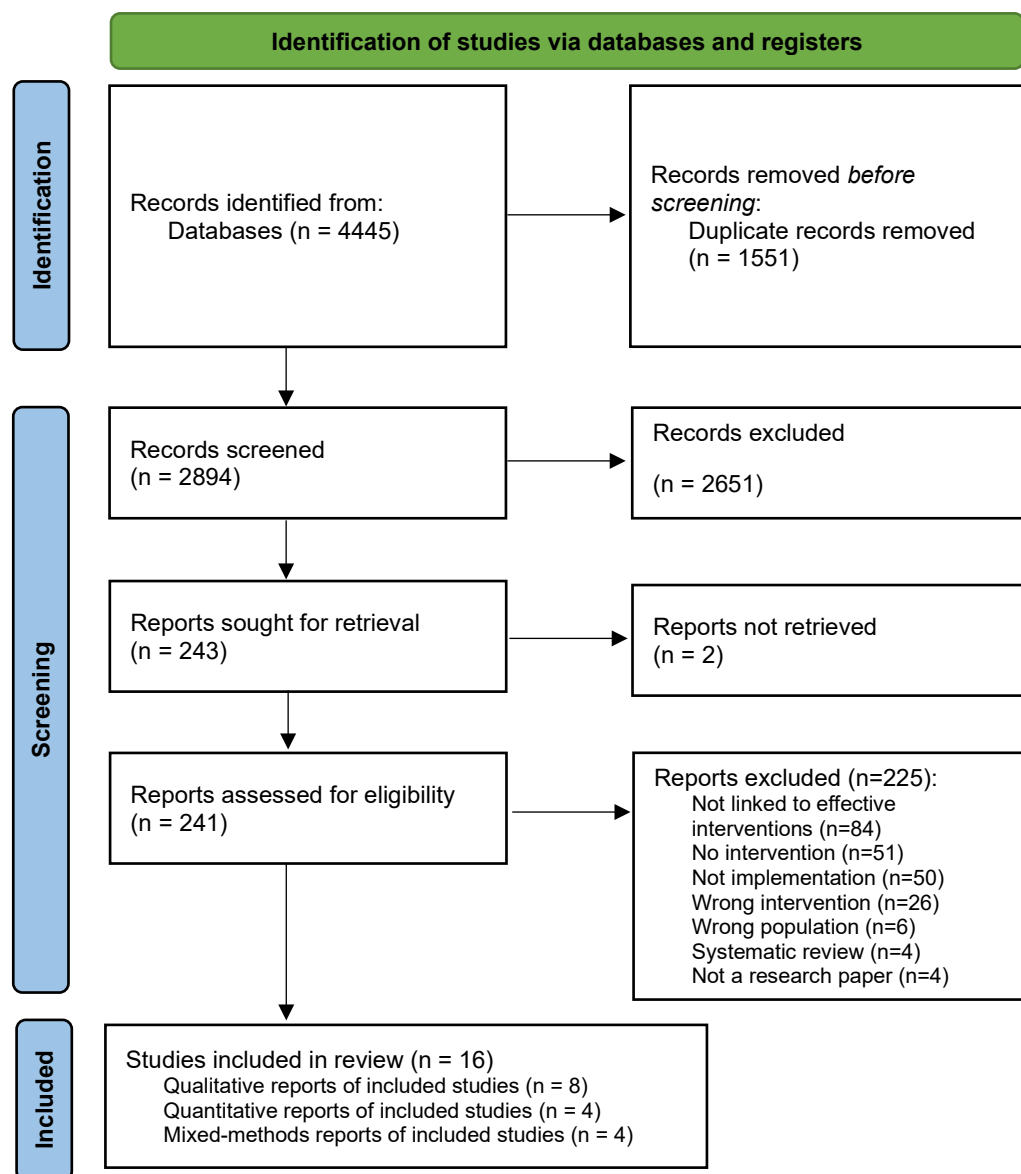


Figure 3. PRISMA Flow Diagram

4.4.2 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 was 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 to have low usefulness.^{94, 95}

4.4.3 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 is 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/facilitators to meet 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 framework. 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* illustrates the distribution of primary studies underpinning each analytical theme and their mapping against the relevant CFIR subdomains.

Table 4. Included studies mapped against relevant sub-domains of the Consolidated Framework for Implementation Research

Included studies (n=16)	Implementation Process (Consolidated Framework for Implementation Research) mapped sub-domains						
	5B – Assessing Needs		5C. Assessing Context	5E – Tailoring Strategies	5F – Engaging	5H – Reflecting & Evaluating	
	1 – Innovation deliverers	2 – Innovation recipients				1 – Implementation	2 – Innovation
	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 2010a ¹⁰⁴	●				●	●	
Nkonki 2010 ⁹⁷	●					●	
Rahman 2011 ⁹⁸	●		●			●	
Ridgway 2016 ¹⁰⁸				●			●
Rujumba 2020 ⁹⁹		●				●	
Teich 2014 ¹⁰⁰				●			

1 Assessing the needs of those delivering and receiving breastfeeding support interventions

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

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

10 One key strategy reported to both identify and address the needs of breastfeeding support providers
11 was through training.^{94-96, 98, 103, 105, 107} Studies largely reported that intervention deliverers felt
12 training prepared them well, both in terms of counselling skills and in terms of technical competence
13 (e.g., being able to show how to breastfeed correctly). All of which was perceived as key to ensure
14 consistency in intervention delivery.

15 Other issues that could be addressed through training were to do with the practical expectations of
16 undertaking the breastfeeding supporter role. Uncertainties about safety, transport and
17 reimbursement whilst delivering support, were among the most reported needs for those delivering
18 community-based interventions^{94, 95} as well as around more complex issues, such as managing
19 difficult scenarios or the interplay of cultural beliefs and breastfeeding practice. The latter was
20 particularly relevant to lay breastfeeding supporters delivering interventions at community level.
21 They noted the importance of acknowledging that trainees themselves belong to a range of
22 communities which might be systematically exposed to certain issues/inequities more than others
23 (e.g., rural isolation, HIV prevalence in the community) and/or might hold cultural beliefs about
24 breastfeeding or breastfeeding-related practices which could act as barriers. These should be
25 identified and addressed in a culturally sensitive manner and without antagonising the communities,
26 enabling lay providers to appropriately and inclusively support breastfeeding women from a range of
27 communities.^{94, 95, 97}

28 Those in implementation leadership roles also emphasised the importance of effective management
29 and supervision. This was reported as a key facilitator for some interventions,^{94, 97} particularly to
30 ensure that certain needs of intervention deliverers will continue to be addressed beyond the
31 provision of formal training. For example, for those engaged in interventions relying on peer, lay
32 and/or volunteer supporters, there was an important need to provide them with ongoing emotional
33 support, including mentoring and motivation.

34 Overall, the breastfeeding supporters felt their role was important, satisfying and rewarding¹⁵ with
35 implications that were perceived to go beyond the specific breastfeeding support encounters to act
36 as triggers of the wider support network of the breastfeeding women.^{95, 96}

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

39 Breastfeeding women perceived the provision of support as positive, important and needed.^{99, 107}
40 Key to this was being offered the opportunity to ask questions and being allowed to spend enough
41 time to address any issues.^{103, 104} Also important was accessing support flexibly as needed, rather
42 than having to fit support around fixed working hours or at times which 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 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 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 with 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 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 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 wider community;¹⁰² and helpful to improve breastfeeding knowledge,⁹³ to ensure early establishing of breastfeeding,⁹³ and to enable 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 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 included: 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 rather than a replacement for face-to-face support.^{101, 103}

4.5 Chapter summary

This review included 16 studies linked to ten 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 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, or usefulness.

Chapter 5: Health economic evaluation

5.1 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 health care 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.

5.2 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 to 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.

5.3 Methods

5.3.1 Eligibility criteria

Guidance on searching for economic evidence and conducting reviews of economic evidence were 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 that 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 who were 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 it 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 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 was considered 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 within the economic evaluation. These included, but were not limited to, health-related quality of life and health care 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). Lastly, types of studies included were full economic evaluations (cost-effectiveness, cost-benefit and cost-utility analyses), in addition to partial economic evaluations (cost-consequence 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.

5.3.2 Search strategy

A search strategy was developed encompassing three domains: (i) breastfeeding, (ii) support, and (iii) 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', 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, HMIC via Ovid, 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, NHS Economic Evaluation database (NHS EED), Paediatric Economic Database Evaluation (PEDE), IDEAS economics database via RePEc, 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, e.g., 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 02 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.

5.3.3 Selection process

Returned records from database searches were transferred into the reference management software EndNote Version 20.3 and duplicate records were removed. All unfilled references were then transferred into Covidence to screen 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 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

5.3.4 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,¹¹¹ which is separated into two sections. Section 1 assesses 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 checklist¹¹⁴ 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 developing National Institute for Health and Care Excellence (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 was dependent 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.

5.3.5 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 incremental cost-effectiveness ratios. 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 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 that 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 Queen’s University Belfast Research Portal (<https://pure.qub.ac.uk/>).

5.4 Results

5.4.1 Study selection

Following engagement with stakeholders, as reported in *Chapter 2*, agreement was made 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 available, 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 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 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 were 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 are awaiting classification with no response from corresponding authors. Of the 199 records screened for eligibility, 162 were excluded. The main reason for exclusion was the wrong study 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.

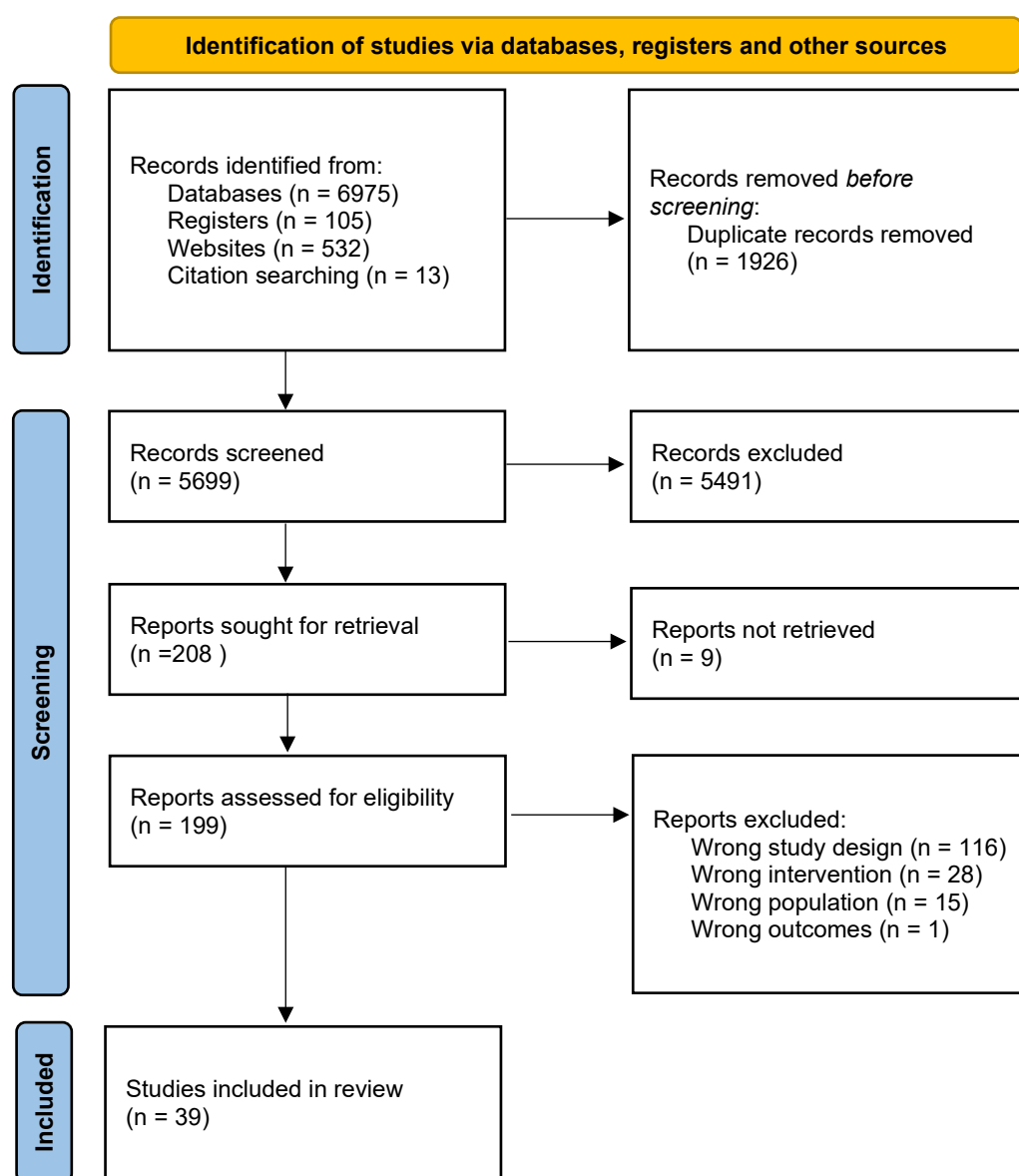


Figure 4. PRISMA Flow Diagram for Review of Economic Evidence for Breastfeeding Support Interventions for Healthy Mothers with Healthy Babies

5.4.2 Study characteristics

Of the 39 studies, seven were conducted in a UK-setting,¹¹⁶⁻¹²² 14 were conducted in OECD settings with seven in the USA,¹²³⁻¹²⁹ five across Australia and/or New Zealand,¹³⁰⁻¹³⁴ and one each in Canada,¹³⁵ and Ireland.¹³⁶ The remaining 18 studies were conducted in non-OECD settings with ten conducted in sub-Saharan Africa,¹³⁷⁻¹⁴⁶ three in Asia/South East Asia,¹⁴⁷⁻¹⁴⁹ three in Latin America,¹⁵⁰⁻¹⁵² and two across multiple countries with high adult and child mortality or undernutrition.^{153, 154}

Studies that assessed 'breastfeeding only' support interventions (n=21) were shorter in duration lasting from a minimum 7 days¹³⁵ to a maximum 10 weeks postpartum¹³⁸ and were delivered by professionals,^{117, 121, 135, 136, 149, 150, 152} lay providers,^{120, 126, 138, 139, 144, 147, 154} or both.^{118, 119, 123, 125, 128, 137}

'Breastfeeding plus' support interventions were assessed in 18 of the 39 evaluations, with primary aims of obesity prevention,¹³⁰⁻¹³³ improving nutrition,^{140, 141, 153} and maternal and infant care and/or

support.^{116, 120, 122, 127, 143, 145, 146} Four studies conducted economic evaluations related to Baby Friendly Hospital Initiative (BFHI) accreditation or Ten Steps to Successful Breastfeeding.^{124, 134, 148, 151} The duration of 'breastfeeding plus' interventions ranged from a short time frame with hospitalisation for labour and delivery^{124, 143} to a longer time frame from pregnancy to infant age 2 years.^{145, 155}

There were a range of methods used for the economic evaluations. Sixteen studies were partial economic evaluations with a cost analysis comparing two or more alternatives^{117, 120, 122, 124-126, 128, 130, 135} or a cost/cost-outcome description with one alternative.^{121, 123, 139, 141, 144, 146, 147} Full economic evaluations were reported in the remaining 23 studies, with nine studies reporting a cost-effectiveness analysis (CEA),^{118, 131, 133, 137, 142, 145, 149, 151-153} six studies reporting a cost-benefit analysis (CBA), five studies a CEA and cost-utility analysis (CUA)^{127, 129, 134, 136, 140, 148} and two studies a CUA alone.^{119, 154} Eighteen of the studies were trial-based economic evaluations, with thirteen of these aligned with RCTs^{116-118, 125, 128, 130-132, 135, 138, 140, 144, 156} reported in the Cochrane Review.

5.4.3 Applicability

At this stage of the review process, studies conducted in OECD settings at the time of being conducted progressed to quality assessment. An evidence table of 21 economic evaluations identified for inclusion that were conducted 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 on 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, either providing 'breastfeeding only' support^{117-119, 121, 123, 125, 126, 128, 129, 135, 136} or breastfeeding plus support.^{116, 120, 122, 124, 127, 130-134}

Twelve studies were judged not applicable. The use of a payer perspective taken for the costing of the intervention and/or health care resource use in an organisational setting was considered too diverse from a UK provider perspective in six of the studies.^{123-127, 129} In addition, studies that only provided costs for one alternative or a cost comparison were deemed not applicable.^{117, 121-123, 125, 129, 130, 134, 136} 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, they 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 one year. The remaining studies were judged to be partially applicable. Either the setting and system where the study was conducted was not the UK^{128, 132, 133, 135, 155} or the limited time horizon and/or scope for the economic evaluation indicated that not all relevant costs and outcomes were accounted for.^{118, 128, 135, 156}

5.4.4 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, 128, 135} and breastfeeding plus support.^{116, 132, 133, 155, 156} Base case

1 results for incremental costs, incremental effects and incremental cost-effectiveness are provided.
2 Costs have been converted and uplifted to 2022 GBP £ for ease of comparison. Two of the
3 'breastfeeding only' support studies^{128, 135} provided healthcare costs and outcomes of effect on
4 breastfeeding separately and did not evaluate in terms of incremental costs per additional woman
5 breastfeeding. For illustrative purposes, we estimated ICERs from the events data on breastfeeding
6 (any and exclusive) for these studies.

7 The evidence of cost-effectiveness for breastfeeding only interventions in terms of incremental cost
8 per QALY gained comes from one well-conducted model-based CUA by Mavranezouli and
9 colleagues.¹¹⁹ At a UK willingness to pay (WTP) threshold of £20,000-30,000 per QALY gained, the
10 modelled intervention (+ standard care) was not considered cost-effective in comparison to standard
11 care alone. Three evaluations^{118, 128, 135 118, 128, 135} have estimates of the cost per additional woman
12 exclusively breastfeeding, which ranged from £67 at 5-12 days, £112 at 8 weeks, and £2446 at 6
13 months postpartum. For the cost per additional woman breastfeeding (any), ICERs ranged from £108
14 at 8 weeks and £4226 at 6 months postpartum, the latter due in large part to a lower effect.
15 However, without understanding of the threshold for health providers' WTP for an additional
16 woman breastfeeding, exclusively or any, it is unclear whether breastfeeding only support is cost-
17 effective.

18 The evidence of cost-effectiveness for breastfeeding plus interventions in terms of incremental cost
19 per QALY gained comes from two evaluations: one trial-based without extrapolation beyond study
20 timeframe of infant age one year¹¹⁶ and a second trial- and model-based CUA up to child aged 15
21 years.¹³² At a UK WTP threshold of £20,000-30,000 per QALY gained, both interventions (+ standard
22 care) were not considered cost-effective in comparison to standard care alone. The evidence of cost-
23 effectiveness for breastfeeding plus interventions in terms of incremental cost per QALY gained
24 comes from two evaluations: one trial-based without extrapolation beyond study timeframe of
25 infant age 1 year¹¹⁶ and a second trial- and model-based CUA up to child aged 15 years.¹³² At a UK
26 WTP threshold of £20,000-30,000 per QALY gained, both interventions (+ standard care) were not
27 considered cost-effective in comparison to standard care alone. Three evaluations^{118, 128, 135} have
28 estimates of the cost per additional woman exclusively breastfeeding, which ranged from £67 at 5-
29 12 days, £112 at 8 weeks, and £2446 at 6 months postpartum. None of the studies assessing
30 breastfeeding plus interventions estimated the incremental cost per additional woman
31 breastfeeding. Additional ICERs related to cost per unit BMI averted for interventions that had a
32 broad aim of obesity prevention in children. One study¹⁵⁵ provided an Australian WTP threshold of
33 \$500 (equivalent to GBP £236 at 2012 prices) suggesting that these interventions are cost-effective.

34

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 (£) ¹	Effect	ICER (£/effect) ¹	
Hoddinott <i>et al.</i>, 2012¹¹⁸	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	0.23	107.52 per additional woman breastfeeding	Measures of uncertainty not reported. Alternative intervention costing scenarios suggest costs would be sensitive to varying staff requirements and period of coverage.
			24.87	0.22	112.47 per additional woman exclusively breastfeeding	
Mavranzouli <i>et al.</i>, 2022¹¹⁹	Directly applicable UK setting, provider perspective, cost per QALY gained reported, time horizon from birth up to 1yr 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 <i>et al.</i>, 2002¹²⁸	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	0.136	2446.22 per additional woman exclusively breastfeeding at 6 months ²	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.
			332.06	0.08	4226.21 per additional woman breastfeeding (any) at 6 months ²	

Stevens <i>et al.</i>, 2006¹³⁵	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 ²	Incremental costs were not statistically significant. ICER estimated herein without addressing uncertainty.
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¹ Costs converted and uplifted to 2022 GBP £; ² ICER estimated using trial-based events data

5.4.5 Appraisal of limitations and uncertainty in the results

Methodological limitations were judged as minor,¹¹⁹ potentially serious^{116, 131-133, 156} or very serious.^{118,128} The latter 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 within the analysis, such as costs of hospitalisations for infant morbidity, which would likely change the conclusions about cost-effectiveness. The timeframes were short and reflect the duration of the intervention and the time horizon for the economic evaluation. Mavrnezouli *et al.*,¹¹⁹ was the only 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; while 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, 131, 133, 156} Tan *et al.*,¹³² 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 health care 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, 133} The remaining studies either did not handle uncertainty^{132, 135} or made allowance for methodological uncertainty with scenario analyses from the base case.^{118, 128, 131, 156} These analyses suggested 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.

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			Uncertainty
			Cost (£) ¹	Effect	ICER (£/effect) ¹	
Barnes <i>et al.</i>, 2017¹¹⁶	Directly applicable UK setting, provider perspective, cost per QALY gained reported, time horizon from pregnancy up to infant aged 1 yr.	Potentially serious limitations Data not extrapolated beyond study context; broader outcomes not considered which likely would affect cost-effectiveness estimates.	2377.38 (-967.25, 5723.16)	-0.01 (-0.05, 0.03)	-283,960.75 per QALY gained	The value of the ICERs held with the sensitivity analysis. The probability of group Family Nurse Partnership (FNP) + usual care being more cost-effective than usual care alone at a willingness-to-pay threshold of £20,000 per QALY gained ranged from 0 to 3%.
Hayes <i>et al.</i>, 2014¹³¹	Partially applicable OECD setting, provider perspective, cost per unit BMI avoided reported, within-trial time horizon from birth to infant age 2 yrs.	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, 1189.91) 825.95 (487.34, 1189.91)	0.33 (-0.043, 0.662) 0.23 (0.026, 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 willingness-to-pay threshold of \$500 per 0.1 BMI z-score reduction was 66%, compared to the base case 30%.
Morrell <i>et al.</i>, 2002¹⁵⁶	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, 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 <i>et al.</i>, 2020¹³²	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 e.g., mother's health-related quality-of-life; health care 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, 330.65) 297.17 (265.78, 330.65) 314.43 (305.02, 324.90)	0.006 (-0.007, 0.017) -0.11 (-0.38, 0.16) -0.09 (-0.28, 0.11)	49,528.15 per QALY gained (age 15 yrs) 2701.72 per BMI avoided (age 15 yrs) 3493.81 per BMI avoided (age 5 yrs)	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 health care costs.
Wen <i>et al.</i>, 2017¹³³	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	Telephone 266.81 (207.28, 339.60) SMS 90.37 (53.12, 134.34)	Telephone -0.05 (-0.35, 0.23) SMS -0.03 (-0.03, 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

		breastfeeding outcomes, nor longer-term costs and outcomes.				<p>SMS support remained more favourable than for telephone support when compared to usual care alone.</p> <p>Unclear whether either intervention is cost-effective without understanding of the threshold for health providers' WTP for the prevention of BMI gain.</p>
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¹Costs converted and uplifted to 2022 GBP £; ² ICER estimated using events data

5.4.5.6 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 only support evaluation estimated the cost per QALY, which indicated an intervention that was unlikely to be cost-effective when compared to 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 2017 reported a negative ICER, as the intervention was more costly and less effective than the control; while Tan *et al.*,¹³² 2020 reported a positive ICER that exceeded the threshold value, similar to findings by Mavranezouli *et al.*,¹¹⁹ 2022. 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) up to 6 months against obesity is recognised;¹⁵⁷ hence the support for breastfeeding in these broader interventions.^{132, 133, 155} There was less consistency between studies assessing breastfeeding plus interventions.

5.5 Chapter summary

Thirty-nine studies were identified that conducted a partial or full economic evaluation of a breastfeeding support intervention for healthy women compared to 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 interventions were cost-effective. One model-based CUA 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 not to be value for money.

We judged there was uncertainty in the findings of cost-effectiveness due to the limited number of studies and 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 only costed the intervention and did not record health service resource use of the mother or infant. These limitations suggest uncertainty in the findings. In terms of consistency between studies, for the studies evaluating breastfeeding only support in terms of cost per additional woman breastfeeding (any or exclusive) there appeared to be consistency. 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 it difficult to compare.

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

6.1 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 which looked at the effectiveness of breastfeeding support for women with LTCs.

6.2 Aim and objectives

The aim of this systematic review was to identify the effectiveness of breastfeeding support interventions in women with long-term conditions.

The objectives were to:

1. Identify breastfeeding support interventions which have been designed for women with long-term conditions.

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 long-term conditions.

6.3 Methods

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

6.3.1 Eligibility criteria

Inclusion criteria

Types of studies

We included individually and cluster RCTs.

We excluded the following types of study designs: non-randomised controlled trials; 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 are from the following groups: pregnant women; mothers who may initiate breastfeeding; 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 GDM as this group has a ten-fold increased risk in the development of 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.^{158, 159}

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

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

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

Intervention

To be eligible for inclusion, breastfeeding support interventions had to be **two-way** between the supporter and 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, phone, 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 stop any breastfeeding at 3-4 months
2. Number of women 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 NICU 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-randomised controlled trials; quasi-experimental studies; one group before-and-after studies; cohort studies; case control studies; case reports; and qualitative studies.

Participants

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

6.3.2 Searches

Electronic databases

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

- Breastfeeding terms;
- Support terms;
- Long-term condition terms based on the list developed as part of the MuM-PreDiCT study;⁵⁹
- Randomised controlled trial 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.

6.3.3 Study selection

We imported all records identified via electronic databases into Covidence which is a web-based collaboration software platform that streamlines the production of systematic and other literature reviews.⁸⁴ The title and abstract of each record was 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 reported in a PRISMA flow chart (see *Figure 5*).

6.3.4 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, socio-economic status, details on condition, delivery method).
- Intervention – details of person providing support, delivery method (e.g., face-to-face, phone, digital), number of contacts, timing of support (e.g., antenatal, postnatal), description of intervention, theoretical basis.

AG extracted study outcome data into an excel spreadsheet and it was 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 this 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.

6.3.5 Risk of bias assessment

We assessed risk of bias using the Cochrane Risk of Bias Tool 1 in Covidence.¹⁶⁰ Two review members conducted this independently (AG, AMcF, FXV, PB, SC, SS) and conflicts were addressed by AG.

6.3.6 Measures of treatment effect

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

6.3.7 Unit of analysis issues

Cluster-randomised trials

Sample sizes were adjusted using the methods described in the Cochrane Handbook, incorporating an estimate of the intra-cluster correlation coefficient derived from the trial.⁸⁷ For one study there was insufficient data to calculate this adjustment, so we conducted sensitivity analyses to investigate the impact of including this study.¹⁶¹

Trials with multiple arms

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

6.3.8 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.

6.3.9 Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the Tau², I² and Chi² statistics. We regarded heterogeneity as substantial if the I² was greater than 30% and either the Tau² was greater than zero, or there was a low P value (less than 0.10) in the Chi² 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).

6.3.10 Assessment of reporting biases

For all outcomes where there were at least ten 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.¹⁶² If there was funnel plot asymmetry in the presence of high levels of heterogeneity, we compared the findings of our random-effects model with a fixed-effect model.¹⁶³ If the random-effects model showed a more beneficial effect, we considered this as being suggestive as the intervention was 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.

6.3.11 Data synthesis

Statistical analysis of the main outcomes was performed using Review Manager 5.4.¹⁶⁴ 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 group. 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, with 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.¹⁶⁵ We explored the impact of this further via sensitivity analysis (see below). Secondly, there is multi-morbidity between the conditions. For instance, antenatal depression has been reported to be associated with obesity,¹⁶⁶ and obesity is a risk factor for GDM.¹⁶⁷ Finally, the prevalence of some of the LTCs is higher in areas of high socioeconomic deprivation,⁵⁸ which may make the external factors influencing breastfeeding rates in the studies more similar.

The results were presented as the average treatment effect with 95% confidence intervals, and the estimates of Tau² and I².

6.3.12 Subgroup analysis and investigation of heterogeneity

Due to the small numbers of studies for each outcome, we considered that sub-group analysis or meta-regression would not be meaningful. However, *post-hoc* we considered that the studies with women with HIV were considerably different to 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.¹⁶⁵ We therefore conducted a sensitivity analysis to assess whether the studies with women with HIV have not biased the overall findings.

6.3.13 Sensitivity analysis

In addition to the sensitivity analysis which separated studies with women with HIV and women with non-communicable diseases, we performed sensitivity analyses based on risk of bias. We first

removed studies at high or unclear risk of bias for allocation concealment. We then removed studies 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 that we could not calculate a design effect for, we also conducted a sensitivity analysis to assess the impact of these studies on our findings.

6.3.13 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 (*Effects of Interventions*).

6.4 Results

6.4.1 Description of studies

6.4.1.1 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) = 45; not women with LTCs = 27; ongoing study = 16; wrong study design = 14; wrong comparator = 3; and intervention specifically targeted at infants in neonatal units = 2 (see Figure 5). We searched Medline and Google for study results for any ongoing studies identified in our database search that we could not link to study within 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 just referred to the main paper for each study within the text. We have included additional references in the table of characteristics (Appendix 4, Table 17).

6.4.1.2 Included studies

Of the 22 studies included, 20 contributed data to the review. Four studies did not contribute data. First, Martin *et al.*,¹⁷¹ did not report breastfeeding rates by intervention group. Secondly, Fan *et al.*,¹⁶⁸ did not provide the number of women with each condition randomised to each group. Thirdly, Ijumba *et al.*,¹⁶⁹ did not provide the raw data in a way that could be used in a meta-analysis. Finally, Lewkowicz *et al.*,¹⁷⁰ did not measure any of the breastfeeding outcomes included in the meta-analyses. Thus at least 5048 mother-infant pairs were included in the meta-analysis. Three studies only provided partial outcome data as only some of the relevant outcomes were reported in a way that could be used in a meta-analysis.¹⁷¹⁻¹⁷³

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

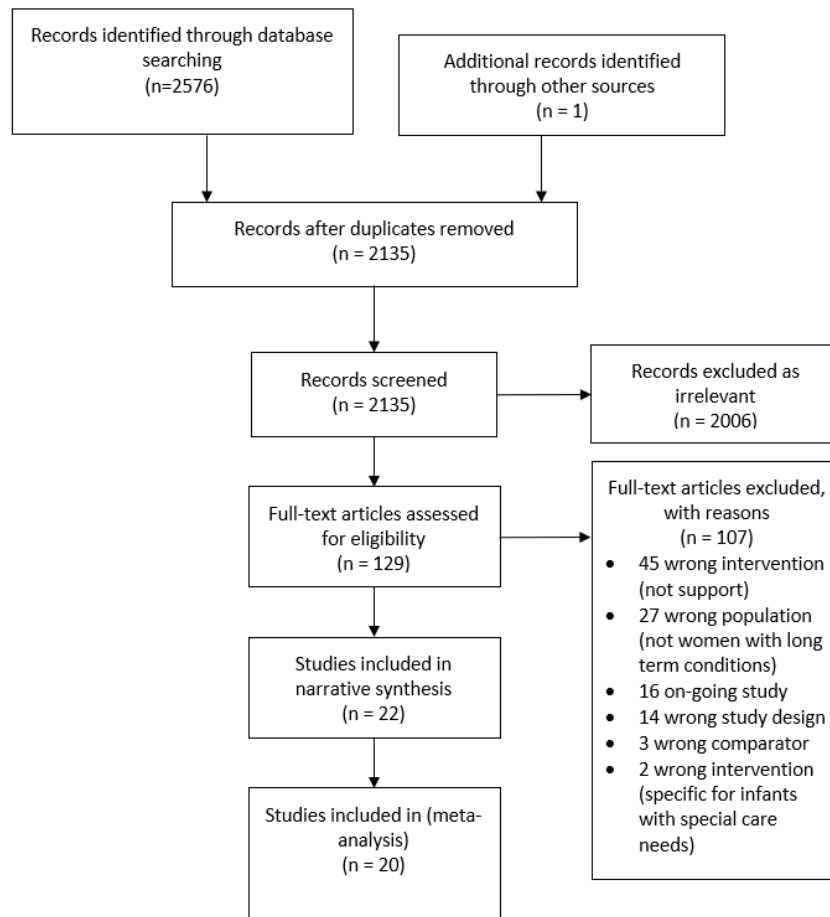


Figure 5. PRISMA flow diagram illustrating study selection

One study reported on two separate interventions: BIBS 1 and BIBS 2.¹⁷⁴ BIBS 1 investigated the effectiveness of breastfeeding support by 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: USA (n=8);^{161, 170, 173-178} Australia (n=3);^{168, 171, 179} Denmark (n=1);¹⁸⁰ Ireland (n=1);¹⁸¹ UK (n=1).¹⁸² A further five studies were conducted in the following upper middle-income countries: South Africa (n=3);^{169, 183, 184} China (n=1);¹⁸⁵ Colombia (n=1).¹⁸⁶ Two studies were conducted in lower middle countries: Kenya (n=1);¹⁸⁷ India (n=1).¹⁸⁸ Only study in a lower income country was identified: Uganda (n=1).¹⁷²

6.4.1.3 Methods used in trials

Most studies were individually randomised two-arm trials (n=14). Six studies used cluster-randomised designs to compare two interventions.^{161, 169, 183, 184, 187, 188} We were unable to adjust for clustering in one of these studies.¹⁶¹

Two studies were three arm studies. For one study we included both interventions.¹⁷² 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.¹⁷¹ We therefore included 23 interventions in the review.

6.4.1.4 Participants

Long-term conditions

Nineteen of the studies specifically included women with an LTC. However, three studies included both women with and without a specific LTC and reported findings for these separately. First, two cluster RCTs included women with and without HIV and analysed this data separately,^{169, 187} however, data from one of these studies was not presented in a way that we could include it in the meta-analysis.¹⁶⁹ Another study analysed breastfeeding rates separately in women with obesity or depression.¹⁶⁸ However, as the denominators were not reported in this conference abstract, we could not include it in our meta-analysis.

The most common condition was overweight and obesity, with nine interventions focused on this.^{170, 171, 173-175, 177, 180, 181, 186} The BMI score required for inclusion ranged from 25-30. A further three studies focused on GDM.^{161, 176, 185} With the exception of one,¹⁸⁶ these studies were conducted in HICs.

Substance misuse was the focus of two studies.^{179, 182} Only one study specifically included breastfeeding support for women with depression.¹⁷⁸

Within LMICs, HIV was the most common condition with five studies focused on this.^{169, 172, 183, 184, 188} All women included in these studies received treatment with antiretrovirals.

Socio-economic status

Four of the studies aimed at women with overweight or obesity were specifically targeted at low-income women.^{170, 173, 175, 177}

A further five studies mainly included women who experienced higher levels of socio-economic deprivation than the national average.^{161, 171, 172, 174, 179}

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 15-57%.

Mode of birth

Of the nine studies that reported mode of birth, eight reported that most women had a vaginal delivery,^{170, 173-175, 179, 180, 182, 183} however, rates of caesarean section ranged from 25-45%. Only one study reported that more women gave birth via Caesarean Section.¹⁸⁵

6.4.1.5 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.^{86, 168, 174, 175, 181, 185}

Other studies provided additional components to help with the LTC of interest. All the interventions aimed specifically for HIV positive women included other aspects of prevention of mother to child transmission (PMTCT).^{172, 183, 184, 187, 188} Four studies which focused on either women with GDM, or who were overweight or obese, also provided weight loss support (e.g., diet and exercise).^{161, 171, 176, 177} Finally, the 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 wellbeing;¹⁷⁷⁻¹⁷⁹ aspects of infant wellbeing such as growth and immunizations;^{173, 179, 180, 182, 183} and wider parenting skills such as sleep and activities.^{170, 173, 177}

Provider

Half of the included studies used an intervention that was provided either exclusively or in part by a lactation consultant,^{161, 168, 171, 173, 174, 176, 178, 180, 181, 185} or certified breastfeeding consultant.¹⁸⁶ Only a few studies involved support from other healthcare professionals including midwives,^{179, 181} nurses,¹⁷⁴ and maternity support workers.¹⁸² Two studies of obese women also included dietician support.^{171, 176}

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.^{169, 170, 173, 175, 184, 187, 188} In two studies it involved online peer support from other breastfeeding mothers with GDM or obesity.^{177, 185} In another study it involved a family member or friend being nominated as supporter.¹⁷² These studies tended to be conducted in LMICs or areas of socioeconomic deprivation within HICs.^{177, 185}

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 of sessions.^{173, 177, 183}

Mode of delivery

Most studies included at least some face-to-face support. Ten studies only utilised face-to-face support.^{169, 170, 172, 173, 179, 182-184, 187, 188} Five studies used a combination of face-to-face and phone support.^{161, 171, 174-176} Often the calls were used to provide reactive additional support for women with difficulties.

Three studies used a combination of digital, phone and face-to-support. In two studies the digital element took the form of online support groups.^{168, 177} One study was conducted in the Covid pandemic and so face-to-face group clinics were replaced with video calls (or individual face-to-face appointments).

Only two studies used the phone as the sole delivery mode.^{168, 180} One study only used a digital approach which included online lessons, video calls and messaging.¹⁷⁸

Timing of delivery

Most interventions were delivered both in the antenatal and postnatal period.^{161, 169, 171, 173-178, 181, 183-188} Five studies were postnatal only^{168, 172, 179, 180, 182} and one study was antenatal only.¹⁷⁰

Number of contacts

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

Intensity levels

Just over half the interventions were judged to be of moderate intensity.^{168, 169, 171-174, 179, 182-186} However, a number of these interventions also offered reactive support as required so the number of contacts may have been higher. Conversely, we judged eight of the interventions to be high intensity.^{161, 175-178, 180, 181, 187} This may be an over-estimation as for some breastfeeding was not the sole focus or it depended upon women engaging digital content such as support groups. No studies were low intensity and two did not specify.^{170, 188}

6.4.1 6 Control group care

Most studies compared the intervention with standard care.^{168, 172-176, 180-182, 184-188} However, there are considerable differences as to what constituted standard care between the studies, for example

the provision of lactation consultants or peer supporters or care in a Baby Friendly Hospital (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.^{169, 171, 177, 178}

Finally, two studies compared the breastfeeding support intervention with limited breastfeeding support.^{170, 179}

6.4.2 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 low risk for this domain (n=18). Four studies did not provide sufficient information.^{168, 174, 179, 184}

Allocation concealment (selection bias)

We only judged eight studies as being at low risk of allocation concealment.^{171, 173, 177, 179-181, 185, 186}

One study was judged to be high risk.¹⁸² All other studies did not provide sufficient information, so we judged them as unclear.

Blinding of personnel and participants (performance bias)

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

Blinding of outcome assessment (detection bias)

As breastfeeding data was all self-reported by mothers, we judged 21 of the studies as high risk of bias in this domain. We judged one cluster RCT to be 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.¹⁸⁸

Incomplete outcome data (attrition bias)

Half of studies were judged as being high risk of attrition bias, which we defined as greater than 20% loss to follow-up.^{161, 171, 173, 175, 178, 181-184, 186, 188} Nine studies were judged as having a low risk of bias in this domain.^{169, 170, 172, 174, 176, 177, 180, 185, 187} Finally, two studies were judged to be unclear risk of bias. One study had higher attrition in the control group (12%) versus the intervention group (4%) and no details were provided.¹⁷⁹ Secondly, Fan et al.,¹⁶⁸ provided insufficient information to make a judgement.

Selective outcome reporting (reporting bias)

We judged most studies (n=15), as being 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 high risk of bias for the following reasons: not reporting outcomes detailed in protocol or methods;^{161, 173, 183} not fully reporting outcomes;¹⁷⁵ not stating when breastfeeding would be measured;¹⁷⁶ or adding in breastfeeding outcomes post-hoc.^{170, 180}

Other biases

We only judged two studies to be at low risk of bias in this domain.^{170, 176} Eleven studies were judged as high risk of bias for one or more the following reasons: insufficient information to adjust for clustering;¹⁶¹ baseline imbalance;^{173, 174, 177, 183, 184} industry funding/support;^{174, 177, 183} financial conflicts of interest;¹⁸⁸ loss of clusters;¹⁸³ issues with intervention implementation;¹⁷⁴ and reporting errors.¹⁷³ For the remaining nine studies there was insufficient information to judge this domain.

6.4.3 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 (*Tables 19-24*) and the funnel plots for studies with at least ten studies in *Appendix 6, Figures 16-18*.

Table 7. Summary of findings table - Breastfeeding support compared to usual care for women with long-term conditions

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº 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 1,000	305 per 1,000 (261 to 359)	RR 0.90 (0.77 to 1.06)	1385 (10 RCTs)	⊕⊕⊕○ Moderate ^a
Not exclusive breastfeeding at 4-8 weeks	686 per 1,000	631 per 1,000 (570 to 707)	RR 0.92 (0.83 to 1.03)	2165 (10 RCTs)	⊕⊕○○ Low ^{a,b}
Not any breastfeeding at 6 months	513 per 1,000	425 per 1,000 (343 to 518)	RR 0.83 (0.67 to 1.01)	1018 (6 RCTs)	⊕⊕⊕○ Moderate ^a
Not exclusive breastfeeding at 6 months	820 per 1,000	779 per 1,000 (730 to 820)	RR 0.95 (0.89 to 1.00)	3206 (12 RCTs)	⊕⊕⊕○ Moderate ^b

Explanations

a. We downgraded 1 level for serious concerns in imprecision. Small number of participants and 95% CI overlaps the line of no effect and fails to exclude important benefit.

b. We downgraded 1 level for serious concerns about substantial and unexplained heterogeneity.

6.4.3.1 Primary outcomes

Stopping any breastfeeding at four to eight weeks

Ten studies with 1385 participants measured stopping any breastfeeding at 4-8 weeks.^{161, 173, 174, 176, 178-182, 185} Breastfeeding support interventions probably has little to no impact on the number of women stopping any breastfeeding at 4-8 weeks (RR 0.90, 95% CI 0.77-1.06; *moderate-certainty evidence*). There was no evidence of any significant statistical heterogeneity ($\text{Tau}^2 = 0.01$, $I^2 = 16\%$, $\text{Chi}^2 = 10.71$, $P=0.30$). See *Appendix 5, Figure 9*.

Sensitivity analysis using only studies assessed as having low risk of bias for allocation concealment found very similar effect estimates. Sensitivity analysis excluding studies 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, 1.67). Similarly, sensitivity analysis excluding studies with cluster RCTs, which we could not calculate a design effect for, found similar effect estimates to the main analysis. No studies in this analysis included interventions for women with HIV. See *Appendix 5, Table 19*.

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.^{161, 173-175, 178, 180, 181, 185, 187, 188} 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 0.83-1.03; *low-certainty evidence*). There was evidence of substantial statistical heterogeneity ($\text{Tau}^2 = 0.01$, $I^2 = 53\%$, $\text{Chi}^2 = 19.32$, $p=0.02$). See *Appendix 5, Figure 10*.

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, sensitivity analysis excluding studies with interventions for women with HIV found similar effect estimates. Excluding the cluster RCT which we could not calculate a design effect changed the effect estimate and 95% minimally (RR 0.94, 95% CI 0.84, 1.06). See *Appendix 5, Table 20*.

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. *Appendix 5, Figure 16*.

Stopping any breastfeeding at six months

Five studies reporting on six interventions in studies with 1018 participants measured stopping any breastfeeding at 6 months.^{172, 176, 179, 181, 185} Breastfeeding support interventions probably have no impact on the number of women stopping any breastfeeding at 6 months (RR 0.83, 95% CI 0.67-1.01; *moderate-certainty evidence*). There was no evidence of any significant statistical heterogeneity ($\text{Tau}^2 = 0.00$, $I^2 = 0\%$, $\text{Chi}^2 = 1.21$, $p=0.98$). *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% CI. There were no cluster RCTs for which we could not calculate a design effect. See *Appendix 5, Table 21*.

Assessment of publication bias via Funnel Plot inspection was not possible due to the small number of studies.

Stopping exclusive breastfeeding at 6 months

Eleven studies reporting on 12 interventions in studies with 3206 participants measured stopping exclusive breastfeeding at 6 months.^{172, 175, 177, 179-181, 183-185, 187, 188} 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 0.89-1.00; *moderate-certainty evidence*). There was evidence of substantial statistical heterogeneity ($\text{Tau}^2 = 0.01$, $I^2 = 84\%$, $\text{Chi}^2 = 67.87$, $p < 0.00001$). *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% CI. There were no cluster RCTs for which we could not calculate a design effect. See *Appendix 5, Table 22*.

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. *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, and instead a narrative summary is provided.

6.4.3.2 Additional Outcomes: breastfeeding

Not initiating breastfeeding

Eight studies with 903 participants measured not initiating any breastfeeding.^{170, 171, 174, 177-181}

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 was initiated. This led to some studies having higher rates of breastfeeding at 4-8 weeks than at initiation which was non-sensical. A post-hoc decision was therefore made to exclude this outcome from the review.

Stopping any breastfeeding at 3-4 months

Four studies with 522 participants measured stopping any breastfeeding at 3-4 months.^{174, 178, 181, 185}

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 0.53-1.38; *low-certainty evidence*). There was evidence of substantial statistical heterogeneity ($\text{Tau}^2 = 0.14$, $I^2 = 68\%$, $\text{Chi}^2 = 9.29$, $p=0.03$). See *Appendix 5, Figure 13*.

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*.

Assessment of publication bias via Funnel Plot inspection was not possible due to the small number of studies.

Stopping exclusive breastfeeding at 3-4 months

Five studies with six interventions and 785 participants measured stopping exclusive breastfeeding at 3-4 months.^{172, 176, 179, 181, 185} Breastfeeding support interventions may have a beneficial effect on the number of women exclusively breastfeeding at 3-4 months (RR 0.77, 95% CI 0.59-1.00; *low-certainty evidence*). There was evidence of substantial statistical heterogeneity ($\text{Tau}^2 = 0.06$, $I^2 = 76\%$, $\text{Chi}^2 = 20.89$, $p=0.0009$). See *Appendix 5, Figure 14*.

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, 1.02). Removal of the one study for HIV positive women widened the 95% CI marginally (RR 0.77, 95% CI 0.59, 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, 0.80). There were no studies for which a design effect could not be calculated. See *Appendix 5, Table 24*.

Assessment of publication bias via Funnel Plot inspection was not possible due to the small number of studies.

6.4.3.3 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 measured outcome was infant growth (six studies). Five studies were focused on overweight/obesity or gestational diabetes mellitus (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.*,¹⁸⁶ calculated scores at four 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.*,¹⁷³ 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.*,¹⁷⁷ reported there was no difference in weight-for-length Z scores (raw data not provided). Carlsen *et al.*,¹⁸⁰ measured infant weight at six months and found no differences between the intervention and control groups (8169g +/- 963 vs 8356g +/- 959, $p = 0.18$). Similarly, an additional paper for the study by Steube *et al.*,¹⁸⁹ found no difference in infant length, weight, BMI percentile, biceps circumference, 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 two and 12 months (odds ratio [OR] 1.08, $p = 0.035$).¹⁸⁴

Only one study, which was an intervention for women with substance misuse, measured rates of immunizations at two, four and six months and found no differences between the groups at any time points ($p = 0.757$, $p = 0.477$, $p = 0.283$).¹⁷⁹

Only one study measured rates of hospital admissions and childhood infectious diseases. Chapman *et al.*,¹⁷⁵ found beneficial effects in terms of infant hospitalisations in the intervention compared to the control in the first three months (10% vs 26%, $p = .03$) and six months after birth (11% vs 28%, $p = .03$). There were also higher rates of diarrhoea at six months in control infants but not at three months (details not provided). There was no difference in rates of otitis media or attendance at the emergency department.

One study which examined support for HIV positive women included infant mortality as an outcome and did not identify any differences between intervention and control groups (adjusted OR 1.6, 95%CI 0.37-6.91).¹⁸⁸

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 (NB in some studies the comparator included a weight loss component). All studies measured maternal weight using different measures. Aldana-Parry *et al.*,¹⁸⁶ compared the mean maternal weight loss between first week post-partum and four months and found no difference between the intervention (1.9 kg +/- 4.7) and the control (4.2 kg +/- 5.1, $p = 0.07$). Similarly, in the DEBI study, there were no differences between intervention and control groups in weight, BMI, and skinfolds at six weeks, four months, seven months or ten months.^{161, 189} The intervention group had a slightly smaller waist circumference at seven months compared to the control group (104.70 cm vs 115.60, $p = 0.046$). However, there was no difference at any other time points. A linked paper to Ehrlich *et al.*,¹⁹⁰ reported that although women with GDM in the intervention group had higher rates of meeting their post-partum weight loss goals compared to controls at six weeks (20.9% vs 17.4%, $p = 0.54$), seven 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.*,¹⁷¹ reported no difference in BMI in the intervention compared to the control group at three months (30.6 +/- 5.4 vs 30.7 +/- 4.1, p value not reported) or six 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 found no differences in fasting insulin and two-hour glucose at any time points.¹⁸⁹ Similarly Martin *et al.*,¹⁷¹ found no differences in HBA1c, insulin or glucose levels at any time points.

Two studies included maternal physical activity as an outcome and found no differences between the groups. The DEBI study found no difference in levels of physical activity at six weeks ($p = 0.92$) or seven months ($p = 0.91$).¹⁸⁹ Fiks *et al.*,¹⁷⁷ also included number of periods of physical activity per weeks as an outcome measure and found no difference between intervention and control groups at six months (2.2 vs 2.0), $p > 0.05$).

Two studies included measures related to diet (percentage of calories from dietary fat) and found a small reduction in the intervention group compared to the control group at seven months (8.04% vs 7.47%, $p = 0.002$).¹⁹⁰ This was not significant at six weeks (7.44% vs 8.02%, $p = 0.54$). The DEBI study included 23 variables related to diet which were measured at six weeks, four months, seven months and ten months.¹⁸⁹ There were only differences in four of these, and with the exception of water consumption favoured the control group: sweetened beverages at six weeks (intervention = 79.49% vs 53.85%, $p = 0.03$); drinking water at four months (78.57% vs 47.83%, $p = 0.76$); fast food (88% vs 52%, $p = 0.01$); and using fat for cooking (100% vs 77.78%, $p = 0.04$).

One study measured maternal substance use with the opiate treatment index and found similar scores between 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, $p = 0.52$).¹⁷⁹ A higher score suggests more use. Findings were similar at six months.

Finally, one study which provided support for women with HIV measured maternal mortality and found no difference between the intervention and control group (adjusted OR 0.58, 95% CI 0.23, 1.34).¹⁸⁸

Maternal mental health outcomes

Two studies included depression as an outcome with mixed findings. First, in a study for HIV positive women, the intervention group had a larger decrease in depressed mood by 12 months than women in the control group (OR 1.08, $p = 0.002$).¹⁸⁴ However, Pezley *et al.*,¹⁷⁸ provided cognitive behavioural therapy for the management of depression and anxiety to both intervention and control groups. Depression scores and anxiety scores remained consistent from baseline, in the 3rd trimester and at six- and 12-weeks post-partum (significance levels not reported).

Two studies included a measure of stress. In a support intervention 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, $p > 0.05$).¹⁷⁷

The DEBI study for women with GDM included stress management as an outcome and found no difference between the groups at six weeks, four months, seven months or ten months.¹⁸⁹

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.*,¹⁷⁰ asked participants if they were likely to breastfeed again if they had another child and there was no difference between intervention and control groups (RR 1.03, 95% CI 0.86 – 1.25).

Maternal satisfaction with feeding method

Only one study measured satisfaction with care. MacVicar *et al.*,¹⁸² examined support for women receiving opioid substitution and reported that the intervention group intervention 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.

6.5 Strengths and limitations

We followed Systematic Review methods outlined in the Cochrane Handbook,⁸⁷ however, there is a potential for bias to be introduced into the review. First, due to resource constraints we were only able to include studies published in English so there is a risk of language bias. Secondly, whilst we have attempted to identify all published and unpublished trials on breastfeeding support for women with LTCs, it is possible that not all existing trials have been identified. Funnel plot analyses suggested some possible asymmetry, however, interpretation is limited by the small number of studies. Thirdly, we were unable to adjust for clustering in one of the studies, however, sensitivity analysis in which that study was removed did not change the effect estimate. Fourthly, there was considerably variability in how breastfeeding initiation was measured (e.g., within 24hrs 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.

6.6 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 MLTCs.

The most common condition was 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 long-term condition. 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 effect estimates. We considered the overall risk of bias in the included trials to be mixed. Sensitivity analyses excluding studies at high or unclear risk of bias for allocation concealment and attrition also did not alter 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. Due to heterogeneity in outcomes meta-analysis was not possible and 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

7.1 Introduction

As part of our additional funding for multiple long-term conditions, we sought to complement the evidence on effectiveness from Review 4 (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.

7.2 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.

7.3 Methods

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

7.3.1 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 long-term conditions published by 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 which aims 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 search websites of organisations related to key conditions (e.g., Diabetes UK, Crohn's and Colitis UK, Epilepsy Action).

7.3.1 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 policymakers.

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 which 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 when breastfeeding (e.g., neonatal hypoglycaemia, delayed lactogenesis, preterm birth).

Studies reporting 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 within 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 based 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 which only included 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.

7.3.2 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.

7.3.3 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.¹⁹¹ We used the Axis tool to assess the quality of cross-sectional surveys.¹⁹² 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 for poor quality.

7.3.4 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 long-term conditions across multiple contexts/settings. The qualitative and quantitative findings from syntheses 1 and 2 were then 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.

7.4 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 due to studies not reporting views and experiences of breastfeeding support (e.g., views and experiences of breastfeeding) (n=37), followed by studies involving study designs not eligible for inclusion in this review (e.g., effectiveness studies) (n=22). Other reasons for exclusion were due to abstract only records (e.g., conference proceedings) (n=19), studies focusing on ineligible populations (n=8), studies 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 (*Figure 6*).

7.4.1 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, including 16 qualitative¹⁹³⁻²⁰⁸, two quantitative²¹⁰⁻²¹¹ and six mixed-methods^{209, 212-216} studies. Studies reported data from 12 countries (Australia, Canada, Ghana, Ireland, Japan, Kenya, Malawi, South Africa, Uganda, UK, USA, 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-positive (8 studies),^{193, 198, 200, 204-206, 213-214} obesity and overweight (5 studies),^{197, 196, 202, 207, 211} substance use (5 studies),^{195, 199, 203, 209, 215} diabetes in pregnancy (3 studies),^{201, 210, 216} women with disabilities (2 studies),^{194, 208} and women with a rare genetic disorder (1 study).²¹² The eight studies of HIV-positive women were all from LMIC, while for all other conditions, studies were all from HICs.

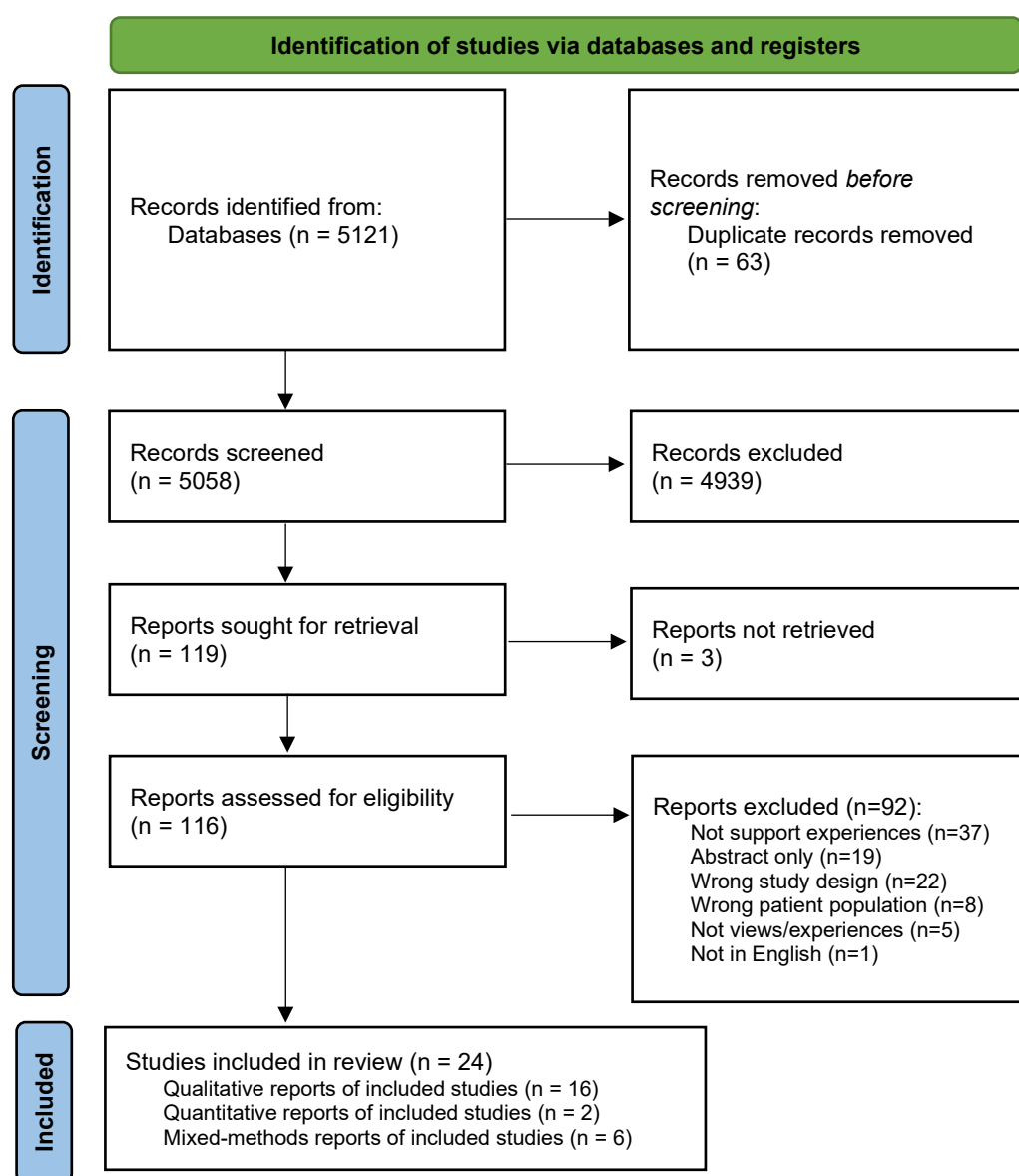


Figure 6. PRISMA Flow Diagram

7.4.2 Quality appraisal

We assessed 16 qualitative studies¹⁹³⁻²⁰⁸ and the qualitative components of five mixed methods studies.²⁰⁹⁻²¹¹ Three cross-sectional surveys¹⁰⁵⁻¹⁰⁸ and the survey component of one mixed-methods study²¹² were assessed. The quantitative components of four mixed methods studies²¹³⁻²¹⁶ 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 provided full details of methods for recruitment, data collection and rigorous analysis; most other studies had at least partially addressed these aspects.^{193, 197, 214} Three studies provided insufficient information to assess the rigour of data analysis.^{200, 212, 213} O'Reilly *et al.*,²⁰⁷ 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.*,¹⁹⁴ failed to report ethics approval and provided no discussion of ethical issues other than the use of consent forms. Howard *et al.*,¹⁹⁹ stated that their

study was exempt from Institutional Review Board approval without giving reasons and did not discuss any ethical issues. All but one study²⁰⁰ at least partially addressed 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.*,²¹² and Rasmussen *et al.*,²¹¹ provided very little information on which to assess quality and did not address key quality criteria. Matsunaga *et al.*,²¹⁰ 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.*²¹¹ Three studies^{209, 210, 212} discussed some limitations of their studies but only Matsunaga *et al.*,²¹⁰ presented conclusions that were justified by the results.

7.4.3 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) 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,^{197, 199, 202, 208, 210} as well as concerns and difficulties relating to any conditions or medical interventions needed for the infant.^{201, 209, 210} 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 on antiretroviral medicine) were reported in several studies.^{195, 198, 199, 204, 205} These experiences could result in pressure to stop breastfeeding and to adopt other feeding options, with the potential for abrupt weaning and breast complications.^{198, 199, 204, 205} In some contexts, breastfeeding practices were reported as more driven by finance or family pressures than by health information.²⁰⁴

The emotional implications of breastfeeding challenges experienced by those living with a long-term condition were reported in several studies.^{197, 206, 212, 213, 216} These impacts included difficulties with

contact and bonding^{199, 202} 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,¹⁹⁹ with a few studies reporting issues associated with perceived breast milk insufficiency^{194, 198, 201, 208} and latching.^{194, 208} One study found emotional comorbidity to be linked to perceived failure to breastfeed,²¹² with two other studies reporting women with LTCs to be less likely to fully breastfeed²¹⁶ and more likely to breastfeed for a shorter duration²¹³ 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,^{195, 201, 207-209, 212, 214} particularly when multiple healthcare settings beyond maternity care are taken into consideration. For example, one study found that health professionals in a mother-to-child HIV transmission programme infrequently advised women on breastfeeding (41% of visits), and in another study only 23.3% of women reported healthcare staff from an opioid dependence treatment centre to have discussed breastfeeding with them.²¹⁴ Alongside insufficient breastfeeding support, some of these studies also reported women's perceived lack or limited information received from professionals or available in hospital settings.^{195, 200, 201, 208, 210}

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.^{204, 211, 212} Conversely, one study found that specialist breastfeeding clinics were perceived as useful by women, however, these were found to be underused.²⁰³ The hospital environment can be both a source of support and tension for breastfeeding mothers with LTCs,¹⁹⁹ and a range of organisational barriers were reported,²¹⁰ 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 coordinating 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.²⁰⁹ 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.^{202, 215}

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 which could align to impact (positively or negatively) the complex journeys of breastfeeding mothers with LTCs.

Some studies echoed a range of positive interactions with breastfeeding supporters,^{193, 194, 201, 203, 208, 215} including several strategies and forms of support that had enabled them 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), or 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.^{203, 206, 215} One study found that women who were encouraged to breastfeed by healthcare staff were more likely to breastfeed for longer durations.²⁰⁹

Most studies, however, echoed support experiences shaped by a range of negative interactions (e.g., communication difficulties)^{193, 194, 201, 203, 208, 215} as well as barriers faced by breastfeeding supporters. Breastfeeding support could sometimes be overshadowed by condition-related support.^{204, 213} The provision of breastfeeding support for women with LTCs was described as requiring more time and effort, more challenging personally and in terms of competence.^{197, 210} Some studies reported breastfeeding supporters as lacking specialist training,^{195, 200, 204, 211} with some women not feeling well understood by health professionals²¹² and reporting trust in health professionals as a source of advice to be an important factor.²¹⁴ 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.²⁰⁵

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, feeling like breastfeeding was characterised as the only acceptable choice, which led to expressions of fear and anxiety about not being able to successfully breastfeed;⁵ in another study, health professionals reported encouraging mothers to practice exclusive breastfeeding as a policy directive, and concluded that mothers were not given an opportunity to weigh the pros and cons of other feeding options;¹⁹⁸ there were also examples where avoiding breastfeeding was promoted as the ideal option;²¹³ other studies identified inconsistent and inaccurate messaging on complementary^{200, 214} and mixed^{205, 216} feeding options; some studies identified encouragement of formula supplementation, which some women associated with difficulties in establishing breastfeeding.^{201, 202, 207}

Information and knowledge provision was reported as one key aspect of breastfeeding support to help empower informed maternal feeding decisions.^{199, 207, 213} However, within the healthcare community, women obtained information and misinformation about breastfeeding in the context of their health condition.^{195, 200, 201, 203, 208, 210} Understanding of perceived benefits of breastfeeding was reported as an important driver of successful breastfeeding support,^{195, 213} which could in turn drive the motivation,¹⁹⁵ determination,²⁰⁷ self-confidence,¹⁹⁶ and resilience¹⁹⁹ 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 to improve 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.^{193, 195, 196, 201, 202, 206-208, 214, 216} Another important suggestion was to increase the provision of education and raise awareness among health professionals,^{197, 207, 211, 212} to improve their understanding of specific breastfeeding support needs of mothers with LTCs and to help them identify feeding problems earlier. One study sought women's views and feasibility tested 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.^{203, 215} Another suggestion for improvement echoed 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.^{197, 198, 201, 216}

7.5 Chapter summary

This review included 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, women with disabilities and women with 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 long-term conditions; 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 which could impact women's experiences.

Chapter 8 Review of economic evidence for women with LTCs

8.1 Overview

The previous two chapters reported a systematic review identifying (i) which interventions were effective in providing breastfeeding support for women with single LTCs, and (ii) the barriers and facilitators to 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 was known about the cost-effectiveness of breastfeeding support interventions for mothers with LTCs.

8.2 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 and uncertainties in the applicable economic evaluations
4. Examine the level of consistency between applicable economic evaluations

8.3 Methods

8.3.1 Eligibility criteria

The methods for conducting the systematic review of economic evidence followed those reported in *Chapter 5* of this report 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 that 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 it 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 health care 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. Lastly, types of studies included were full economic evaluations (cost-effectiveness, cost-benefit and cost-

utility analyses), in addition to partial economic evaluations (cost-consequence 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.

8.3.1 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: (i) breastfeeding, (ii) support, and (iii) 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', 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, HMIC via Ovid, 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, NHS Economic Evaluation database, Paediatric Economic Database Evaluation (PEDE), IDEAS economics database via RePEc, 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, e.g., NHS Economic Evaluation database 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.

8.3.2 Selection process

Returned records from database searches were transferred into the reference management software EndNote Version 20.3 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 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 PRSIMA flow diagram was completed to illustrate the selection process.

8.3.3 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 MS 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 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.

8.3.4 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 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/>).

8.4 Results

8.4.1 Study selection

Figure 7 presents the PRISMA flow diagram for the study selection process. Following 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, as 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.

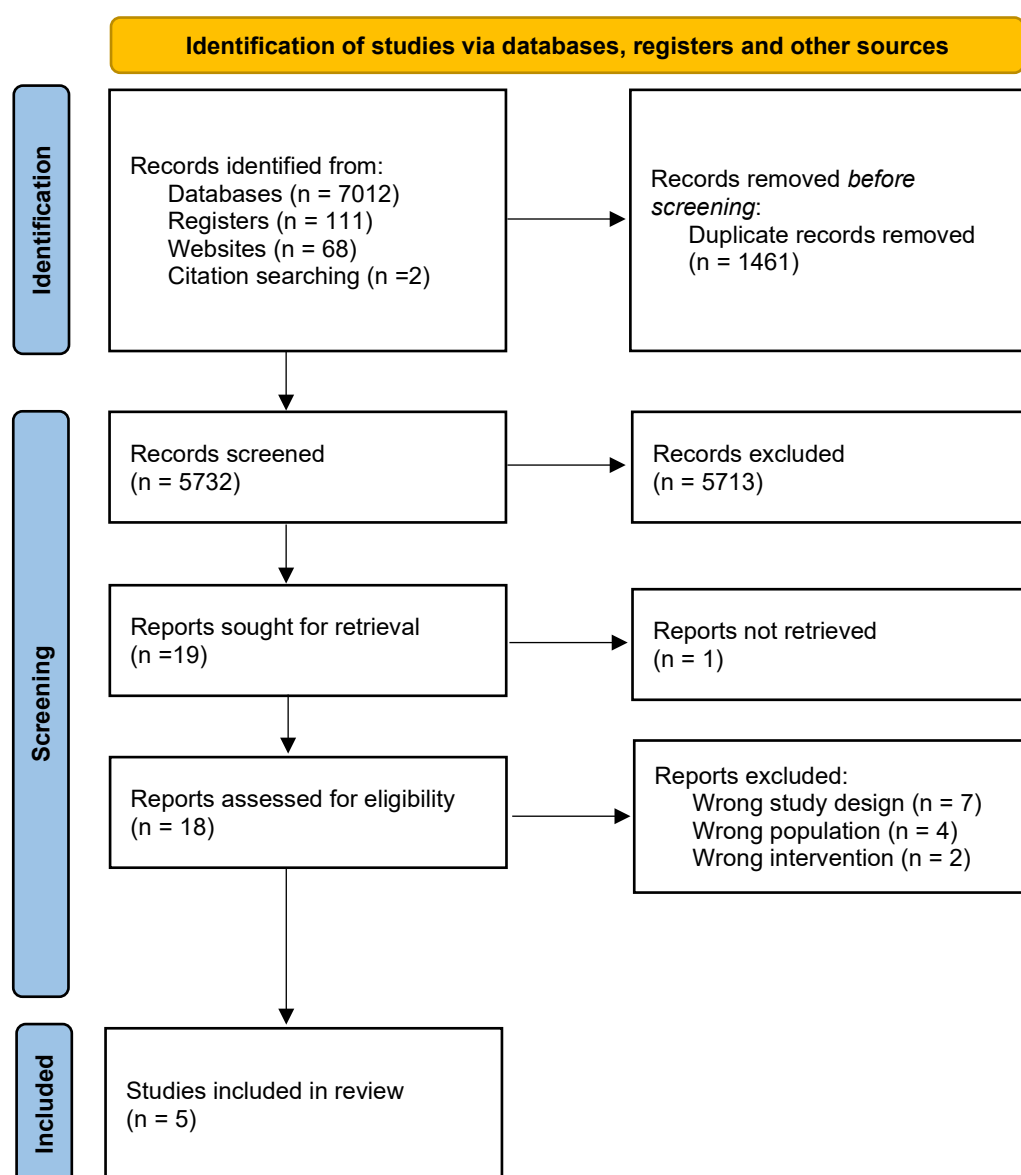


Figure 7. PRISMA 2020 Flow Diagram for Review of Economic Evidence for Breastfeeding Support Interventions for Women with LTCs

8.4.2 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 on applicability to the review question. Of the five studies, one was conducted in a UK-setting and included women with a BMI >25 kg/m².²¹⁷ Two were conducted in OECD settings of the USA: one addressing women/infant dyads with prenatal use of opioids²¹⁸ and a second that presented data for a subgroup of medically high-risk women.¹²⁷ The remaining two studies were conducted in South Africa addressing support for women living with HIV.^{219, 220}

Three studies assessed breastfeeding only support interventions.²¹⁸⁻²²⁰ Avram *et al.*,²¹⁸ 2020 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.*,²¹⁹ 2008 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.*,²²⁰ 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,²¹⁷ and Doula support during pregnancy and up to 8 weeks postpartum.¹²⁷

There were a range of methods used for the economic evaluations. One study reported a partial economic evaluation alongside a feasibility RCT, with a cost-outcome description comparing two alternatives.²¹⁷ Full economic evaluations were reported in the remaining four studies, with one study reporting a trial and model-based CEA assessing cost per increased month of exclusive breastfeeding,²¹⁹ one reporting a trial-based CBA with the return on investment,¹²⁷ one study a model-based CUA with incremental cost per disability-adjusted life year (DALY) averted reported, respectively,²¹⁸ and a model-based CUA with cost per QALY gained.²¹⁸

8.4.3 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,²¹⁸⁻²²⁰ or reported a positive return on investment. Avram and colleagues,²¹⁸ 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 testing the sensitivity of the ICER 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.*,²¹⁹ 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 intervention cost; however, it was balanced with 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.*,²²⁰ similarly modelled the cost utility of various infant feeding strategies for women living with HIV compared to 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 DALY averted. However, the ICER did not hold in one-way sensitivity analysis for a range of modelled study parameters. Those living in a rural setting and provided breastfeeding support had lower estimated costs compared to current practice; however, this was offset by an increase in number of HIV infections.

Mottl-Santiago *et al.*,¹²⁷ recruited women from low-income communities and subsequently conducted a subgroup analysis for consideration of heterogeneity in the results of the return on investment for Doula support. The author reported a higher return on investment (USD \$276:\$1) when assessing Doula support during pregnancy up to 8 weeks postpartum for women considered medically high-risk, compared to full sample's return on investment (USD \$18: \$1) at 2018 prices. However, the evaluation did not consider health resource use and costs (cost savings) beyond the study time horizon.

8.4.4 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 due to the system in which the studies were conducted being too different to the UK context, making it difficult to translate findings of cost-effectiveness.^{219, 220} Two further studies were deemed not applicable due to the payer perspective taken for the costing of the intervention and/or health care resource use in an organisational setting that is too diverse to the UK NHS and personal social services (PSS).^{127, 218} 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,²²¹ was applicable in terms of the country setting (UK) and the provider perspective taken of the NHS and PSS; 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 to a control. If at a future date, the study progressed to a full trial and conducted a CUA as planned, findings would likely be judged applicable.

8.4.5 Appraisal of limitations

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

8.5 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 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, 222} 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.

8.6 Chapter summary

Five studies were identified that examined the incremental cost and/or cost-effectiveness of breastfeeding support interventions for women with LTCs compared to a control or provided a cost-outcome description. The conditions assessed in the studies were women with HIV, obesity, prenatal opioid use, and women considered 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 were deemed cost-effective for the base case. On appraisal, none of the studies were 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

9.1 Aims

The final stage of the research aimed to develop and refine a toolkit for 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.

9.2 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 review⁸³
- 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 multi-morbidities 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.²²³⁻²²⁹

9.3 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 hrs of discharge and regular phone 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 four weeks there will be a weekly proactive phone call and beyond that support will be provided monthly until three months or when breastfeeding ceases. Women can also contact infant feeding advisors as needed via phone or SMS during this three-month period and beyond it 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.

9.4 Workshops

Four one-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 policymakers including government bodies, and public health and social care organisations; 4) academic researchers. Invitations were disseminated via the research team's networks, members of the stakeholder working groups 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.

9.4.1 Workshop participants

There were 87 participants across the four workshops and all sectors were represented as shown in *Table 8* although there was no policymaker 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 were the largest group followed by service users/third sector organisations. There were relatively few policymakers. 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.

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 policymakers	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

9.4.2 Workshop activities

Following an overview of the main study and the additional work for women with LTCs, and 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 is 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 multi-morbidities.

Participants were presented with a hypothetical case study of a women 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 would be needed for the prototype intervention to meet the needs of breastfeeding women with multi-morbidities.

The consensus across the workshops was that the intervention needed significant modifications. There was highest consensus 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 don't have to repeat their stories; 3) infant feeding advisors should be included in joint obstetric and medical clinics.

Other modifications mentioned frequently:

- 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 multi-morbidities 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 feeding positions. 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 three-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 long-term conditions. 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 multi-morbidities in the multi-disciplinary team including GPs. Supporting women with multi-morbidities to breastfeed should be included in routine breastfeeding training updates;
- services should be co-ordinated with infant feeding advisor as the key point of contact for the multi-disciplinary team.

1 *Activity 2: Identified barriers to implementation of prototype intervention for healthy women and*
2 *women with multi-morbidities*

3 Participants were asked within their groups to discuss and list barriers to implementing, and for
4 parents, to accessing the prototype intervention in their settings. Open discussion was encouraged;
5 however, facilitators were provided with a prompt sheet comprising the domains and constructs
6 adapted from the CFIR²³⁰ to stimulate consideration of all aspects of implementation and
7 accessibility. The lists of barriers were collated and, along with the 18 barriers identified by the
8 stakeholder working group and parents panel (see *Chapter 2*), mapped to the updated CFIR.⁹² There
9 was a high degree of overlap within and across the workshops and between the workshops and
10 stakeholder and parents panel discussions. We present the main themes under each domain of the
11 CFIR,⁹² while acknowledging that there is overlap between constructs within a domain and between
12 domains. Constructs of the CFIR are denoted in italics in the following text.

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

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

42 **Inner setting domain:** there were twice as many barriers identified under the inner setting domain
43 as for any of the other domains. The most frequent themes linked to *work infrastructure*, *culture* and
44 *available resources*. Workforce challenges such as staff shortages, high turnover of staff and lack of
45 time/protected time were the most frequently mentioned. Other barriers related to *work*
46 *infrastructure* included lack of the right skill mix and over dependency on one or a small group of

individuals. Overlapping with *work infrastructure*, were barriers relating to *relational connections* and *communications* e.g., poor communication and working practices across the multi-disciplinary team, fragmented services, and challenges to embracing peer support within the health settings. The latter included peer support not being valued and 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, 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 considering 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 following birth. 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 mapped to the *capability* (knowledge, skills, interpersonal competence) of *innovation deliverers* resulting in conflicting information for breastfeeding women. The main concern was lack of experience and training of many staff who would be delivering the intervention. This included lack of access to high quality education. A frequently mentioned barrier was negative attitudes to breastfeeding of some staff that 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 valuing (*capability and motivation*), of the innovation by *high- and mid-level leaders* i.e., key strategic decision-makers and those whose remit is to operationalise strategic decisions, without whose support the implementation was unlikely to succeed. The stakeholder working group identified lack of champions and skilled implementation leads as further barriers. A final theme under individuals related to *innovation recipients* with barriers to *opportunity* such as lack of time, lack of knowledge of, or access to services.

Implementation process domain: at the workshops, there were fewer barriers linked to this domain compared to the other domains. The only barriers mentioned by more than one group related to *engaging* e.g., staff lack of engagement or resistance to change, and *planning* in the lack of management oversight to ensure 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 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 Supplementary file 1. *Table 9* presents the five strategies chosen most frequently along with examples of the barriers these were selected to overcome.

Table 9. Most frequently selected strategies with examples of barriers

Strategy	No. 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 multi-disciplinary 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 multi-disciplinary team
Revise roles as needed to support the intervention- e.g., 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

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

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

7 Involve parents, peer supporters and charities in adapting the intervention, for the local area and to

8 encourage uptake (#10 in the overall strategy ranking).

9 The differences between the workshops can most likely be explained by a combination of the

10 different balance of participants at each workshop (more parents and third sector representatives at

11 the Edinburgh workshop) and the different policy contexts of the four nations.

12 *Activity 4: Considerations for evaluating breastfeeding support interventions*

13 Participants discussed how the prototype intervention could be evaluated and were prompted to

14 consider outcomes that are important to parents, timing of breastfeeding outcome data collection,

15 important data related to processes, and how to assess the impact on health inequalities.

16 Important outcomes for parents were suggested to be meeting their feeding goals and expectations,

17 whether the support and information was helpful, and how confident or empowered the woman felt

18 after the intervention.

19 **Timing of breastfeeding outcomes data collection:** the most frequently mentioned was to collect

20 data on 'any' and 'exclusive' breastfeeding at the following timepoints:

- 21 • First feed within one hour after birth
- 22 • Discharge from hospital
- 23 • 6-8 weeks
- 24 • 6 months

25 Other suggestions with high consensus were 10-12 days (to coincide with discharge from routine

26 midwifery care), 3 to 4 months and 1 year. Other comments related to collecting breastfeeding

27 outcome related to definitions of any and exclusive and whether these need to be subdivided

28 further.

29 Other outcomes felt to be important included health outcomes e.g., number of infants admitted to

30 hospital and reasons for stopping breastfeeding.

31 **Process data**

32 The most frequently mentioned were the views and experiences of those receiving and delivering

33 the intervention (including women, healthcare practitioners and peer supporters), women's

34 satisfaction, and intervention fidelity (did women receive all components of the intervention). There

35 was discussion that data could be collected early to capture those who cease to engage with the

36 intervention and to gain feedback from those who declined the intervention. Many methods for

37 collecting data were suggested including digital options such as WhatsApp and there was high

38 consensus that participants in studies should be offered options for follow-up e.g., between online,

39 telephone, email, post, or a phone app.

40 **Impact on inequalities**

Discussions around evaluating the impact on health inequalities centred around gathering background information such as maternal characteristics (age, ethnicity, socio-economic status) and making sure the intervention and evaluation are inclusive e.g., addressing language barriers.

Activity 5: Willingness to pay for a breastfeeding support intervention

To evaluate stakeholders' preferences for a breastfeeding support intervention, participants at the workshop were presented with a stated preference discrete choice experiment (DCE). DCEs are a method used to elicit 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 terms of the attributes of the product/service for the individual to choose their preferred alternative.²³¹ The theoretical underpinnings of the experiment are derived from (i) Random Utility Maximisation,²³² where it is assumed that individuals' choice behaviours are made to maximise their satisfaction while allowing for unobserved sources of utility, and (ii) 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.²³³ 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.²³⁴ DCEs have been used increasingly over the last twenty 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.²³⁵ 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.^{236, 237} 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 the exercise is capable of deriving preferences.²³¹ 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*.

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

Attributes	Attribute Levels				
	1	2	3	4	5
Number of contacts	3 or less	4 to 8	9 or more	-	-
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	-
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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 breastfeeding at 6 weeks. Only one of the two clinical outcome attributes was presented in any given experiment to each participant. Lastly 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. An Orthogonal Main Effects Plan, using Statistical Package for Social Sciences 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 respect to the 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 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 or less	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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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. Prior to commencing the activity, 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 there may be several outcomes of effect 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 MS Excel. Data entry was carried out using a multiple-line format, where 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 using guidance provided by.²³⁸ 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.

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 or less ^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
On-line	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

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

With regards 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 less ($\beta = 0.35$, SE = 0.122, $p < 0.01$); provision from a range of providers over healthcare professional alone ($\beta = 0.46$, SE = 0.172, $p < 0.01$); and, valued face-to-face support over telephone support ($\beta = -0.29$, SE = 0.135, $p < 0.05$). While there was a positive value for a proactive approach to support over reactive support, this was not statistically significant ($\beta = 0.16$, SE = 0.117, $p > 0.05$). Thus, suggesting that stakeholders did not consider the different approaches to support (reactive, proactive, hybrid) within their decision-making process. Both clinical outcome attributes of reducing the number of women stopping any breastfeeding ($\beta = 0.26$, SE = 0.018, $p < 0.01$) or exclusive breastfeeding ($\beta = 0.52$, 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 ($\beta = -0.02$, SE = 0.002, $p < 0.01$), upholding underlying assumptions of individuals acting to minimise cost.²³⁴ 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 ($\beta = -1.16$, 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 willingness to pay 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 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 willingness to pay 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.

9.4.3 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

10.1 Summary of findings

The aim of this study was to synthesise global and UK evidence to co-create with stakeholders a framework to guide implementation and evaluation of cost-effective breastfeeding support interventions in the NHS. The original focus of the study was on women without long-term conditions; however, we broadened the scope to include women with MLTCs when additional funding was awarded. Given the anticipated paucity in evidence for women with MLTCs, 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 and facilitators to breastfeeding support in women with LTCs; and
- 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 only included breastfeeding support (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 had 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, 0.97) for stopping any breastfeeding at 6 months to RR 0.81, (95% CI 0.77, 0.95) for stopping exclusive breastfeeding at 3-4 months. Effect estimates were generally greater for exclusive breastfeeding compared to 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, and exclusive breastfeeding at 6 months. The evidence suggests that 'breastfeeding plus' support probably results in little to no difference for any of the other outcomes. Effect estimates ranged from RR 0.94 (95% CI 0.91, 0.97) for stopping any breastfeeding at 6 months to RR 0.73 (95% CI 0.57, 0.95) for stopping exclusive breastfeeding at 4-6 weeks. Again, effect estimates were generally greater for exclusive breastfeeding compared to 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 categorized 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 lower 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, despite categorising interventions into

1 'breastfeeding only' and 'breastfeeding plus', there was still substantial heterogeneity in
2 interventions.

3 Meta-regression was conducted to further explore heterogeneity. This suggested that moderate-
4 intensity (four to eight visits) versus low intensity (three or less) support, may be beneficial for
5 reducing the number of women stopping exclusive breastfeeding at 4-6 weeks or 6 months.
6 Additionally, women in LMICs were less likely to have stopped exclusive breastfeeding at 6 months
7 and this may be explained by the higher background breastfeeding rates at 6 months in LMICs.¹⁴
8 However, beyond this the meta-regression did not explain the high levels of heterogeneity. As we
9 did not want to increase the likelihood of false positives from the meta-regression, we limited the
10 number of variables to four⁸⁸ and these were determined in conjunction with stakeholders. There is
11 therefore a possibility that variables not included in the meta-regression, may be contributing to the
12 high levels of heterogeneity. For example, just under half of the included studies focused on
13 populations described as high poverty, deprivation and poor health outcomes and it is possible that
14 this may explain some of the heterogeneity as breastfeeding rates typically are lower within groups
15 of high levels of deprivation in HICs.¹⁴

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

33 The third work package comprised a review of economic evidence of both trial- and model-based
34 evaluations of the incremental cost and incremental cost-effectiveness of breastfeeding support
35 interventions. Of the 39 studies identified, nine were deemed directly or partially applicable to the UK
36 system. Evidence of cost-effectiveness using the UK recommended incremental cost per QALY gained
37 was limited and inconsistent. For breastfeeding only support, one study provided evidence that the
38 estimated ICER for the intervention was not cost-effective at £56,075/QALY gained. This ICER held
39 with deterministic and probabilistic sensitivity analysis. However, there were notable limitations to
40 the model with the exclusion of costs (cost-savings) and benefits to infants beyond one-year of age
41 and clinical conditions that were excluded, such as obesity. A lack of good quality epidemiological
42 data and cost data warranted the exclusion but highlights the uncertainty in the findings and the need
43 for more robust evidence to inform future economic evaluations. There was evidence for the
44 incremental cost per additional woman breastfeeding (any or exclusive) with ICERs ranging from £67-
45 £112 from 2 weeks up to 8 weeks postpartum; and £2446-£4226 up to 6 months postpartum.
46 However, we judged the findings to be uncertain due to 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 the findings were cost-effective was unclear. Evidence for breastfeeding plus support suggested they were 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, which delivered 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 which provide breastfeeding support for women with LTCs. We identified 22 studies which 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); depression (one study). Interventions varied in terms of whether they only provided breastfeeding support or if they also provided support for the LTC. No studies were identified for women with MLTCs. In contrast to the Cochrane Review on 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 MLTCs. 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, 1.01) for stopping any breastfeeding at 6 months to RR 0.95 (95% CI 0.89, 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 long-term condition 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 socio-economic deprivation. Moreover, only a few studies had beneficial intervention effects for at least one outcome.^{185, 186, 188} It is therefore not possible to make any conclusions as to support being more or less effective in 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 MLTCs comprised a mixed methods synthesis of experiences of breastfeeding support for women with long-term conditions. The 24 included studies covered health conditions including HIV-positive, obesity and overweight, substance use, diabetes in pregnancy, women with disabilities and women with a rare genetic disorder. Key findings were that women with long-term conditions have additional breastfeeding support needs, but that breastfeeding support can be difficult to access. Women and healthcare providers reported challenges including overshadowing of breastfeeding support by condition-related support and supporters lacking in knowledge and skills. Suggested strategies to improve breastfeeding support for mothers with long-term conditions included acknowledging the influence of partners, families

1 and friends and training healthcare providers to improve their understanding of the specific
2 breastfeeding support needs of women with LTCs.

3 The third work package for women with MLTCs conducted a review of economic evidence for
4 breastfeeding support interventions for women with LTCs. Five evaluations were identified that
5 assessed cost and effect for women with a small range of health conditions: HIV, obesity, prenatal
6 opioid use, and women considered medically high-risk (maternal hypertension and diabetes prior to
7 birth). There was a lack of evidence for cost-effectiveness from full economic evaluations, with
8 limited scope in the costs and benefits valued. One CEA study reported a cost of USD \$88 per
9 increased month of exclusive breastfeeding to support women living with HIV to breastfeed, while a
10 CUA study reported promoting breastfeeding to be less costly and more effective, in terms of DALYs
11 averted, for women living with HIV in rural areas than the current scenario. A third CUA study
12 reported less cost and more effect, in terms of QALYs gained, for breastfeeding support through the
13 use of rooming-in after childbirth for women with prenatal opioid use. However, none of the studies
14 met the applicability criteria for the UK system making it likely that these conclusions of cost-
15 effectiveness would change if tested in a UK setting.

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

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

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

10.2 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 which suggested that more highly motivated mothers may benefit more from breastfeeding support.²³⁹ 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 return to employment influence breastfeeding rates²⁴⁰ and may not be considered in the interventions included. The results of this meta-analysis are similar to effect estimates that have been reported by a review looking at breastfeeding counselling Interventions.²⁴¹ Other systematic reviews looking at support interventions have shown greater effect estimates,²⁴² 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 multi-component breastfeeding support (i.e., providing different aspects of breastfeeding support in a combination of settings such as BFHI).^{40, 243, 244} We did initially aim to categorize 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 a review looking at breastfeeding support which was provided on a remote basis only.²⁴⁵ 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 on alternative methods to increase breastfeeding rates have identified a relatively small number of studies and no clear intervention effects, for example incentives²⁴⁶ or workplace-based strategies.²⁴⁷

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 which have shown effectiveness in randomised controlled trials. However, some existing reviews have looked more widely at the views and experiences of those delivering and receiving breastfeeding support interventions, and reported findings which are well aligned with our review. These included the importance of key intervention strategies perceived by women as supportive, such as those relying on the provision of both practical/technical expertise²⁴⁸⁻²⁵⁰ and emotional support/encouragement^{248, 249, 251} which are person-centred and socio-culturally specific^{249, 250, 252} as well as key implementation issues such as the importance of contextual factors.^{252, 253} In terms of the review on effectiveness of breastfeeding support for women with LTCs, our findings are consistent with a Cochrane review on support targeted at women with overweight and obesity whereby only a few small-scale studies were identified.²⁵⁴ Meta-analysis similarly identified small effect estimates and imprecision. A further systematic review which 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 have any impact on improving breastfeeding rates.²⁵⁵ To the best of our knowledge there is 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.^{256, 257} Similar to our review, Chang *et al.*,²⁵⁶ concluded that health care professionals require education to enable them to provide tailored non-judgemental breastfeeding support. Cummins *et al.*,²⁵⁸ made similar recommendations based on their systematic review of in-hospital support for women with GDM. Tanganhito *et al.*,²⁵⁹ emphasised the influence of family and friends and professional support for women with postnatal depression.

1 In terms of the review of economic evidence, our findings resonate with one previous economic
2 evidence review.²⁶⁰ This review was conducted to inform NICE guidance on postnatal care and
3 included seven studies. They judged the existing evidence to be inconclusive. While their inclusion
4 criteria had a wider remit of breastfeeding education, advice and support interventions, which
5 included financial incentives, their findings were consistent with the findings in the current review
6 for breastfeeding only support. The review highlighted similar limitations and inconsistencies
7 between studies, such as the limited time horizon, different economic outcomes estimated and the
8 different scope of costs and benefits measured and valued, which impact on the strength of any
9 conclusions.

10 10.3 Strengths and limitations

11 This study has several key strengths. First, a criticism of Systematic Reviews is a lack of uptake of
12 review findings into policy and practice,²⁶¹ however, the mixed-methods reviews and stakeholder
13 engagement have enabled us to understand how interventions could be effectively implemented
14 in practice. To address this, we included two mixed-methods syntheses, which aimed to explore how
15 such support could be implemented in the NHS for all women. We believe this is the first
16 comprehensive synthesis of evidence of effectiveness of breastfeeding support and of barriers and
17 strategies to implementing breastfeeding support for women with and without long-term
18 conditions. Furthermore, our work has been underpinned by implementation frameworks providing
19 theoretically-informed recommendations in the form of a toolkit. Finally, and perhaps most
20 importantly, it had extensive PPI and stakeholder involvement that ensured a co-created output,
21 grounded in the realities of women's experiences of breastfeeding, particularly those from socially-
22 disadvantaged groups, and NHS context and practice. Hopefully this gives a sense of ownership to
23 those involved in the project. The toolkit should be relevant and adaptable to the four UK nations.
24 Secondly, the two effectiveness reviews and meta-analyses followed Cochrane methodology to
25 ensure rigour. Thirdly, the update of Cochrane Review on breastfeeding support,⁸³ included the use
26 of a new trustworthiness checklist which helps ensure that the findings of this review are not based
27 on fraudulent data.⁸⁶

28 However, there are several limitations that should be considered. For all the systematic reviews
29 there is the potential for bias to be introduced. First, whilst we did involve two reviewers in all
30 review processes (e.g., study selection, data extraction, critical appraisal, synthesis, GRADE), these
31 judgements are subjective in nature. Second, except for the Cochrane Review, studies not published
32 in English, were excluded so there is a risk of language bias. Third, whilst we attempted to identify all
33 available evidence meeting our inclusion criteria, it is possible, that we did not identify all studies
34 and the Cochrane Review in particular showed some evidence of funnel plot asymmetry which may
35 be suggestive of publication bias. Fourth, issues in reporting meant that there was often insufficient
36 information about intervention characteristics (e.g., person providing the intervention, number of
37 contacts, theoretical basis, definitions of exclusive breastfeeding, nature of standard care). Fifth, the
38 systematic reviews on effectiveness identified a lack of digitally provided interventions. As the Covid-
39 19 pandemic has led to an increase in remotely provided maternity care,²⁴⁵ this evidence is perhaps
40 limited in a post-Covid world. Sixth, our syntheses were limited by the mixed quality and lack of
41 published process evaluations linked to effective interventions, and the relative dearth and poor
42 quality of studies of experiences of breastfeeding support for women with long-term conditions. The
43 latter body of evidence covers a very limited range of conditions with many being studies of HIV-
44 positive women in LMICs, and of obese/overweight women in HICs. We did not find any studies of
45 experiences of breastfeeding for women with mental health conditions. Seventh, there was a lack of
46 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 which look at digital support post-Covid. Ninth, a post-hoc decision was made to exclude breastfeeding initiation from the review on effectiveness of support for women with LTCs. Studies which included this as an outcome used considerably different definitions (e.g., within 1 hr vs ever) which gave rise to some nonsensical findings such as within 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 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 may be 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.

10.4 Strengths and limitations of PPI 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.²⁶² There was significant involvement of stakeholders and PPI in this project. As well as 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 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.²⁶³

Stakeholder engagement and PPI were identified as a cross-cutting theme in the study protocol, co-led by co-applicants PB and JM ensuring 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 co-morbidities. 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 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 two-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 timepoints. Holding the workshops face-to-face was a huge

1 advantage and participants provided very positive feedback about the activities and the benefits of
2 working with others on such an important topic. For many, it was their first experience of a face-to-
3 face event since the Covid-19 restrictions were lifted.

4 All those involved have been remunerated for attendance at meetings, as well as travel expenses to
5 the workshops. NHS organisations were reimbursed for releasing staff to attend meetings and
6 workshops.

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

12 There were several limitations to this component of the study. We acknowledge that recruiting
13 parents via a third sector organisation could have led to participants who were from middle class
14 backgrounds. We feel we mitigated this by conducting the focus group discussions. However, we did
15 not collect socio-demographic data from participants in parents panels and focus groups. We did not
16 recruit women to the parents panels and focus group discussions who had exclusively formula fed
17 their babies, and this could be considered a limitation. However, this was because the focus of our
18 work was on support for women who had chosen to breastfeed to continue longer, and to increase
19 exclusivity. Nevertheless, our parents panels and focus group discussion participants included
20 several women who had combined formula feeding and breastfeeding, and those who had breastfed
21 initially but had switched to formula feeding because of the challenges they faced. We believe this
22 brought a wide range of views to our work. We had originally intended to conduct the initial
23 meeting of the main study stakeholder working group face-to-face, but this was not possible due to
24 Covid-19 restrictions. A face-to-face meeting may have helped build rapport and allow for informal
25 conversations. We were aware that some participants would access meetings via their mobile
26 phones and tried to plan activities accordingly, but it was still challenging for some. Finding a
27 convenient time for meetings was difficult, and although we offered evenings for the parents panels,
28 this was not taken up. Nevertheless, some parents were disappointed that they could not attend all
29 meetings. Several members of the stakeholder working group changed roles during the study, and
30 offered replacements but this inevitably lost some continuity. The University processes for
31 reimbursement were bureaucratic and time consuming for the participants and the project
32 manager. Although we had good attendance at the workshops, many more people registered than
33 attended. The workshops were held in November 2022 at a time of high levels of winter illnesses
34 (Covid and flu), travel disruption and high demand in the NHS which all affected attendance. Some
35 members of the parents panels were disappointed not to be able to attend a workshop due to
36 distance and full-time employment. One suggestion from the parents panel was to have a combined
37 meeting with the parents panel and the stakeholder working group. We held the meetings
38 separately to ensure the parents voices were heard but will consider at least one combined meeting
39 in future projects.

40 10.5 Implications for practice

41 Considering the importance of breastfeeding for public health and the existence of high quality,
42 moderate-certainty evidence of what works to support healthy women to breastfeed, the key
43 challenge is overcoming the barriers to implementing breastfeeding support interventions. Decision-
44 makers and frontline practitioners can use the toolkit to inform implementation efforts and to
45 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. Regarding reducing inequalities, interventions must be adapted to be accessible to all women for example by ensuring venues are accessible at 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.*,²³⁹ 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 there is less research evidence available on how to provide effective breastfeeding support for women with LTCs, our stakeholder engagement and PPI work highlighted additional support needs and proposed strategies for achieving this which could be implemented. Health services could consider implementing proposals to integrate infant feeding specialist with the multi-disciplinary team to give infant-feeding 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 standards²⁶⁴ should be a minimum level for those providing care for 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 long-term conditions.

The toolkit can be used by those leading breastfeeding support services to guide implementation efforts. This will probably require 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, 265} While this needs a whole system approach beyond the scope of our work, one strategy emphasised by our project was to involve partners and wider families in breastfeeding support interventions as found in Bengough *et al.*,²⁵² Regarding reducing inequalities in breastfeeding, the current economic climate and cost-of-living crisis is likely to exacerbate inequalities requiring consideration of minimising costs to breastfeeding women such as ensuring accessible venues and 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.

10.6 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 to the large volume 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. Whilst further inspection of the Cochrane review findings did identify specific interventions which had larger effects and could form the basis of an 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, 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 MLTCs which takes account of these aspects. In particular, this work identified a very small number of studies for women with mental health conditions. In addition, whilst 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,²⁴⁵ there is also a need to consider how digital technologies could be utilised. However, both our work with stakeholders and existing research²⁶⁶ suggest that remotely provided support cannot be a replacement for face-to-face support and thus it should be provided alongside the provision of face-to-face breastfeeding support.

More research is needed on the experiences of receiving and providing breastfeeding support for women with LTCs and those with multi-morbidities.

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 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 CUA 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.

10.7 Equality, Diversity and Inclusion

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

- Our work focusses on support for breastfeeding women; women of childbearing age and pregnant women are recognised as under-served 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 of the most socially-marginalised groups in the UK) and two fathers (men are rarely included in breastfeeding research);
- The parents panel for women with MLTCs 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 socio-economically 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 focussed 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 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 which somewhat restricted those who engaged with us. In future work, we will consider different strategies to optimise diversity.

10.8 Conclusions

'Breastfeeding only' support probably has a small reduction in the number of women stopping any and exclusive breastfeeding. For 'breastfeeding plus' and for breastfeeding support for women with LTCs there is probably 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.

Acknowledgements

We would like to thank all members of our stakeholder working groups, parents panels, focus group participants and workshop attendees for their time and insights.

We also thank members of the study steering committee for their invaluable advice and encouragement

Thanks to the following people for their contribution to the project

- Karen Allum
- Sharon Carstairs
- Sushila Chowdhry
- Shadrach Dare
- Wendy Jones
- Jayne Samples
- Jonathan West
- Flavia Ximenes Vasconcelos

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

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) 24th June 2021.

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Publication

Gavine A, Shinwell SC, Buchanan P, Farre A, Wade A, Lynn F, Marshall J, Cumming SE, Dare S, McFadden A. Support for healthy breastfeeding mothers with healthy term babies. Cochrane Database of Systematic Reviews 2022, Issue 10. Art. No.: CD001141. DOI: 10.1002/14651858.CD001141.pub6.

Data-sharing statement

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

Department of Health Disclaimer

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References

1. Bowatte G, Tham R, Allen K, Tan D, Lau M, Dai X, et al. Breastfeeding and childhood acute otitis media: a systematic review and meta-analysis. *Acta Paediatrica*. 2015;104:85-95.
2. Horta B, Victora C. A systematic review on the benefits of breastfeeding on diarrhoea and pneumonia mortality. World Health Organization. 2013.
3. Li R, Ware J, Chen A, Nelson JM, Kmet JM, Parks SE, et al. Breastfeeding and post-perinatal infant deaths in the United States, a national prospective cohort analysis. *The Lancet Regional Health-Americas*. 2022;5:100094.
4. Sankar MJ, Sinha B, Chowdhury R, Bhandari N, Taneja S, Martines J, et al. Optimal breastfeeding practices and infant and child mortality: a systematic review and meta-analysis. *Acta paediatrica*. 2015;104:3-13.
5. Horta BL, Loret de Mola C, Victora CG. Long-term consequences of breastfeeding on cholesterol, obesity, systolic blood pressure and type 2 diabetes: a systematic review and meta-analysis. *Acta paediatrica*. 2015;104:30-7.
6. Peres KG, Cascaes AM, Nascimento GG, Victora CG. Effect of breastfeeding on malocclusions: a systematic review and meta-analysis. *Acta Paediatrica*. 2015;104:54-61.
7. Tham R, Bowatte G, Dharmage SC, Tan DJ, Lau MX, Dai X, et al. Breastfeeding and the risk of dental caries: a systematic review and meta-analysis. *Acta paediatrica*. 2015;104:62-84.
8. Heikkilä K, Kelly Y, Renfrew MJ, Sacker A, Quigley MA. Breastfeeding and educational achievement at age 5. *Maternal & child nutrition*. 2014;10(1):92-101.
9. Heikkilä K, Sacker A, Kelly Y, Renfrew MJ, Quigley MA. Breast feeding and child behaviour in the Millennium Cohort Study. *Archives of disease in childhood*. 2011;96(7):635-42.
10. Horta BL, Loret de Mola C, Victora CG. Breastfeeding and intelligence: a systematic review and meta-analysis. *Acta paediatrica*. 2015;104:14-9.
11. Chowdhury R, Sinha B, Sankar MJ, Taneja S, Bhandari N, Rollins N, et al. Breastfeeding and maternal health outcomes: a systematic review and meta-analysis. *Acta paediatrica*. 2015;104:96-113.
12. Rameez RM, Sadana D, Kaur S, Ahmed T, Patel J, Khan MS, et al. Association of maternal lactation with diabetes and hypertension: a systematic review and meta-analysis. *JAMA Network Open*. 2019;2(10):e1913401.
13. Tschiderer L, Seekircher L, Kunutsor SK, Peters SA, O'Keeffe LM, Willeit P. Breastfeeding is associated with a reduced maternal cardiovascular risk: Systematic review and meta-analysis involving data from 8 studies and 1 192 700 parous women. *Journal of the American Heart Association*. 2022;11(2):e022746.
14. Victora CG, Bahl R, Barros AJ, França GV, Horton S, Krasevec J, et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. *The Lancet*. 2016;387(10017):475-90.
15. NHS. Benefits of breastfeeding 2020 [updated 16 Jan 2023; cited 2023 Jan 16th]. Available from: <https://www.nhs.uk/conditions/baby/breastfeeding-and-bottle-feeding/breastfeeding/benefits/>
16. World Health Organization. Global strategy for infant and young child feeding. Geneva: World Health Organization; 2003. Report No.: 9241562218.
17. Rollins NC, Bhandari N, Hajeerhoy N, Horton S, Lutter CK, Martines JC, et al. Breastfeeding 2: why invest, and what it will take to improve breastfeeding practices. *Lancet*. 2016;387(10017):491-504.
18. Bartick MC, Schwarz EB, Green BD, Jegier BJ, Reinhold AG, Colaizy TT, et al. Suboptimal breastfeeding in the United States: Maternal and pediatric health outcomes and costs. *Maternal & child nutrition*. 2017;13(1):e12366.
19. van Tulleken C. Overdiagnosis and industry influence: how cow's milk protein allergy is extending the reach of infant formula manufacturers. *Bmj*. 2018;363.
20. Joffe N, Webster F, Shenker N. Support for breastfeeding is an environmental imperative. *British Medical Journal Publishing Group*; 2019.

21. Karlsson JO, Garnett T, Rollins NC, Rööös E. The carbon footprint of breastmilk substitutes in comparison with breastfeeding. *Journal of Cleaner Production*. 2019;222:436-45.
22. Office for Health Improvement and Disparities. Fingertips public health data: Child and maternal health 2022 [cited 2023 Jan 17th]. Available from: <https://fingertips.phe.org.uk/profile/child-health-profiles/data#page/1/gid/1938133228>.
23. Welsh Government. A review of breastfeeding support and practices in the maternity and early years settings in Wales 2018 [cited 2023 Jan 17th]. Available from: <https://gov.wales/sites/default/files/publications/2019-03/a-review-of-breastfeeding-support-and-practices-in-the-maternity-and-early-years-settings-in-wales.pdf>
24. Information Services Division. Infant feeding statistics Scotland: financial year 2018/19 2017 [cited 2023 Jan 17th]. Available from: <https://www.isdscotland.org/Health-Topics/Child-Health/Publications/2019-10-29/2019-10-29-Infant-Feeding-Report.pdf>.
25. Public Health Agency. Health Intelligence Briefing: Breastfeeding in Northern Ireland 2021 [cited 2023 Jan 17th]. Available from: <https://www.publichealth.hscni.net/sites/default/files/2021-11/HI%20Brief%20Breastfeeding%202021%20FINAL%20Nov%2021.pdf>.
26. McAndrew F, Thompson J, Fellows L, Large A, Speed M, Renfrew MJ. Infant feeding survey 2010. 2012. Contract No.: 1.
27. Brown A, Rance J, Bennett P. Understanding the relationship between breastfeeding and postnatal depression: the role of pain and physical difficulties. *Journal of advanced nursing*. 2016;72(2):273-82.
28. Gregory EF, Butz AM, Ghazarian SR, Gross SM, Johnson SB. Are unmet breastfeeding expectations associated with maternal depressive symptoms? *Academic pediatrics*. 2015;15(3):319-25.
29. Theurich MA, Davanzo R, Busck-Rasmussen M, Díaz-Gómez NM, Brennan C, Kylberg E, et al. Breastfeeding rates and programs in Europe: a survey of 11 national breastfeeding committees and representatives. *Journal of Pediatric Gastroenterology and Nutrition*. 2019;68(3):400-7.
30. Health Service Executive. Irish maternity indicator system: National Report 2019. 2020.
31. UNICEF. Protecting health and saving lives: a call to action. 2016.
32. Brown A, Shenker N. Experiences of breastfeeding during COVID-19: Lessons for future practical and emotional support. *Maternal & child nutrition*. 2021;17(1):e13088.
33. Grant A, McEwan K, Tedstone S, Greene G, Copeland L, Hunter B, et al. Availability of breastfeeding peer support in the United Kingdom: A cross-sectional study. *Maternal & child nutrition*. 2018;14(1):e12476.
34. Cook EJ, Powell F, Ali N, Penn-Jones C, Ochieng B, Randhawa G. Improving support for breastfeeding mothers: a qualitative study on the experiences of breastfeeding among mothers who reside in a deprived and culturally diverse community. *International Journal for Equity in Health*. 2021;20:1-14.
35. McFadden A, Toole G. Exploring women's views of breastfeeding: a focus group study within an area with high levels of socio-economic deprivation. *Maternal & child nutrition*. 2006;2(3):156-68.
36. Hunt L, Thomson G, Whittaker K, Dykes F. Adapting breastfeeding support in areas of socio-economic deprivation: a case study approach. *International Journal for Equity in Health*. 2021;20(1):1-13.
37. Rayment J, McCourt C, Vaughan L, Christie J, Trenchard-Mabere E. Bangladeshi women's experiences of infant feeding in the London Borough of Tower Hamlets. *Maternal & Child Nutrition*. 2016;12(3):484-99.
38. McFadden A, Renfrew MJ, Atkin K. Does cultural context make a difference to women's experiences of maternity care? A qualitative study comparing the perspectives of breast-feeding women of Bangladeshi origin and health practitioners. *Health Expectations*. 2013;16(4):e124-e35.
39. Haroon S, Das JK, Salam RA, Imdad A, Bhutta ZA. Breastfeeding promotion interventions and breastfeeding practices: a systematic review. *BMC public health*. 2013;13(3):1-18.

40. Sinha B, Chowdhury R, Sankar MJ, Martinez J, Taneja S, Mazumder S, et al. Interventions to improve breastfeeding outcomes: A systematic review and meta-analysis. *Acta paediatrica*. 2015;104:114-34.
41. 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 of Systematic Reviews*. 2017(2).
42. Kim SK, Park S, Oh J, Kim J, Ahn S. Interventions promoting exclusive breastfeeding up to six months after birth: A systematic review and meta-analysis of randomized controlled trials. *International Journal of Nursing Studies*. 2018;80:94-105.
43. Hoddinott P, Britten J, Pill R. Why do interventions work in some places and not others: a breastfeeding support group trial. *Social science & medicine*. 2010;70(5):769-78.
44. Hoddinott P, Seyara R, Marais D. Global evidence synthesis and UK idiosyncrasy: why have recent UK trials had no significant effects on breastfeeding rates? *Maternal & Child Nutrition*. 2011;7(3):221.
45. Jolly K, Ingram L, Khan KS, Deeks JJ, Freemantle N, MacArthur C. Systematic review of peer support for breastfeeding continuation: metaregression analysis of the effect of setting, intensity, and timing. *Bmj*. 2012;344.
46. Clarke JL, Ingram J, Johnson D, Thomson G, Trickey H, Dombrowski SU, et al. An assets-based intervention before and after birth to improve breastfeeding initiation and continuation: the ABA feasibility RCT. *Public Health Research*. 2020;8(7).
47. Paranjothy S, Copeland L, Merrett L, Grant A, Phillips R, Gobat N, et al. A novel peer-support intervention using motivational interviewing for breastfeeding maintenance: a UK feasibility study. *Health Technology Assessment (Winchester, England)*. 2017;21(77):1.
48. NHS England. Better Births. Improving Outcomes of Maternity Services in England. A Five Year Forward View for Maternity Care. London; 2016.
49. Jølling LR, Nielsen J, Kesmodel US, Nielsen RG, Beck-Nielsen SS, Nørgård BM. Prevalence of maternal chronic diseases during pregnancy—a nationwide population based study from 1989 to 2013. *Acta obstetrica et gynecologica Scandinavica*. 2016;95(11):1295-304.
50. Nishikawa E, Oakley L, Seed PT, Doyle P, Oteng-Ntim E. Maternal BMI and diabetes in pregnancy: Investigating variations between ethnic groups using routine maternity data from London, UK. *PLoS One*. 2017;12(6):e0179332.
51. Sultan AA, West J, Ban L, Humes D, Tata LJ, Fleming KM, et al. Adverse pregnancy outcomes among women with inflammatory bowel disease: a population-based study from England. *Inflammatory bowel diseases*. 2016;22(7):1621-30.
52. RCOG. Epilepsy in Pregnancy. Green-top Guideline No. 68. 2016.
53. Fallon V, Davies SM, Silverio SA, Jackson L, De Pascalis L, Harrold JA. Psychosocial experiences of postnatal women during the COVID-19 pandemic. A UK-wide study of prevalence rates and risk factors for clinically relevant depression and anxiety. *Journal of Psychiatric Research*. 2021;136:157-66.
54. Farrar D, Simmonds M, Griffin S, Duarte A, Lawlor DA, Sculpher M, et al. The identification and treatment of women with hyperglycaemia in pregnancy: an analysis of individual participant data, systematic reviews, meta-analyses and an economic evaluation. *Health technology assessment*. 2016;20(86):1-348.
55. Vounzoulaki E, Khunti K, Abner SC, Tan BK, Davies MJ, Gillies CL. Progression to type 2 diabetes in women with a known history of gestational diabetes: systematic review and meta-analysis. *Bmj*. 2020;369.
56. Head A, Fleming K, Kypridemos C, Schofield P, Pearson-Stuttard J, O'Flaherty M. Inequalities in incident and prevalent multimorbidity in England, 2004–19: a population-based, descriptive study. *The Lancet Healthy Longevity*. 2021;2(8):e489-e97.

57. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. *The Lancet*. 2012;380(9836):37-43.
58. Lee SI, Azcoaga-Lorenzo A, Agrawal U, Kennedy JI, Fagbamigbe AF, Hope H, et al. Epidemiology of pre-existing multimorbidity in pregnant women in the UK in 2018: a cross-sectional study. *The Lancet*. 2021;398:S7.
59. MuM PreDiCT. List of Conditions 2022 [cited 2023 Jan 17th]. Available from: <https://mumpredict.org/portfolio/shared-findings/>.
60. Taskforce on Multiple Conditions. "Just one thing after another" Living with multiple conditions. 2018.
61. Harrison S, Ayers S, Quigley M, Stein A, Alderdice F. Prevalence and factors associated with postpartum posttraumatic stress in a population-based maternity survey in England. *Journal of Affective Disorders*. 2021;279:749-56.
62. Šumilo D, Kurinczuk JJ, Redshaw ME, Gray R. Prevalence and impact of disability in women who had recently given birth in the UK. *BMC pregnancy and childbirth*. 2012;12(1):1-6.
63. Brown J, Ceysens G, Boulvain M. Oral anti-diabetic pharmacological therapies for the treatment of women with gestational diabetes *Cochrane Database of Systematic Reviews*. 2017(6).
64. Bromley R, Weston J, Adab N, Greenhalgh J, Sanniti A, McKay AJ, et al. Treatment for epilepsy in pregnancy: neurodevelopmental outcomes in the child. *Cochrane Database of Systematic Reviews*. 2014(10).
65. Dennis CL, Dowswell T. Psychosocial and psychological interventions for preventing postpartum depression. *Cochrane database of systematic reviews*. 2013(2).
66. Plachcinski R, Moss N. Evidently Cochrane: Contemplating pregnancy with long-term health conditions: *Cochrane UK*; 2021 [cited 2023 Feb 23rd]. Available from: <https://www.evidentlycochrane.net/contemplating-pregnancy-with-long-term-health-conditions/>.
67. Sokou R, Parastatidou S, Iliodromiti Z, Lampropoulou K, Vrachnis D, Boutsikou T, et al. Knowledge Gaps and Current Evidence Regarding Breastfeeding Issues in Mothers with Chronic Diseases. *Nutrients*. 2023;15(13):2822.
68. Scime NV, Patten SB, Tough SC, Chaput KH. Maternal chronic disease and breastfeeding outcomes: a Canadian population-based study. *The Journal of Maternal-Fetal & Neonatal Medicine*. 2022;35(6):1148-55.
69. Johnson EL, Burke AE, Wang A, Pennell PB. Unintended pregnancy, prenatal care, newborn outcomes, and breastfeeding in women with epilepsy. *Neurology*. 2018;91(11):e1031-e9.
70. Ince-Askan H, Hazes JM, Dolhain RJ. Breastfeeding among women with rheumatoid arthritis compared with the general population: results from a nationwide prospective cohort study. *The Journal of rheumatology*. 2019;46(9):1067-74.
71. Williams D, Webber J, Pell B, Grant A, Sanders J, Choy E, et al. "Nobody knows, or seems to know how rheumatology and breastfeeding works": Women's experiences of breastfeeding whilst managing a long-term limiting condition – A qualitative visual methods study. *Midwifery*. 2019;78:91-6.
72. Renfrew MJ, Pokhrel S, Quigley M, McCormick F, Fox-Rushby J, Dodds R, et al. Preventing disease and saving resources: the potential contribution of increasing breastfeeding rates in the UK. 2012.
73. Ahsan S, Jain S, Walters DD. The new cost of not breastfeeding tool 2022 [cited 2023 Sept 5th]. Available from: <https://www.aliveandthrive.org/en/the-new-cost-of-not-breastfeeding-tool>.
74. Office for National Statistics. Gross National Income: Current price: Seasonally adjusted £m. UK Economic Accounts time series (UKEA) 2023 [cited 2023 Sept 5th].
75. National Institute for Health and Care Excellence. BNF Child Specialised formulas: infant and child 2023 [cited 2023 Aug 25th]. Available from: <https://bnfc.nice.org.uk/borderline-substances/specialised-formulas/specialised-formulas-infant-and-child/>

76. Hickey G, Brearley S, Coldham T, Denegri S, Green G, Staniszewska S, et al. Guidance on co-producing a research project. Southampton; 2018.
77. Pollock A, Campbell P, Struthers C, Synnot A, Nunn J, Hill S, et al. Stakeholder involvement in systematic reviews: a scoping review. *Systematic reviews*. 2018;7:1-26.
78. Boote J, Baird W, Sutton A. Involving the public in systematic reviews: a narrative review of organizational approaches and eight case examples. *Journal of comparative effectiveness research*. 2012;1(5):409-20.
79. Pollock A, Campbell P, Struthers C, Synnot A, Nunn J, Hill S, et al. Development of the ACTIVE framework to describe stakeholder involvement in systematic reviews. *Journal of health services research & policy*. 2019;24(4):245-55.
80. Maxey D, Kezar A. Leveraging the Delphi technique to enrich knowledge and engage educational policy problems. *Educational Policy*. 2016;30(7):1042-70.
81. Schloemer T, Schröder-Bäck P. Criteria for evaluating transferability of health interventions: a systematic review and thematic synthesis. *Implementation Science*. 2018;13:1-17.
82. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation science*. 2015;10(1):1-14.
83. Gavine A, Shinwell SC, Buchanan P, Farre A, Wade A, Lynn F, et al. Support for healthy breastfeeding mothers with healthy term babies. *Cochrane Database of Systematic Reviews*. 2022(10).
84. Covidence systematic review software. Melbourne, Australia: Veritas Health Innovation; 2022.
85. Schünemann H, Brożek J, Guyatt G, Oxman A, editors. GRADE handbook for grading quality of evidence and strength of recommendations. Updated October 2013.: The GRADE Working Group; 2013.
86. Alfirevic Z, Kellie F, Stewart F, Jones L, Hampson L, on behalf of Pregnancy and Childbirth Editorial Board. Identifying and handling potentially untrustworthy trials in Pregnancy and Childbirth *Cochrane Reviews* 2021.
87. Higgins JP, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al. *Cochrane Handbook for Systematic Reviews of Interventions* version 6.3 (updated February 2022): Cochrane; 2022.
88. Deeks JJ, Higgins JP, Altman DG. Chapter 10: Analysing data and undertaking meta-analyses. In: Higgins JP, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al., editors. *Cochrane Handbook for Systematic Reviews of Interventions* version 6.3 (updated February 2022): Cochrane; 2022.
89. Shepherd J, Kavanagh J, Picot J, Cooper K, Harden A, Barnett-Page E, et al. The effectiveness and cost-effectiveness of behavioural interventions for the prevention of sexually transmitted infections in young people aged 13-19: a systematic review and economic evaluation. *Health technology assessment (Winchester, England)*. 2010;14(7):1-206, iii.
90. Popay J, Roberts H, Sowden A, Petticrew M, Arai L, Rodgers M, et al. Guidance on the conduct of narrative synthesis in systematic reviews. 2006. Contract No.: 1.
91. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. *BMC Medical Research Methodology*. 2008;8(1):45.
92. Damschroder LJ, Reardon CM, Widerquist MAO, Lowery J. The updated Consolidated Framework for Implementation Research based on user feedback. *Implementation Science*. 2022;17(1):1-16.
93. Andaya E, Bonuck K, Barnett J, Lischewski-Goel J. Perceptions of Primary Care-Based Breastfeeding Promotion Interventions: Qualitative Analysis of Randomized Controlled Trial Participant Interviews. *Breastfeeding Medicine*. 2012;7(6):417-22.
94. Daniels K, Nor B, Jackson D, Ekström E-C, Doherty T. Supervision of community peer counsellors for infant feeding in South Africa: an exploratory qualitative study. *Human Resources for Health*. 2010;8(1):6.

95. Nankunda J, Tumwine JK, Soltvedt Å, Semiyaga N, Ndeezi G, Tylleskär T. Community based peer counsellors for support of exclusive breastfeeding: experiences from rural Uganda. *International Breastfeeding Journal*. 2006;1(1):19.
96. Nankunda J, Tylleskär T, Ndeezi G, Semiyaga N, Tumwine JK, Group ftP-ES. Establishing individual peer counselling for exclusive breastfeeding in Uganda: implications for scaling-up. *Maternal & Child Nutrition*. 2010;6(1):53-66.
97. Nkonki LL, Daniels KL, group P-Es. Selling a service: experiences of peer supporters while promoting exclusive infant feeding in three sites in South Africa. *International Breastfeeding Journal*. 2010;5(1):17.
98. Rahman A, Haq Z, Sikander S, Ahmad I, Ahmad M, Hafeez A. Using cognitive-behavioural techniques to improve exclusive breastfeeding in a low-literacy disadvantaged population: Cognitive-behavioural techniques to improve breastfeeding rates. *Maternal & Child Nutrition*. 2012;8(1):57-71.
99. Rujumba J, Ndeezi G, Nankabirwa V, Kwagala M, Mukochi M, Diallo AH, et al. "If I have money, I cannot allow my baby to breastfeed only ..." barriers and facilitators to scale-up of peer counselling for exclusive breastfeeding in Uganda. *International Breastfeeding Journal*. 2020;15(1):43.
100. Teich AS, Barnett J, Bonuck K. Women's Perceptions of Breastfeeding Barriers in Early Postpartum Period: A Qualitative Analysis Nested in Two Randomized Controlled Trials. *Breastfeeding Medicine*. 2014;9(1):9-15.
101. Ahmed AH, Ouzzani M. Interactive Web-Based Breastfeeding Monitoring: Feasibility, Usability, and Acceptability. *Journal of Human Lactation*. 2012;28(4):468-75.
102. Cramer RL, McLachlan HL, Shafiei T, Amir LH, Cullinane M, Small R, et al. Implementation and evaluation of community-based drop-in centres for breastfeeding support in Victoria, Australia. *International Breastfeeding Journal*. 2017;12(1):46.
103. Hoddinott P, Craig L, MacLennan G, Boyers D, Vale L. Process evaluation for the FEeding Support Team (FEST) randomised controlled feasibility trial of proactive and reactive telephone support for breastfeeding women living in disadvantaged areas. *BMJ Open*. 2012;2(2):e001039.
104. Nankunda J, Tumwine JK, Nankabirwa V, Tylleskär T, Group P-ES. "She would sit with me": mothers' experiences of individual peer support for exclusive breastfeeding in Uganda. *International Breastfeeding Journal*. 2010;5(1):16.
105. Bronner Y, Barber T, Vogelhut J, Resnik AK. Breastfeeding Peer Counseling: Results From the National WIC Survey. *Journal of Human Lactation*. 2001;17(2):119-25.
106. Chapman D, Damio G, Young S, Pérez-Escamilla R, editors. *Association of Degree and Timing of Exposure to Breastfeeding Peer Counseling Services with Breastfeeding Duration* 2004 2004. Boston, MA: Springer US.
107. Dennis C-L. Breastfeeding Peer Support: Maternal and Volunteer Perceptions from a Randomized Controlled Trial. *Birth*. 2002;29(3):169-76.
108. Ridgway L, Cramer R, McLachlan HL, Forster DA, Cullinane M, Shafiei T, et al. Breastfeeding Support in the Early Postpartum: Content of Home Visits in the SILC Trial. *Birth*. 2016;43(4):303-12.
109. Tylleskär T, Jackson D, Meda N, Engebretsen IMS, Chopra M, Diallo AH, et al. Exclusive breastfeeding promotion by peer counsellors in sub-Saharan Africa (PROMISE-EBF): a cluster-randomised trial. *The Lancet*. 2011;378(9789):420-7.
110. Glanville J, Paisley S. *Searching for evidence for cost-effectiveness decisions*. New York; 2010.
111. Health Nif, Care Excellence. *Developing NICE guidelines: the manual [PMG20]* National Institute for Health and Care Excellence (NICE); 2022 [cited 2023 Jan 17th]. Available from: <https://www.nice.org.uk/process/pmg20/chapter/introduction>.
112. Shemilt I, McDaid D, Marsh K, Henderson C, Bertranou E, Mallander J, et al. Issues in the incorporation of economic perspectives and evidence into Cochrane reviews. *Systematic reviews*. 2013;2:1-10.

113. Page MJ, Moher D, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. PRISMA 2020 explanation and elaboration: updated guidance and exemplars for reporting systematic reviews. *BMJ*. 2021;372.
114. Evers S, Goossens M, De Vet H, Van Tulder M, Ament A. Criteria list for assessment of methodological quality of economic evaluations: Consensus on Health Economic Criteria. *International journal of technology assessment in health care*. 2005;21(2):240-5.
115. Husereau D, Drummond M, Petrou S, Carswell C, Moher D, Greenberg D, et al. Consolidated health economic evaluation reporting standards (CHEERS) statement. *International journal of technology assessment in health care*. 2013;29(2):117-22.
116. Barnes J, Stuart J, Allen E, Petrou S, Sturgess J, Barlow J, et al. Randomized controlled trial and economic evaluation of nurse-led group support for young mothers during pregnancy and the first year postpartum versus usual care. *Trials*. 2017;18(1):1-15.
117. Hoddinott P, Britten J, Prescott GJ, Tappin D, Ludbrook A, Godden DJ. Effectiveness of policy to provide breastfeeding groups (BIG) for pregnant and breastfeeding mothers in primary care: Cluster randomised controlled trial. *BMJ*. 2009;338(7691):388-92.
118. Hoddinott P, Craig L, MacLennan G, Boyers D, Vale L. The FEeding Support Team (FEST) randomised, controlled feasibility trial of proactive and reactive telephone support for breastfeeding women living in disadvantaged areas. *BMJ Open*. 2012;2:e000652.
119. Mavranouzouli I, Varley-Campbell J, Stockton S, Francis J, Macdonald C, Sharma S, et al. The cost-effectiveness of antenatal and postnatal education and support interventions for women aimed at promoting breastfeeding in the UK. *BMC Public Health*. 2022;22(1):153.
120. Morrell CJ, Spiby H, Stewart P, Walters S, Morgan A. Costs and benefits of community postnatal support workers: a randomised controlled trial. *Health Technology Assessment (Winchester, England)*. 2000;4(6):1-100.
121. Paranjothy S, Copeland L, Merrett L, Grant A, Phillips R, Gobat N, et al. A novel peer-support intervention using motivational interviewing for breastfeeding maintenance: a UK feasibility study. *Health Technology Assessment (Winchester, England)*. 2017;21(77):1-138.
122. Spiby H, Green JM, Darwin Z, Willmot H, Knox D, McLeish J, et al. NIHR Journals Library Health Services and Delivery Research. 2015;03:03.
123. Delgado RI, Gill SL. A Microcosting Study of Establishing a Baby Café® in Texas. *Journal of Human Lactation*. 2018;34(1):77-83.
124. DelliFraine J, Langabeer J, Williams JF, Gong AK, Delgado RI, Gill SL. Cost comparison of baby friendly and non-baby friendly hospitals in the United States. *Pediatrics*. 2011;127(4):e989-94.
125. Frick KD, Pugh LC, Milligan RA. Costs related to promoting breastfeeding among urban low-income women. *Journal of obstetric, gynecologic, and neonatal nursing : JOGNN / NAACOG*. 2012;41(1):144-50.
126. Haider SJ, Chang LV, Bolton TA, Gold JG, Olson BH. An evaluation of the effects of a breastfeeding support program on health outcomes. *Health Services Research*. 2014;49(6):2017-34.
127. Mottl-Santiago J. A mixed methods economic analysis of doula-service enhanced maternity care as compared with standard maternity care. 2020.
128. Pugh LC, Milligan RA, Frick KD, Spatz D, Bronner Y. Breastfeeding duration, costs, and benefits of a support program for low-income breastfeeding women. *Birth*. 2002;29(2):95-100.
129. Wouk K, Chetwynd E, Vitaglione T, Sullivan C. Improving Access to Medical Lactation Support and Counseling: Building the Case for Medicaid Reimbursement. *Maternal & Child Health Journal*. 2017;21(4):836-44.
130. Brown V, Tan EJ, Hayes A, Baur L, Campbell K, Taylor R, et al. Cost comparison of five Australasian obesity prevention interventions for children aged from birth to two years. *Pediatric Obesity*. 2020;15(12):e12684.
131. Hayes A, Lung T, Wen LM, Baur L, Rissel C, Howard K. Economic evaluation of “healthy beginnings” an early childhood intervention to prevent obesity. *Obesity*. 2014;22(7):1709-15.

132. Tan EJ, Taylor RW, Taylor BJ, Brown V, Hayes AJ. Cost-Effectiveness of a Novel Sleep Intervention in Infancy to Prevent Overweight in Childhood. *Obesity*. 2020;28(11):2201-8.
133. Wen LM, Baur LA, Rissel C, Flood V, Simpson JM, Hayes A, et al. Healthy Beginnings Trial Phase 2 study: follow-up and cost-effectiveness analysis. *Contemporary Clinical Trials*. 2017;33(2):396-401.
134. Pramono AY, Desborough JL, Smith JP, Bourke S. The social value of implementing the ten steps to successful breastfeeding in an Indonesian hospital: A case study. *Yale Journal of Biology and Medicine*. 2021;94(3):429-58.
135. Stevens B, Guerriere D, McKeever P, Croxford R, Miller K-L, Watson-MacDonell J, et al. Economics of home vs. hospital breastfeeding support for newborns. *Journal of Advanced Nursing (Wiley-Blackwell)*. 2006;53(2):233-43.
136. Hanafin S, O'Dwyer K, Creedon M, Clune Mulvaney C. Social return on investment: PHN-facilitated breastfeeding groups in Ireland. 2018.
137. Chola L, Fadnes LT, Engebretsen IMS, Nkonki L, Nankabirwa V, Sommerfelt H, et al. Cost-effectiveness of peer counselling for the promotion of exclusive breastfeeding in Uganda. *PLoS ONE*. 2015;10(11):e0142718.
138. Chola L, Nkonki L, Kankasa C, Nankunda J, Tumwine J, Tylleskar T, et al. Cost of individual peer counselling for the promotion of exclusive breastfeeding in Uganda. *Cost Effectiveness and Resource Allocation*. 2011;9 (11).
139. George G, Mudzingwa T, Horwood C. The cost of the training and supervision of community health workers to improve exclusive breastfeeding amongst mothers in a cluster randomised controlled trial in South Africa. *BMC Health Services Research*. 2020;20(1):1-8.
140. Kimani-Murage EW, Kyobutungi C, Ezeh AC, Wekesah F, Wanjohi M, Muriuki P, et al. Effectiveness of personalised, home-based nutritional counselling on infant feeding practices, morbidity and nutritional outcomes among infants in Nairobi slums: Study protocol for a cluster randomised controlled trial. *Trials*. 2013;14(1).
141. Lamstein S, Perez-Escamilla R, Koniz-Booher P, France B, Adeyemi S, Kaligirwa C, et al. The Community Infant and Young Child Feeding Counselling Package in Kaduna State, Nigeria: A Mixed Methods Evaluation. Final Report. Arlington, VA.; 2018.
142. Lewycka S, Mwansambo C, Rosato M, Kazembe P, Phiri T, Mganga A, et al. Effect of women's groups and volunteer peer counselling on rates of mortality, morbidity, and health behaviours in mothers and children in rural Malawi (MaiMwana): a factorial, cluster-randomised controlled trial. *Lancet*. 2013;381(9879):1721-35.
143. Manasyan A, Chomba E, McClure EM, Wright LL, Krzywanski S, Carlo WA, et al. Cost-effectiveness of essential newborn care training in urban first-level facilities. *Pediatrics*. 127(5):e1176-81.
144. Nkonki LL, Daviaud E, Jackson D, Chola L, Doherty T, Chopra M, et al. Costs of promoting exclusive breastfeeding at community level in three sites in South Africa. *PLoS ONE*. 2014;9(1):e79784.
145. Wynn A, Rotheram-Borus MJ, Leibowitz AA, Weichle T, Roux II, Tomlinson M. Mentor mothers program improved child health outcomes at a relatively low cost in South Africa. *Health Affairs*. 2017;36(11):1947-55.
146. Daviaud E, Nkonki L, Ijumba P, Doherty T, Lawn JE, Owen H, et al. South-Africa (Goodstart III) trial: community-based maternal and newborn care economic analysis. *Health policy and planning*. 2017;32(suppl_1):i53-i63.
147. Nguyen TT, Hajeebhoy N, Li J, Do CT, Mathisen R, Frongillo EA. Community support model on breastfeeding and complementary feeding practices in remote areas in Vietnam: implementation, cost, and effectiveness. *International Journal for Equity in Health*. 2021;20(1):1-14.
148. Pramono A, Smith J, Desborough J, Bourke S. Social value of maintaining baby-friendly hospital initiative accreditation in Australia: case study. *International Journal for Equity in Health*. 2021;20(22).

149. Patel A, Kuhite P, Puranik A, Khan SS, Borkar J, Dhande L. Effectiveness of weekly cell phone counselling calls and daily text messages to improve breastfeeding indicators. *BMC pediatrics*. 2018;18:1-12.
150. Horton S, Sanghvi T, Phillips M, Fiedler J, Perez-Escamilla R, Lutter C, et al. Breastfeeding promotion and priority setting in health. *Health policy and planning*. 1996;11(2):156-68.
151. Silva OLO, Rea MF, Sarti FM, Buccini G. Cost-effectiveness analysis of Baby-Friendly Hospital Initiative in promotion of breast-feeding and reduction of late neonatal infant mortality in Brazil. *Public Health Nutrition*. 2021;24(8):2365-75.
152. Valdes V, Perez A, Labbok M, Pugin E, Zambrano I, Catalan S. The impact of a hospital and clinic-based breastfeeding promotion programme in a middle class urban environment. *Journal of Tropical Pediatrics*. 1993;39(3):142-51.
153. Bhutta ZA, Das JK, Rizvi A, Gaffey MF, Walker N, Horton S, et al. Evidence-based interventions for improvement of maternal and child nutrition: what can be done and at what cost? *The lancet*. 2013;382(9890):452-77.
154. Adam T, Lim SS, Mehta S, Bhutta ZA, Fogstad H, Mathai M, et al. Cost effectiveness analysis of strategies for maternal and neonatal health in developing countries. *BMJ*. 2005;331(7525):1107.
155. Hayes A, Tan E, Brown V, Taylor B, Taylor R. A sleep modification programme in early infancy is a cost-effective and affordable approach to obesity prevention in young children. *Obesity Reviews Conference: European and International Congress on Obesity, ECOICO*. 2020;21(SUPPL 1).
156. Morrell CJ. Postnatal support who wants it, what is its benefit and how much does it cost? 2002(U157214):1.
157. Rito AI, Buoncristiano M, Spinelli A, Salanave B, Kunešová M, Hejgaard T, et al. Association between characteristics at birth, breastfeeding and obesity in 22 countries: The WHO European Childhood Obesity Surveillance Initiative–COSI 2015/2017. *Obesity facts*. 2019;12(2):226-43.
158. Nguyen PTH, Pham NM, Chu KT, Van Duong D, Van Do D. Gestational diabetes and breastfeeding outcomes: a systematic review. *Asia Pacific Journal of Public Health*. 2019;31(3):183-98.
159. Finkelstein S, Keely E, Feig D, Tu X, Yasseen III A, Walker M. Breastfeeding in women with diabetes: lower rates despite greater rewards. A population-based study. *Diabetic Medicine*. 2013;30(9):1094-101.
160. Higgins J, Altman D, JAC S. Chapter 8: Assessing risk of bias in included studies. In: Higgins J, Green S, editors. *Cochrane handbook for systematic reviews of interventions version 510* (updated March 2011): The Cochrane Collaboration; 2011.
161. Stuebe AM, Bonuck K, Adatorwovor R, et al. A cluster randomized trial of tailored breastfeeding support for women with gestational diabetes. *Breastfeeding Medicine*. 2016;11(10):504-13.
162. Harbord RM, Egger M, Sterne JA. A modified test for small-study effects in meta-analyses of controlled trials with binary endpoints. *Statistics in medicine*. 2006;25(20):3443-57.
163. Sterne JA, Sutton AJ, Ioannidis JP, Terrin N, Jones DR, Lau J, et al. Recommendations for examining and interpreting funnel plot asymmetry in meta-analyses of randomised controlled trials. *BMJ*. 2011;343.
164. Review Manager (RevMan). 5.4 ed: The Cochrane Collaboration; 2020.
165. Coovadia HM, Rollins NC, Bland RM, Little K, Coutsooudis A, Bennish ML, et al. Mother-to-child transmission of HIV-1 infection during exclusive breastfeeding in the first 6 months of life: an intervention cohort study. *The Lancet*. 2007;369(9567):1107-16.
166. Steinig J, Nagl M, Linde K, Zietlow G, Kersting A. Antenatal and postnatal depression in women with obesity: a systematic review. *Archives of women's mental health*. 2017;20:569-85.
167. Chu SY, Callaghan WM, Kim SY, Schmid CH, Lau J, England LJ, et al. Maternal obesity and risk of gestational diabetes mellitus. *Diabetes care*. 2007;30(8):2070-6.
168. Fan WQ, Chan C, Paterson S, Foster K, Morrow M, Bourne D, et al. Weekly lactation consultant led telephone calls in the first month postpartum improves breast feeding rates over

standard care - a randomized controlled trial. *Journal of paediatrics and child health*. 2022;58(SUPPL 2):11.

169. Ijumba P, Doherty T, Jackson D, Tomlinson M, Sanders D, Swanevelder S, et al. Effect of an integrated community-based package for maternal and newborn care on feeding patterns during the first 12 weeks of life: a cluster-randomized trial in a South African township. *Public health nutrition*. 2015;18(14):2660-8.

170. Lewkowitz AK, López JD, Stein RI, Rhoades JS, Schulz RC, Woolfolk CL, et al. Effect of a Home-Based Lifestyle Intervention on Breastfeeding Initiation Among Socioeconomically Disadvantaged African American Women with Overweight or Obesity. *Breastfeeding Medicine*. 2018;13(6):418-25.

171. Martin J, MacDonald-Wicks L, Hure A, Smith R, Collins CE. Reducing postpartum weight retention and improving breastfeeding outcomes in overweight women: a pilot randomised controlled trial. *Nutrients*. 2015;7(3):1464-79.

172. Namale-Matovu J, Owora AH, Onyango-Makumbi C, Mubiru M, Namuli PE, Motevalli-Oliner M, et al. Comparative effects of three methods of promoting breastfeeding among human immunodeficiency virus-infected women in Uganda: a parallel randomized clinical trial. *International health*. 2018;10(6):430-41.

173. Reifsnider E, McCormick DP, Cullen KW, Todd M, Moramarco MW, Gallagher MR, et al. Randomized Controlled Trial to Prevent Infant Overweight in a High-Risk Population. *Academic Pediatrics*. 2018;18(3):324-33.

174. Rasmussen KM, Dieterich CM, Zelek ST, Altabet JD, Kjolhede CL. Interventions to increase the duration of breastfeeding in obese mothers: the bassett improving breastfeeding study. *Breastfeeding Medicine*. 2011;6:69-75.

175. Chapman DJ, Morel K, Bermudez-Milan A, et al. Breastfeeding education and support trial for overweight and obese women: a randomized trial. *Pediatrics*. 2013;131(1):e162-70.

176. Ehrlich SF, Hedderson MM, Quesenberry CP, Feng J, Brown SD, Crites Y, et al. Post-partum weight loss and glucose metabolism in women with gestational diabetes: the DEBI Study. *Diabetic medicine*. 2014;31(7):862-7.

177. Fiks AG, Gruver RS, Bishop-Gilyard CT, SuhAndrew W, KalraGurpreet K, DeRussoPatricia A, et al. A social media peer group for mothers to prevent obesity from infancy: the Grow2Gether randomized trial. *Childhood Obesity*. 2017;13(5):356-68.

178. Pezley L, Tussing-Humphreys L, Koenig MD, Maki P, Odoms-Young A, Freels S, et al. Feasibility of a Web-Based Intervention to Prevent Perinatal Depression and Promote Human Milk Feeding: Randomized Pilot Trial. *JMIR Formative Research*. 2022;6(5):e32226.

179. Bartu A, Sharp J, Ludlow J, Doherty DA. Postnatal home visiting for illicit drug-using mothers and their infants: a randomised controlled trial. *Australian & New Zealand Journal of Obstetrics & Gynaecology*. 2006;46(5):419-26.

180. Carlsen EM, Kyhnaeb A, Renault KM, Cortes D, Michaelsen KF, Pryds O. Telephone-based support prolongs breastfeeding duration in obese women: a randomized trial. *American Journal of Clinical Nutrition*. 2013;98(5):1226-32.

181. O'Brien E, O'Reilly S, Sheehy L, O'Hagan L, McGuinness D, Coughlan B, et al. Latchon: a multi-centre, randomised controlled trial of perinatal support to improve Breastfeeding outcomes in women with overweight and obesity. *Archives of disease in childhood*. 2019;104:A359-.

182. MacVicar S, Humphrey T, Forbes-McKay KE. Breastfeeding and the substance-exposed mother and baby. *Birth (Berkeley, Calif)*. 2018;45(4):450-8.

183. Reimers P, Israel-Ballard K, Craig M, Spies L, Thior I, Tanser F, et al. A Cluster Randomised Trial to Determine the Efficacy of the "Feeding Buddies" Programme in Improving Exclusive Breastfeeding Rates Among HIV-Infected Women in Rural KwaZulu-Natal, South Africa. *AIDS and behavior*. 2018;22(1):212-23.

184. Rotheram-Borus MJ, Richter LM, Van Heerden A, Van Rooyen H, Tomlinson M, Harwood JM, et al. A cluster randomized controlled trial evaluating the efficacy of peer mentors to support South African women living with HIV and their infants. *PLoS ONE*. 2014;9(1):e84867.

185. You H, Anjiang L, Jie X, Yan W, Biru L, Juan H, et al. Effects of breastfeeding education based on the self-efficacy theory on women with gestational diabetes mellitus: A CONSORT-compliant randomized controlled trial. *Medicine*. 2020;99(16):1-7.
186. Aldana-Parra F, Olaya G, Fewtrell M. Effectiveness of a new breastfeeding counselling intervention on breastfeeding prevalence, infant growth velocity and postpartum weight loss in overweight women: A randomized controlled trial. *Journal of Pediatric Gastroenterology and Nutrition*. 2022;74(2 Supplement 2):976-7.
187. Samburu BM, Young SL, Wekesah FM, Wanjohi MN, Kimiywe J, Muriuki P, et al. Effectiveness of the baby-friendly community initiative in promoting exclusive breastfeeding among HIV negative and positive mothers: a randomized controlled trial in Koibatek Sub-County, Baringo, Kenya. *International Breastfeeding Journal*. 2020;15(1):1-13.
188. Suryavanshi N, Kadam A, Gupte N, Hegde A, Kanade S, Sivalenka S, et al. A mobile health-facilitated behavioural intervention for community health workers improves exclusive breastfeeding and early infant HIV diagnosis in India: a cluster randomized trial. *Journal of the International AIDS Society*. 2020;23(7):e25555.
189. Berry DC, Hall EG, Neal MN, Adatorwovor R, Schwartz TA, Stuebe A. Results of the Optimizing Outcomes in Women with Gestational Diabetes Mellitus and Their Infants, a Cluster Randomized, Controlled Pilot Study: Lessons Learned. *Journal of National Black Nurses' Association: JNBNA*. 2016;27(2):1-10.
190. Ferrara A, Hedderson MM, Albright CL, Ehrlich SF, Quesenberry CP, Peng T, et al. A pregnancy and postpartum lifestyle intervention in women with gestational diabetes mellitus reduces diabetes risk factors: a feasibility randomized control trial. *Diabetes care*. 2011;34(7):1519-25.
191. Critical Appraisal Skills Programme. 2022 [cited 2023 March 1st]. Available from: <https://casp-uk.net/casp-tools-checklists/>.
192. Downes M, Brennan M, Williams H, Dean R. Development of a critical appraisal tool to assess the quality of cross-sectional studies (AXIS) *BMJ Open*. 2016 Dec 08; 6 (12): e011458. doi: 10.1136/bmjopen-2016-011458.
193. Acheampong AK, Naab F, Kwashie A. The voices that influence HIV-positive mothers' breastfeeding practices in an urban Ghanaian society. *Journal of Human Lactation*. 2018;34(1):176-83.
194. Andrews EE, Powell RM, Ayers KB. Experiences of Breastfeeding among Disabled Women. *Women's Health Issues*. 2021;31(1):82-9.
195. Demirci JR, Bogen DL, Klionsky Y. Breastfeeding and Methadone Therapy: The Maternal Experience. *Substance Abuse*. 2015;36(2):203-8.
196. Dieterich R, Chang J, Danford C, Scott PW, Wend C, Demirci J. She "didn't see my weight; she saw me, a mom who needed help breastfeeding": Perceptions of perinatal weight stigma and its relationship with breastfeeding experiences. *Journal of Health Psychology*. 2022;27(5):1027-38.
197. Garner CD, Ratcliff SL, Devine CM, al. e. Health professionals' experiences providing breastfeeding-related care for obese women. *Breastfeeding Medicine*. 2014;9(10):503-9.
198. Hazemba AN, Ncama BP, Sithole SL. Promotion of exclusive breastfeeding among HIV-positive mothers: an exploratory qualitative study. *International Breastfeeding Journal*. 2016;11:1-10.
199. Howard MB, Wachman E, Levesque EM, Schiff DM, Kistin CJ, Parker MG. The joys and frustrations of breastfeeding and rooming-in among mothers with opioid use disorder: A qualitative study. *Hospital Pediatrics*. 2018;8(12):761-8.
200. Israel-Ballard K, Waithaka M, Greiner T. Infant feeding counselling of HIV-infected women in two areas in Kenya in 2008. *International Journal of STD & AIDS*. 2014;25(13):921-8.
201. Jagiello KP, Azulay Chertok IR. Women's Experiences With Early Breastfeeding After Gestational Diabetes. *JOGNN: Journal of Obstetric, Gynecologic & Neonatal Nursing*. 2015;44(4):500-9.

202. Keely A, Lawton J, Swanson V, Denison FC. Barriers to breast-feeding in obese women: A qualitative exploration. *Midwifery*. 2015;31(5):532-9.
203. MacVicar S, Humphrey T, Forbes-McKay KE. Breastfeeding support and opiate dependence: A think aloud study. *Midwifery*. 2017;50:239-45.
204. Nieuwoudt S, Manderson L. Frontline health workers and exclusive breastfeeding guidelines in an HIV endemic South African community: a qualitative exploration of policy translation. *International Breastfeeding Journal*. 2018;13(1):N.PAG-N.PAG.
205. Nor B, Ahlberg BM, Doherty T, al. e. Mother's perceptions and experiences of infant feeding within a community-based peer counselling intervention in South Africa. *Maternal & Child Nutrition*. 2012;8(4):448-58.
206. Nor B, Zembe Y, Daniels K, Doherty T, Jackson D, Ahlberg BM, et al. 'Peer but not peer': Considering the context of infant feeding peer counseling in a high HIV prevalence area. *Journal of Human Lactation*. 2009;25(4):427-34.
207. O'Reilly SL, Conway MC, O'Brien EC, al. e. Exploring Successful Breastfeeding Behaviors Among Women Who Have High Body Mass Indices. *Journal of Human Lactation*. 2022.
208. Powell RM, Mitra M, Smeltzer SC, al. e. Breastfeeding among women with physical disabilities in the United States. *Journal of Human Lactation*. 2018;34(2):253-61.
209. Hicks J, Morse E, Wyant DK. Barriers and Facilitators of Breastfeeding Reported by Postpartum Women in Methadone Maintenance Therapy. *Breastfeeding Medicine*. 2018;13(4):259-65.
210. Matsunaga M, Kataoka Y, Igarashi Y, al. e. Breastfeeding support and barriers to women with gestational diabetes mellitus: a nationwide cross-sectional survey of hospitals in Japan. *BMC Pregnancy and Childbirth*. 2021;21(555).
211. Rasmussen KM, Lee VE, Ledkovsky TB, al. e. A description of lactation counseling practices that are used with obese mothers. *Journal of Human Lactation*. 2006;22(3):322-7.
212. Laws T, Pelentsov L, Steen M, al. e. Informing the midwife on the rare genetic disorders and their effects on mothers breastfeeding - a mixed methods study. *Evidence Based Midwifery*. 2016;14(1):11-5.
213. Fadnes LT, Engebretsen IM, Moland KM, Nankunda J, Tumwine JK, Tylleskar T. Infant feeding counselling in Uganda in a changing environment with focus on the general population and HIV-positive mothers - a mixed method approach. *BMC Health Services Research*. 2010;10:260.
214. Flax V, Hamela G, Mofolo I, Hosseinipour M, Hoffman I, Maman S. Infant and Young Child Feeding Counseling, Decision-Making, and Practices Among HIV-Infected Women in Malawi's Option B+ Prevention of Mother-to-Child Transmission Program: A Mixed Methods Study. *AIDS & Behavior*. 2016;20(11):2612-23.
215. MacVicar S, Humphrey T, Forbes-McKay KE. Breastfeeding and the substance-exposed mother and baby. *Birth*. 2018;45(4):450-8.
216. Misita D, Yamamoto JM, Yuan Y, Donovan LE, Bell RC, Jarman M. An exploration of differences in infant feeding practices among women with and without diabetes in pregnancy: A mixed-methods study. *Diabetic Medicine*. 2021;38(11):e14635.
217. Bick D, Taylor C, Bhavnani V, Healey A, Seed P, Roberts S, et al. Lifestyle information and commercial weight management groups to support maternal postnatal weight management and positive lifestyle behaviour: the SWAN feasibility randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2020;127(5):636-45.
218. Avram CM, Yieh L, Dukhovny D, Caughey AB. A cost-effectiveness analysis of rooming-in and breastfeeding in neonatal opioid withdrawal. *American journal of perinatology*. 2020;37(01):001-7.
219. Desmond C, Bland RM, Boyce G, Coovadia HM, Coutsoydis A, Rollins N, et al. Scaling-up exclusive breastfeeding support programmes: the example of KwaZulu-Natal. *PLoS One*. 2008;3(6):e2454.

220. Maredza M, Bertram MY, Saloojee H, Chersich MF, Tollman SM, Hofman KJ. Cost-effectiveness analysis of infant feeding strategies to prevent mother-to-child transmission of HIV in South Africa. *African Journal of AIDS Research*. 2013;12(3):151-60.
221. Bick D, Taylor C, Bhavnani V, Healey A, Seed P, Roberts S, et al. Lifestyle information and access to a commercial weight management group to promote maternal postnatal weight management and positive lifestyle behaviour: the SWAN feasibility RCT. Southampton; 2020. Report No.: 2050-4381 Contract No.: 9.
222. National Institute of Nursing Research. Evaluation of a Community Health Nurse/Peer Counselor Program to Help Low-Income Women Breastfeed Longer 2006 [cited 2023 Sept 5th]. Available from: <https://ClinicalTrials.gov/show/NCT00608088>.
223. Bonuck K, Stuebe A, Barnett J, Labbok MH, Fletcher J, Bernstein PS. Effect of primary care intervention on breastfeeding duration and intensity. *American Journal of Public Health*. 2014;104(S1):S119-S27.
224. Cavalcanti DS, Cabral CS, de Toledo Vianna RP, Osório MM. Online participatory intervention to promote and support exclusive breastfeeding: Randomized clinical trial. *Maternal & child nutrition*. 2019;15(3):e12806.
225. Fu I, Fong D, Heys M, Lee I, Sham A, Tarrant M. Professional breastfeeding support for first-time mothers: A multicentre cluster randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2014;121(13):1673-83.
226. Hoddinott P, Craig L, MacLennan G, Boyers D, Vale L. The FEeding Support Team (FEST) randomised, controlled feasibility trial of proactive and reactive telephone support for breastfeeding women living in disadvantaged areas. *BMJ open*. 2012;2(2):e000652.
227. McLachlan HL, Forster DA, Amir LH, Cullinane M, Shafiei T, Watson LF, et al. Supporting breastfeeding In Local Communities (SILC) in Victoria, Australia: a cluster randomised controlled trial. *BMJ open*. 2016;6(2):e008292.
228. Unger J, Ronen K, Perrier T, DeRenzi B, Slyker J, Drake A, et al. Short message service communication improves exclusive breastfeeding and early postpartum contraception in a low-to middle-income country setting: a randomised trial. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2018;125(12):1620-9.
229. Wu Q, Huang Y, Liao Z, van Velthoven MH, Wang W, Zhang Y. Effectiveness of WeChat for improving exclusive breastfeeding in Huzhu County China: randomized controlled trial. *Journal of medical Internet research*. 2020;22(12):e23273.
230. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation science*. 2009;4(1):1-15.
231. Lancsar E, Louviere J. Conducting discrete choice experiments to inform healthcare decision making: a user's guide. *Pharmacoeconomics*. 2008;26:661-77.
232. Marschak J. Binary choice constraints on random utility indications. In: Arrow K, editor. *Stanford Symposium on Mathematical Methods in the Social Sciences*: Stanford University Press. Stanford, CA: Stanford University Press; 1960.
233. Lancaster KJ. A new approach to consumer theory. *Journal of political economy*. 1966;74(2):132-57.
234. McFadden D. Economic choices. *American economic review*. 2001;91(3):351-78.
235. Clark MD, Determann D, Petrou S, Moro D, de Bekker-Grob EW. Discrete choice experiments in health economics: a review of the literature. *Pharmacoeconomics*. 2014;32:883-902.
236. Johnson FR, Lancsar E, Marshall D, Kilambi V, Mühlbacher A, Regier DA, et al. Constructing experimental designs for discrete-choice experiments: report of the ISPOR conjoint analysis experimental design good research practices task force. *Value in health*. 2013;16(1):3-13.
237. Street DJ, Burgess L. *The construction of optimal stated choice experiments: Theory and methods*: John Wiley & Sons; 2007.

238. Croissant Y. Estimation of random utility models in R: the mlogit package. *Journal of Statistical Software*. 2020;95:1-41.
239. Trickey H, Thomson G, Grant A, Sanders J, Mann M, Murphy S, et al. A realist review of one-to-one breastfeeding peer support experiments conducted in developed country settings. *Maternal & Child Nutrition*. 2018;14(1):e12559.
240. Alianmoghaddam N, Phibbs S, Benn C. Reasons for stopping exclusive breastfeeding between three and six months: a qualitative study. *Journal of pediatric nursing*. 2018;39:37-43.
241. McFadden A, Siebelt L, Marshall JL, Gavine A, Girard L-C, Symon A, et al. Counselling interventions to enable women to initiate and continue breastfeeding: a systematic review and meta-analysis. *International Breastfeeding Journal*. 2019;14(1):1-19.
242. Brockway M, Benzie K, Hayden KA. Interventions to improve breastfeeding self-efficacy and resultant breastfeeding rates: a systematic review and meta-analysis. *Journal of Human Lactation*. 2017;33(3):486-99.
243. Beake S, Pellowe C, Dykes F, Schmied V, Bick D. A systematic review of structured compared with non-structured breastfeeding programmes to support the initiation and duration of exclusive and any breastfeeding in acute and primary health care settings. *Maternal & child nutrition*. 2012;8(2):141-61.
244. Pérez-Escamilla R, Martinez JL, Segura-Pérez S. Impact of the Baby-friendly Hospital Initiative on breastfeeding and child health outcomes: a systematic review. *Maternal & child nutrition*. 2016;12(3):402-17.
245. Gavine A, Marshall J, Buchanan P, Cameron J, Leger A, Ross S, et al. Remote provision of breastfeeding support and education: Systematic review and meta-analysis. *Maternal & Child Nutrition*. 2022;18(2):e13296.
246. Moran VH, Morgan H, Rothnie K, MacLennan G, Stewart F, Thomson G, et al. Incentives to promote breastfeeding: a systematic review. *Pediatrics*. 2015;135(3):e687-e702.
247. Vilar-Compte M, Hernández-Cordero S, Ancira-Moreno M, Burrola-Méndez S, Ferre-Eguiluz I, Omaña I, et al. Breastfeeding at the workplace: a systematic review of interventions to improve workplace environments to facilitate breastfeeding among working women. *International journal for equity in health*. 2021;20(1):1-21.
248. Chang Y-S, Beake S, Kam J, Lok KY-W, Bick D. Views and experiences of women, peer supporters and healthcare professionals on breastfeeding peer support: A systematic review of qualitative studies. *Midwifery*. 2022;108:103299.
249. MacVicar S, Kirkpatrick P, Humphrey T, Forbes-McKay KE. Supporting breastfeeding establishment among socially disadvantaged women: A meta-synthesis. *Birth*. 2015;42(4):290-8.
250. Schmied V, Beake S, Sheehan A, McCourt C, Dykes F. Women's perceptions and experiences of breastfeeding support: a metasynthesis. *Birth*. 2011;38(1):49-60.
251. Leeming D, Marshall J, Hinsliff S. Self-conscious emotions and breastfeeding support: A focused synthesis of UK qualitative research. *Maternal & Child Nutrition*. 2022;18(1):e13270.
252. Bengough T, Dawson S, Cheng HL, McFadden A, Gavine A, Rees R, et al. Factors that influence women's engagement with breastfeeding support: A qualitative evidence synthesis. *Maternal & Child Nutrition*. 2022;18(4):e13405.
253. Chesnel MJ, Healy M, McNeill J. Experiences that influence how trained providers support women with breastfeeding: A systematic review of qualitative evidence. *Plos one*. 2022;17(10):e0275608.
254. Fair FJ, Ford GL, Soltani H. Interventions for supporting the initiation and continuation of breastfeeding among women who are overweight or obese. *Cochrane Database of Systematic Reviews*. 2019(9).
255. Reichental ZL, O'Brien VM, O'Reilly SL. Interventions to support women with overweight or obesity or gestational diabetes mellitus to initiate and continue breastfeeding: Systematic review and meta-analysis. *Obesity Reviews*. 2022;23(3):e13371.

256. Chang YS, Glaria AA, Davie P, Beake S, Bick D. Breastfeeding experiences and support for women who are overweight or obese: A mixed-methods systematic review. *Maternal & Child Nutrition*. 2020;16(1):e12865.
257. Lyons S, Currie S, Peters S, Lavender T, Smith DM. The perceptions and experiences of women with a body mass index ≥ 30 kg m² who breastfeed: A meta-synthesis. *Maternal & Child Nutrition*. 2019;15(3):e12813.
258. Cummins L, Meedya S, Wilson V. Factors that positively influence in-hospital exclusive breastfeeding among women with gestational diabetes: An integrative review. *Women and Birth*. 2022;35(1):3-10.
259. Tanganhito DDS, Bick D, Chang Y-S. Breastfeeding experiences and perspectives among women with postnatal depression: A qualitative evidence synthesis. *Women and Birth*. 2020;33(3):231-9.
260. National Institute for Health and Care Excellence. Postnatal care [P] Breastfeeding interventions. NICE guideline NG194: NICE; 2021 [cited 2023 Sept 6th]. Available from: <https://www.nice.org.uk/guidance/ng194/evidence/p-breastfeeding-interventions-pdf-326764485980>.
261. Wallace J, Nwosu B, Clarke M. Barriers to the uptake of evidence from systematic reviews and meta-analyses: a systematic review of decision makers' perceptions. *BMJ open*. 2012;2(5):e001220.
262. Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *bmj*. 2017;358.
263. Shin C-N, Reifsnider E, McClain D, Jeong M, McCormick DP, Moramarco M. Acculturation, Cultural Values, and Breastfeeding in Overweight or Obese, Low-Income, Hispanic Women at 1 Month Postpartum. *Journal of human lactation : official journal of International Lactation Consultant Association*. 2018;34(2):358-64.
264. UNICEF. Guide to the UNICEF UK Baby Friendly Initiative Standards: 2nd edition. 2017.
265. Pérez-Escamilla R, Tomori C, Hernández-Cordero S, Baker P, Barros AJ, Bégin F, et al. Breastfeeding: crucially important, but increasingly challenged in a market-driven world. *The Lancet*. 2023;401(10375):472-85.
266. Lubbe W, Niela-Vilén H, Thomson G, Botha E. Impact of the COVID-19 pandemic on breastfeeding support services and women's experiences of breastfeeding: A review. *International journal of women's health*. 2022;1447-57.
267. Ahmed AH, Roumani AM. Breastfeeding monitoring improves maternal self-efficacy and satisfaction. *MCN: The American Journal of Maternal/Child Nursing*. 2020;45(6):357-63.
268. Gross SM, Caulfield LE, Bentley ME, Bronner Y, Kessler L, Jensen J, et al. Counseling and motivational videotapes increase duration of breast-feeding in African-American WIC participants who initiate breast-feeding. *Journal of the American Dietetic Association*. 1998;98(2):143-8.
269. Chapman DJ, Damio G, Young S, Pérez-Escamilla R. Effectiveness of breastfeeding peer counseling in a low-income, predominantly Latina population: a randomized controlled trial. *Archives of pediatrics & adolescent medicine*. 2004;158(9):897-902.
270. Dennis C-L, Hodnett E, Gallop R, Chalmers B. The effect of peer support on breast-feeding duration among primiparous women: a randomized controlled trial. *Cmaj*. 2002;166(1):21-8.
271. Sikander S, Maselko J, Zafar S, Haq Z, Ahmad I, Ahmad M, et al. Cognitive-behavioral counseling for exclusive breastfeeding in rural pediatrics: a cluster RCT. *Pediatrics*. 2015;135(2):e424-e31.
272. Aldana-Parra F, Olaya G, Fewtrell M. Effectiveness of a new approach for exclusive breastfeeding counselling on breastfeeding prevalence, infant growth velocity and postpartum weight loss in overweight or obese women: protocol for a randomized controlled trial. *International Breastfeeding Journal*. 2020;15(1):1-14.

273. Berry DC, Neal M, Hall EG, Schwartz TA, Verbiest S, Bonuck K, et al. Rationale, design, and methodology for the optimizing outcomes in women with gestational diabetes mellitus and their infants study. *BMC pregnancy and childbirth*. 2013;13:184.
274. Stuebe AM, Bonuck K, Adatorwovor R, Schwartz TA, Berry D. A tailored breastfeeding support intervention for women with gestational diabetes. *American journal of obstetrics and gynecology*. 2016;214(1):S68-.
275. Carlsen EM, Kyhnaeb A, Renault KM, Cortes D, Michaelsen KF, Pryds O. Telephone-based support prolongs breastfeeding duration in obese women: a randomized trial. *MIDIRS Midwifery Digest*. 2014;24(1):92-.
276. Chapman D, Perez-Escamilla R. Exclusive breastfeeding in the first 24 hours postpartum associated with improved breastfeeding outcomes of low-income, overweight and obese women. *FASEB Journal*. 2013;27(Meeting Abstracts).
277. Chapman DJ, Wetzel K, Bermudez-Millan A, Young S, Damio G, Perez-Escamilla R. Effects of breastfeeding peer counseling for obese women on infant health outcomes. *FASEB journal*. 2010;24.
278. Morel K, Chapman DJ, Kyer N, Bermudez-Millan A, Young S, Perez-Escamilla R. Peer counselors improve breastfeeding technique among low-income, obese women. *FASEB Journal*. 2010;24.
279. Clinicaltrials.gov. Breastfeeding Education and Support Trial for Obese Women (BESTOW) 2011 [cited 2023 Sept 5th]. Available from: <https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02017604/full>.
280. O'Reilly SL, O'Brien EC, McGuinness D, Mehegan J, Coughlan B, O'Brien D, et al. Latch On: A protocol for a multi-centre, randomised controlled trial of perinatal support to improve breastfeeding outcomes in women with a raised BMI. *Contemporary Clinical Trials Communications*. 2021;22:100767.
281. McCormick DP, Reyna L, Reifsnider E. Calories, Caffeine and the Onset of Obesity in Young Children. *Academic pediatrics*. 2020;20(6):801-8.
282. Reimers P, Israel-Ballard K, Spies L, Tanser F, Thior I, Scott Gordon W, et al. A Protocol for a Cluster Randomized Trial on the Effect of a "feeding buddy" Program on adherence to the Prevention of Mother-To-Child-Transmission Guidelines in a Rural Area of KwaZulu-Natal, South Africa. *Journal of acquired immune deficiency syndromes (1999)*. 2016;72 Suppl 2:S130-6.

Appendix 1. Search strategies

Medline search strategy for main study mixed methods systematic review (chapter4)

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 "breastfeeding 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"	6,188
S12	MH "Postpartum Period+"	70,902
S13	S7 OR S8 OR S9 OR S10 OR S11 OR S12	988,993
S14	S6 AND S13	7,333
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	1,399

Medline search strategy for main study economic evidence review (chapter 5)

Ovid MEDLINE(R) ALL <1946 to August 17, 2022>

n=2911, searched on 02/02/22

1. exp Breast Feeding/
2. breastfeed*.mp.
3. breastfed.mp.
4. breast-feed*.mp.

1	5. breast-fed.mp.
2	6. breast feed*.mp.
3	7. breast fed.mp.
4	8. infant feed*.mp.
5	9. exp Milk, Human/
6	10. Lactation/
7	11. lactat*.mp.
8	12. support.mp.
9	13. Social Support/
10	14. advice.mp.
11	15. advis*.mp.
12	16. help*.mp.
13	17. supportive adj2 relationship.mp
14	18. counsel*.mp.
15	19. educat*.mp.
16	20. consult*.mp.
17	21. Health Promotion/
18	22. Health Education/
19	23. Economics/
20	24. exp "Costs and cost analysis"/
21	25. "Cost allocation"/
22	26. Cost-benefit analysis/
23	27. "Cost control"/
24	28. "Cost savings"/
25	29. "Cost of illness"/
26	30. "Cost sharing"/
27	31. "deductibles and coinsurance"/
28	32. Medical savings accounts/
29	33. Health care costs/
30	34. Direct service costs/
31	35. Drug costs/
32	36. Employer health costs/

1 37. Hospital costs/
 2 38. Health expenditures/
 3 39. Capital expenditures/
 4 40. Value of life/
 5 41. exp economics, hospital/
 6 42. exp economics, medical/
 7 43. Economics, nursing/
 8 44. Economics, pharmaceutical/
 9 45. exp "fees and charges"/
 10 46. exp budgets/
 11 47. (low adj cost).mp.
 12 48. (high adj cost).mp.
 13 49. (health?care adj cost\$).mp.
 14 50. (fiscal or funding or financial or finance).tw.
 15 51. (cost adj estimate\$).mp.
 16 52. (cost adj variable).mp.
 17 53. (unit adj cost\$).mp.
 18 54. (economic\$ or pharmacoeconomic\$ or price\$ or pricing).tw.
 19 55. or/1-11
 20 56. or/12-22
 21 57. or/23-54
 22 58. 55 and 56 and 57
 23 59. exp animals/ not humans.sh.
 24 60. 58 not 59

25 [Medline search strategy for long-term conditions effectiveness review \(chapter 6\)](#)

26 **Ovid MEDLINE(R) ALL <1946 to August 17, 2022>**

27 n=1144, searched on 18/8/22

28	1	exp Breast Feeding/	42543	
29	2	(breastfeed* or breast-feed* or breast feed*).ab.		38704
30	3	(breastfed or breast-fed or breast fed).ab.	12845	
31	4	lactation.ab.	35254	
32	5	infant feed*.ab.	4936	
33	6	exp Lactation/	46504	

1 7 exp Breast Milk Expression/ 385
2 8 exp Milk, Human/ 21849
3 9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 129346
4 10 ((support* or help or assist* or class* or workshop* or champion* or promot*) adj5
5 (breastfeed* or breast feed* or breastfed or breast fed or lactation or infant feed*)).ab. 7340
6 11 exp Social Support/ 78157
7 12 anticipatory guidance.mp. 1527
8 13 exp Counseling/47862
9 14 counsel*.mp. 152131
10 15 exp Directive Counseling/ 4838
11 16 exp Health Promotion/ 83692
12 17 exp Health Education/ 259211
13 18 peer support.mp. 6270
14 19 professional support.mp. 2017
15 20 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 478908
16 21 exp Chronic Disease/ 598162
17 22 chronic disease*.mp. 339068
18 23 chronic illness*.mp. 18795
19 24 chronic condition*.mp. 23438
20 25 (long term condition* or long-term condition*).mp. [mp=title, book title, abstract, original
21 title, name of substance word, subject heading word, floating sub-heading word, keyword heading
22 word, organism supplementary concept word, protocol supplementary concept word, rare disease
23 supplementary concept word, unique identifier, synonyms] 2409
24 26 exp Comorbidity/ 124635
25 27 (comorbid* or co-morbid*).mp. [mp=title, book title, abstract, original title, name of
26 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
27 supplementary concept word, protocol supplementary concept word, rare disease supplementary
28 concept word, unique identifier, synonyms] 306350
29 28 exp Multimorbidity/ 2332
30 29 (multimorbid* or multi-morbid*).mp. [mp=title, book title, abstract, original title, name of
31 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
32 supplementary concept word, protocol supplementary concept word, rare disease supplementary
33 concept word, unique identifier, synonyms] 8950
34 30 (multidiseas* or multi-diseas*).mp. [mp=title, book title, abstract, original title, name of
35 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
36 supplementary concept word, protocol supplementary concept word, rare disease supplementary
37 concept word, unique identifier, synonyms] 265
38 31 cancer.mp. or exp Neoplasms/ 4276838

1 32 atrial fibrillation.mp. or exp Atrial Fibrillation/ 98446
 2 33 cardiomyopathy.mp. or exp Cardiomyopathies/ 141244
 3 34 heart failure.mp. or exp Heart Failure/ 240900
 4 35 exp Hypercholesterolemia/ or exp Hyperlipidemias/ 69579
 5 36 (hypercholesterol?emia or hyperlipid?emia).mp. [mp=title, book title, abstract, original title,
 6 name of substance word, subject heading word, floating sub-heading word, keyword heading word,
 7 organism supplementary concept word, protocol supplementary concept word, rare disease
 8 supplementary concept word, unique identifier, synonyms] 75870
 9 37 exp Hypertension/ or hypertension.mp. 541419
 10 38 exp Myocardial Ischemia/ 461609
 11 39 (isch?emic heart disease or myocardial infarction).mp. [mp=title, book title, abstract, original
 12 title, name of substance word, subject heading word, floating sub-heading word, keyword heading
 13 word, organism supplementary concept word, protocol supplementary concept word, rare disease
 14 supplementary concept word, unique identifier, synonyms] 296886
 15 40 peripheral vascular disease.mp. or exp Peripheral Vascular Diseases/ 64594
 16 41 exp Stroke/ or stroke.mp. 371135
 17 42 exp Ischemic Attack, Transient/ 21493
 18 43 transient isch?emic attack.mp. 12427
 19 44 congenital heart disease.mp. or exp Heart Defects, Congenital/ 176482
 20 45 valvular heart disease.mp. or exp Heart Valve Diseases/ 135662
 21 46 rheumatic heart disease.mp. or exp Rheumatic Heart Disease/ 14973
 22 47 exp Heart Diseases/ 1235397
 23 48 (heart disease or cardiac disease).mp. [mp=title, book title, abstract, original title, name of
 24 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
 25 supplementary concept word, protocol supplementary concept word, rare disease supplementary
 26 concept word, unique identifier, synonyms] 211888
 27 49 alopecia areata.mp. or exp Alopecia Areata/ 5330
 28 50 vitiligo.mp. or exp Vitiligo/ 8844
 29 51 exp Eczema/ or eczema.mp. 23857
 30 52 psoriasis.mp. or exp Psoriasis/ 59218
 31 53 acne.mp. or exp Acne Vulgaris/ 20890
 32 54 hidradenitis suppurativa.mp. or exp Hidradenitis Suppurativa/ 3821
 33 55 lichen planus.mp. or exp Lichen Planus/ 11081
 34 56 rosacea.mp. or exp Rosacea/ 4650
 35 57 seborrheic dermatitis.mp. or exp Dermatitis, Seborrheic/ 3404
 36 58 allergic rhinitis.mp. or exp Rhinitis, Allergic/ 31279

1 59 allergic conjunctivitis.mp. or exp Conjunctivitis, Allergic/ 4460
2 60 exp Hearing Loss/ 75766
3 61 (hearing loss or deaf*).mp. [mp=title, book title, abstract, original title, name of substance
4 word, subject heading word, floating sub-heading word, keyword heading word, organism
5 supplementary concept word, protocol supplementary concept word, rare disease supplementary
6 concept word, unique identifier, synonyms] 110959
7 62 exp Addison Disease/ or addison* disease.mp. 5996
8 63 exp Adrenocortical Adenoma/ or adren* adenoma.mp. 3139
9 64 exp Pheochromocytoma/ 16444
10 65 ph?eochromocytoma.mp. 23761
11 66 exp Cushing Syndrome/ or cushing* syndrome.mp. 15868
12 67 exp Diabetes Mellitus, Type 2/ or exp Diabetes, Gestational/ or exp Diabetes Mellitus/ or exp
13 Diabetes Mellitus, Type 1/ 485761
14 68 (diabetes or diabetic\$1).mp. [mp=title, book title, abstract, original title, name of substance
15 word, subject heading word, floating sub-heading word, keyword heading word, organism
16 supplementary concept word, protocol supplementary concept word, rare disease supplementary
17 concept word, unique identifier, synonyms] 796593
18 69 exp Parathyroid Diseases/ or (parathyroid dis* or hyperparathyroid* or
19 hypoparathyroid*).mp. 46457
20 70 exp Thyroid Diseases/ or thyroid dis*.mp. 165219
21 71 (hyperthyroid* or hypothyroid* or thyroiditis or graves disease).mp. [mp=title, book title,
22 abstract, original title, name of substance word, subject heading word, floating sub-heading word,
23 keyword heading word, organism supplementary concept word, protocol supplementary concept
24 word, rare disease supplementary concept word, unique identifier, synonyms] 100159
25 72 exp Pituitary Diseases/ or pituitary dis*.mp. 64970
26 73 exp Endocrine System Diseases/1088901
27 74 exp Vision Disorders/ 77172
28 75 (visual* impair* or blindness).mp. [mp=title, book title, abstract, original title, name of
29 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
30 supplementary concept word, protocol supplementary concept word, rare disease supplementary
31 concept word, unique identifier, synonyms] 58699
32 76 exp Cataract/ or cataract.mp. 71192
33 77 exp Diabetic Retinopathy/ 28274
34 78 (diabetic retinopathy or diabetic eye dis*).mp. [mp=title, book title, abstract, original title,
35 name of substance word, subject heading word, floating sub-heading word, keyword heading word,
36 organism supplementary concept word, protocol supplementary concept word, rare disease
37 supplementary concept word, unique identifier, synonyms] 38358

1	79	glaucoma.mp. or exp Glaucoma/	78243
2	80	scleritis.mp. or exp Scleritis/	2363
3	81	episcleritis.mp.	619
4	82	exp Uveitis/ or uveitis.mp.	40674
5	83	retinal detachment.mp. or exp Retinal Detachment/	28643
6	84	exp Eye Diseases/	619560
7	85	alcoholic liver disease.mp. or exp Liver Diseases, Alcoholic/	18468
8	86	autoimmune hepatitis.mp. or exp Hepatitis, Autoimmune/	7214
9	87	sclerosing cholangitis.mp. or exp Cholangitis, Sclerosing/	7796
10	88	primary biliary cirrhosis.mp. or exp Liver Cirrhosis, Biliary/	10926
11	89	chronic hepatitis.mp. or exp Hepatitis, Chronic/	73061
12	90	exp Hepatitis B, Chronic/ or hepatitis B.mp.	108026
13	91	exp Hepatitis C, Chronic/ or hepatitis C.mp.	98802
14	92	liver cirrhosis.mp. or exp Liver Cirrhosis/	111811
15	93	non-alcoholic fatty liver disease.mp. or exp Non-alcoholic Fatty Liver Disease/	26127
16	94	exp Liver Diseases/	608267
17	95	chronic pancreatitis.mp. or exp Pancreatitis, Chronic/	16961
18	96	celiac disease.mp. or exp Celiac Disease/	26258
19	97	food allergy.mp. or exp Food Hypersensitivity/	25939
20	98	cholelithiasis.mp. or exp Cholelithiasis/	40132
21	99	gallstones.mp.	20398
22	100	inflammatory bowel disease.mp. or exp Inflammatory Bowel Diseases/	112247
23	101	exp Crohn Disease/ or crohn* disease.mp.	62081
24	102	ulcerative colitis.mp. or exp Colitis, Ulcerative/	55469
25	103	proctitis.mp. or exp Proctitis/	4698
26	104	irritable bowel syndrome.mp. or exp Irritable Bowel Syndrome/	16561
27	105	lactose intolerance.mp. or exp Lactose Intolerance/	3642
28	106	peptic ulcer.mp. or exp Peptic Ulcer/	88760
29	107	chronic pelvic inflammatory dis*.mp. [mp=title, book title, abstract, original title, name of	
30		substance word, subject heading word, floating sub-heading word, keyword heading word, organism	
31		supplementary concept word, protocol supplementary concept word, rare disease supplementary	
32		concept word, unique identifier, synonyms]	135

1	108	exp Pelvic Inflammatory Disease/	11366
2	109	dysmenorrhea.mp. or exp Dysmenorrhea/	7265
3	110	endometriosis.mp. or exp Endometriosis/	31546
4	111	infertility.mp. or exp Infertility/	103527
5	112	assisted reproduction.mp. or exp Reproductive Techniques, Assisted/	80694
6	113	(in vitro fertilization or IVF).mp. [mp=title, book title, abstract, original title, name of	
7		substance word, subject heading word, floating sub-heading word, keyword heading word, organism	
8		supplementary concept word, protocol supplementary concept word, rare disease supplementary	
9		concept word, unique identifier, synonyms]	40047
10	114	leiomyoma.mp. or exp Leiomyoma/	25329
11	115	fibroids.mp.	5638
12	116	exp Menopause/ or menopause.mp.	74996
13	117	menorrhagia.mp. or exp Menorrhagia/	6281
14	118	exp Urinary Incontinence/ or exp Pelvic Floor Disorders/ or exp Pelvic Organ Prolapse/ or exp	
15		Fecal Incontinence/	54690
16	119	(pelvic floor dysfunction or pelvic floor disorder*).mp. [mp=title, book title, abstract, original	
17		title, name of substance word, subject heading word, floating sub-heading word, keyword heading	
18		word, organism supplementary concept word, protocol supplementary concept word, rare disease	
19		supplementary concept word, unique identifier, synonyms]	2942
20	120	(urinary incontinence or fecal incontinence).mp. [mp=title, book title, abstract, original	
21		title, name of substance word, subject heading word, floating sub-heading word, keyword heading	
22		word, organism supplementary concept word, protocol supplementary concept word, rare disease	
23		supplementary concept word, unique identifier, synonyms]	54435
24	121	pelvic organ prolapse.mp.	7750
25	122	exp Polycystic Ovary Syndrome/ or polycystic ovar* syndrome.mp.	21740
26	123	recurrent miscarriage.mp. or exp Abortion, Habitual/	9651
27	124	exp Blood Coagulation Disorders/ or coagulation disorder.mp.	103883
28	125	hemophilia.mp.	28903
29	126	exp Anemia, Sickle Cell/ or sickle cell.mp.	31815
30	127	thalassemia.mp. or exp Thalassemia/	30118
31	128	thrombophilia.mp. or exp Thrombophilia/	30397
32	129	pernicious anemia.mp. or exp Anemia, Pernicious/	7005
33	130	exp Thrombocytopenia/ or primary thrombocytopenia.mp.	52195
34	131	venous thromboembolism.mp. or exp Venous Thromboembolism/	28924

1 132 deep ve* thrombosis.mp. 31151

2 133 pulmonary embolism.mp. or exp Pulmonary Embolism/ 59166

3 134 HIV.mp. or exp HIV Infections/ 431237

4 135 AIDS.mp. or exp Acquired Immunodeficiency Syndrome/231823

5 136 exp Immunocompromised Host/ 27296

6 137 exp Immunosuppression Therapy/ or exp Immunosuppressive Agents/ 386330

7 138 immunosuppress*.mp. 247166

8 139 exp Transplantation/ 558640

9 140 transplant*.mp.821998

10 141 exp Alcohol-Related Disorders/ 119529

11 142 (alcohol misuse or alcohol abuse or alcohol dependence or alcoholism).mp. [mp=title, book
12 title, abstract, original title, name of substance word, subject heading word, floating sub-heading
13 word, keyword heading word, organism supplementary concept word, protocol supplementary
14 concept word, rare disease supplementary concept word, unique identifier, synonyms] 102278

15 143 exp Substance-Related Disorders/ 303321

16 144 (substance misuse or substance abuse or substance dependence).mp. [mp=title, book title,
17 abstract, original title, name of substance word, subject heading word, floating sub-heading word,
18 keyword heading word, organism supplementary concept word, protocol supplementary concept
19 word, rare disease supplementary concept word, unique identifier, synonyms] 61758

20 145 exp Anxiety/ or exp Anxiety Disorders/ 179995

21 146 anxiety.mp. 287258

22 147 panic disorder.mp. or exp Panic Disorder/ 11686

23 148 phobic disorder.mp. or exp Phobic Disorders/ 12239

24 149 phobia.mp. 9375

25 150 exp Stress Disorders, Post-Traumatic/ 39160

26 151 (post traumatic stress disorder or post-traumatic stress disorder or PTSD).mp. [mp=title,
27 book title, abstract, original title, name of substance word, subject heading word, floating sub-
28 heading word, keyword heading word, organism supplementary concept word, protocol
29 supplementary concept word, rare disease supplementary concept word, unique identifier,
30 synonyms] 36261

31 152 exp Mood Disorders/ 132929

32 153 exp Depression/ or exp Depression, Postpartum/ 148840

33 154 (depression or depressive disorder or mood disorder).mp. [mp=title, book title, abstract,
34 original title, name of substance word, subject heading word, floating sub-heading word, keyword
35 heading word, organism supplementary concept word, protocol supplementary concept word, rare
36 disease supplementary concept word, unique identifier, synonyms] 504128

1 155 dementia.mp. or exp Dementia/ 245230

2 156 eating disorder.mp. or exp "Feeding and Eating Disorders"/ 38341

3 157 (anorexia nervosa or bulimia nervosa).mp. [mp=title, book title, abstract, original title, name
4 of substance word, subject heading word, floating sub-heading word, keyword heading word,
5 organism supplementary concept word, protocol supplementary concept word, rare disease
6 supplementary concept word, unique identifier, synonyms] 21280

7 158 bipolar disorder.mp. or exp Bipolar Disorder/ 54684

8 159 exp "schizophrenia spectrum and other psychotic disorders"/ 159357

9 160 (schizophrenia or psychosis or psychotic disorder or schizoaffective disorder).mp. [mp=title,
10 book title, abstract, original title, name of substance word, subject heading word, floating sub-
11 heading word, keyword heading word, organism supplementary concept word, protocol
12 supplementary concept word, rare disease supplementary concept word, unique identifier,
13 synonyms] 182203

14 161 dissociative disorder.mp. or exp Dissociative Disorders/ 4820

15 162 obsessive compulsive disorder.mp. or exp Obsessive-Compulsive Disorder/ 21228

16 163 personality disorder.mp. or exp Personality Disorders/ 49154

17 164 self harm.mp. or exp Self-Injurious Behavior/ 83262

18 165 exp Mental Disorders/ 1386917

19 166 (mental disorder or psychiatric disorder).mp. [mp=title, book title, abstract, original title,
20 name of substance word, subject heading word, floating sub-heading word, keyword heading word,
21 organism supplementary concept word, protocol supplementary concept word, rare disease
22 supplementary concept word, unique identifier, synonyms] 21591

23 167 (serious mental illness or severe mental illness).mp. [mp=title, book title, abstract, original
24 title, name of substance word, subject heading word, floating sub-heading word, keyword heading
25 word, organism supplementary concept word, protocol supplementary concept word, rare disease
26 supplementary concept word, unique identifier, synonyms] 9002

27 168 exp Attention Deficit Disorder with Hyperactivity/ 33335

28 169 (attention deficit hyperactivity disorder or ADHD).mp. [mp=title, book title, abstract, original
29 title, name of substance word, subject heading word, floating sub-heading word, keyword heading
30 word, organism supplementary concept word, protocol supplementary concept word, rare disease
31 supplementary concept word, unique identifier, synonyms] 36926

32 170 exp Autism Spectrum Disorder/ 39314

33 171 (autism or autistic).mp. [mp=title, book title, abstract, original title, name of substance word,
34 subject heading word, floating sub-heading word, keyword heading word, organism supplementary
35 concept word, protocol supplementary concept word, rare disease supplementary concept word,
36 unique identifier, synonyms] 64227

37 172 cerebral palsy.mp. or exp Cerebral Palsy/ 30646

38 173 intellectual disabilit*.mp. or exp Intellectual Disability/ 113325

1 174 exp Down Syndrome/ or down* syndrome.mp. 32403

2 175 exp Brain Injuries/ or acquired brain injury.mp. 79525

3 176 exp Headache Disorders/ 38752

4 177 (cluster headache or tension headache or chronic headache or migraine).mp. [mp=title,
5 book title, abstract, original title, name of substance word, subject heading word, floating sub-
6 heading word, keyword heading word, organism supplementary concept word, protocol
7 supplementary concept word, rare disease supplementary concept word, unique identifier,
8 synonyms] 47340

9 178 exp Epilepsy/ 122463

10 179 (epilepsy or epileptic).mp. [mp=title, book title, abstract, original title, name of substance
11 word, subject heading word, floating sub-heading word, keyword heading word, organism
12 supplementary concept word, protocol supplementary concept word, rare disease supplementary
13 concept word, unique identifier, synonyms] 167049

14 180 idiopathic intracranial hypertension.mp. or exp Pseudotumor Cerebri/ 5202

15 181 multiple sclerosis.mp. or exp Multiple Sclerosis/ 94760

16 182 peripheral neuropathy.mp. or exp Peripheral Nervous System Diseases/ 171846

17 183 exp Parkinson Disease/ or parkinson* disease.mp. 126506

18 184 exp Neurodegenerative Diseases/ 351658

19 185 (huntington* disease or huntington* chorea).mp. [mp=title, book title, abstract, original
20 title, name of substance word, subject heading word, floating sub-heading word, keyword heading
21 word, organism supplementary concept word, protocol supplementary concept word, rare disease
22 supplementary concept word, unique identifier, synonyms] 20268

23 186 motor neurone disease.mp. 1091

24 187 exp Sleep Wake Disorders/ 104157

25 188 (sleep disorder or narcolepsy or obstructive sleep apn?ea).mp. [mp=title, book title,
26 abstract, original title, name of substance word, subject heading word, floating sub-heading word,
27 keyword heading word, organism supplementary concept word, protocol supplementary concept
28 word, rare disease supplementary concept word, unique identifier, synonyms] 41903

29 189 spina bifida.mp. or exp Spinal Dysraphism/ 12050

30 190 exp Fatigue Syndrome, Chronic/ 6142

31 191 (chronic fatigue syndrome or myalgic encephalomyelitis).mp. [mp=title, book title, abstract,
32 original title, name of substance word, subject heading word, floating sub-heading word, keyword
33 heading word, organism supplementary concept word, protocol supplementary concept word, rare
34 disease supplementary concept word, unique identifier, synonyms] 6471

35 192 fibromyalgia.mp. or exp Fibromyalgia/ 13310

36 193 exp Chronic Pain/ 20443

37 194 exp Complex Regional Pain Syndromes/ 5884

1 195 exp Myofascial Pain Syndromes/ 6762
2 196 (chronic pain or pain syndrome).mp. [mp=title, book title, abstract, original title, name of
3 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
4 supplementary concept word, protocol supplementary concept word, rare disease supplementary
5 concept word, unique identifier, synonyms] 66066
6 197 exp Back Pain/ or chronic back pain.mp. 44337
7 198 osteoarthritis.mp. or exp Osteoarthritis/104568
8 199 exp Osteoporosis/ 60974
9 200 (osteoporosis or osteopenia).mp. [mp=title, book title, abstract, original title, name of
10 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
11 supplementary concept word, protocol supplementary concept word, rare disease supplementary
12 concept word, unique identifier, synonyms] 101668
13 201 scoliosis.mp. or exp Scoliosis/ 28225
14 202 exp Spinal Diseases/ 136461
15 203 exp Fractures, Compression/ 2943
16 204 (compression fracture or collapsed vertebra*).mp. [mp=title, book title, abstract, original
17 title, name of substance word, subject heading word, floating sub-heading word, keyword heading
18 word, organism supplementary concept word, protocol supplementary concept word, rare disease
19 supplementary concept word, unique identifier, synonyms] 2462
20 205 intervertebral disc degeneration.mp. or exp Intervertebral Disc Degeneration/ 8378
21 206 sciatica.mp. or exp Sciatica/ 7190
22 207 spinal stenosis.mp. or exp Spinal Stenosis/ 9544
23 208 spondylosis.mp. or exp Spondylosis/ 11155
24 209 spondylolisthesis.mp. or exp Spondylolisthesis/ 7445
25 210 amputation.mp. or exp Amputation/ 52172
26 211 amputee.mp. 2992
27 212 paralysis.mp. or exp Paralysis/ 116571
28 213 exp Hemiplegia/ or hemiplegia.mp. 16538
29 214 exp Paraplegia/ or paraplegia.mp. 22118
30 215 quadriplegia.mp. or exp Quadriplegia/ 10093
31 216 exp Disabled Persons/ 71645
32 217 (disabled or disabilit*).mp. [mp=title, book title, abstract, original title, name of substance
33 word, subject heading word, floating sub-heading word, keyword heading word, organism
34 supplementary concept word, protocol supplementary concept word, rare disease supplementary
35 concept word, unique identifier, synonyms] 362858

1 218 chronic kidney disease.mp. or exp Renal Insufficiency, Chronic/ 162815
2 219 h?emodialysis.mp. or exp Renal Dialysis/ 146472
3 220 exp Urinary Calculi/ 37823
4 221 (urinary tract stone* or kidney stone*).mp. [mp=title, book title, abstract, original title,
5 name of substance word, subject heading word, floating sub-heading word, keyword heading word,
6 organism supplementary concept word, protocol supplementary concept word, rare disease
7 supplementary concept word, unique identifier, synonyms] 7369
8 222 exp Asthma/ or asthma.mp. 191929
9 223 exp Lung Diseases/ or chronic lung disease.mp. 1147038
10 224 bronchiectasis.mp. or exp Bronchiectasis/ 15082
11 225 exp Pulmonary Disease, Chronic Obstructive/ 64208
12 226 (chronic obstructive pulmonary disease or COPD).mp. [mp=title, book title, abstract, original
13 title, name of substance word, subject heading word, floating sub-heading word, keyword heading
14 word, organism supplementary concept word, protocol supplementary concept word, rare disease
15 supplementary concept word, unique identifier, synonyms] 75276
16 227 cystic fibrosis.mp. or exp Cystic Fibrosis/55910
17 228 interstitial lung disease.mp. or exp Lung Diseases, Interstitial/ 87153
18 229 pulmonary fibrosis.mp. 34100
19 230 pulmonary hypertension.mp. or exp Hypertension, Pulmonary/ 56630
20 231 exp Sarcoidosis/ or sarcoidosis.mp. 33019
21 232 exp Tuberculosis/ or tuberculosis.mp. 272422
22 233 exp Ehlers-Danlos Syndrome/ or ehlers-danlos.mp. 4661
23 234 rheumatoid arthritis.mp. or exp Arthritis, Rheumatoid/ 160931
24 235 exp Sjogren's Syndrome/ 14126
25 236 (sjogren* syndrome or sjogren* disease).mp. [mp=title, book title, abstract, original title,
26 name of substance word, subject heading word, floating sub-heading word, keyword heading word,
27 organism supplementary concept word, protocol supplementary concept word, rare disease
28 supplementary concept word, unique identifier, synonyms] 19617
29 237 exp Raynaud Disease/ or raynaud*.mp. 10156
30 238 systemic sclerosis.mp. or exp Scleroderma, Systemic/ 26894
31 239 scleroderma.mp. 29230
32 240 primary systemic vasculitis.mp. or exp Systemic Vasculitis/ 18109
33 241 marfan* syndrome.mp. or exp Marfan Syndrome/ 8617
34 242 spondyloarthritis.mp. or exp Spondylarthritis/ 31153

1 243 psoriatic arthritis.mp. or exp Arthritis, Psoriatic/ 12337
2 244 ankylosing spondylitis.mp. or exp Spondylitis, Ankylosing/ 21066
3 245 systemic lupus erythematosus.mp. or exp Lupus Erythematosus, Systemic/ 79628
4 246 autoimmune disease.mp. or exp Autoimmune Diseases/ 540341
5 247 frailty.mp. or exp Frailty/ 22139
6 248 exp COVID-19/ or long covid.mp. 181547
7 249 post COVID syndrome.mp. 213
8 250 exp Obesity/ 247988
9 251 (obese or obesity).mp. [mp=title, book title, abstract, original title, name of substance word,
10 subject heading word, floating sub-heading word, keyword heading word, organism supplementary
11 concept word, protocol supplementary concept word, rare disease supplementary concept word,
12 unique identifier, synonyms] 411960
13 252 polypharmacy.mp. or exp Polypharmacy/ 12571
14 253 turner* syndrome.mp. or exp Turner Syndrome/ 9685
15 254 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
16 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
17 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
18 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
19 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
20 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
21 120 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
22 134 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
23 148 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
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25 176 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
26 190 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
27 204 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
28 218 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
29 232 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
30 246 or 247 or 248 or 249 or 250 or 251 or 252 or 253 14314773
31 255 randomized controlled trial.pt. 575118
32 256 controlled clinical trial.pt. 94989
33 257 randomi#ed.ab.684071
34 258 placebo.ab. 230860
35 259 drug therapy.fs.2521208
36 260 randomly.ab. 389335
37 261 trial.ab.612686

1 262 groups.ab. 2394830
2 263 255 or 256 or 257 or 258 or 259 or 260 or 261 or 262 5455224
3 264 exp animals/ not humans.sh. 5037553
4 265 263 not 264 4753806
5 266 9 and 20 and 254 and 265 1144
6 Medline search strategy for long-term conditions mixed methods systematic review
7 (chapter 7)
8 **Ovid MEDLINE(R) ALL <1946 to November 23, 2022>**
9 n=2187, searched on 24/11/22
10 <https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=3uDyNOK9OmKVzA6SxJGV8m3E4uQ3yhNjNIN7F9FuCXTQCQFitgtovOfPHfZlf4xOkt>
11
12
13 1 exp Breast Feeding/ 42954
14 2 (breastfeed* or breast-feed* or breast feed*).ab. 39367
15 3 (breastfed or breast-fed or breast fed).ab. 13012
16 4 lactation.ab. 35775
17 5 infant feed*.ab.4996
18 6 exp Lactation/ 46965
19 7 exp Breast Milk Expression/ 385
20 8 exp Milk, Human/ 22053
21 9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 130890
22 10 ((support* or help or assist* or class* or workshop* or champion* or promot*) adj5
23 (breastfeed* or breast feed* or breastfed or breast fed or lactation or infant feed*)).ab. 7474
24 11 exp Social Support/ 78607
25 12 anticipatory guidance.mp. 1545
26 13 exp Counseling/48142
27 14 counsel*.mp. 154556
28 15 exp Directive Counseling/ 4882
29 16 exp Health Promotion/ 84136
30 17 exp Health Education/ 260144
31 18 peer support.mp. 6522
32 19 professional support.mp. 2070

1 20 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 483065
2 21 exp Chronic Disease/ 602943
3 22 chronic disease*.mp. 342009
4 23 chronic illness*.mp. 19105
5 24 chronic condition*.mp. 24060
6 25 (long term condition* or long-term condition*).mp. [mp=title, book title, abstract, original
7 title, name of substance word, subject heading word, floating sub-heading word, keyword heading
8 word, organism supplementary concept word, protocol supplementary concept word, rare disease
9 supplementary concept word, unique identifier, synonyms] 2474
10 26 exp Comorbidity/ 125267
11 27 (comorbid* or co-morbid*).mp. [mp=title, book title, abstract, original title, name of
12 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
13 supplementary concept word, protocol supplementary concept word, rare disease supplementary
14 concept word, unique identifier, synonyms] 312919
15 28 exp Multimorbidity/ 2454
16 29 (multimorbid* or multi-morbid*).mp. [mp=title, book title, abstract, original title, name of
17 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
18 supplementary concept word, protocol supplementary concept word, rare disease supplementary
19 concept word, unique identifier, synonyms] 9346
20 30 (multidiseas* or multi-diseas*).mp. [mp=title, book title, abstract, original title, name of
21 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
22 supplementary concept word, protocol supplementary concept word, rare disease supplementary
23 concept word, unique identifier, synonyms] 278
24 31 cancer.mp. or exp Neoplasms/ 4329926
25 32 atrial fibrillation.mp. or exp Atrial Fibrillation/ 100464
26 33 cardiomyopathy.mp. or exp Cardiomyopathies/ 143152
27 34 heart failure.mp. or exp Heart Failure/ 245181
28 35 exp Hypercholesterolemia/ or exp Hyperlipidemias/ 69913
29 36 (hypercholesterol?emia or hyperlipid?emia).mp. [mp=title, book title, abstract, original title,
30 name of substance word, subject heading word, floating sub-heading word, keyword heading word,
31 organism supplementary concept word, protocol supplementary concept word, rare disease
32 supplementary concept word, unique identifier, synonyms] 76793
33 37 exp Hypertension/ or hypertension.mp. 547959
34 38 exp Myocardial Ischemia/ 464415
35 39 (isch?emic heart disease or myocardial infarction).mp. [mp=title, book title, abstract, original
36 title, name of substance word, subject heading word, floating sub-heading word, keyword heading

1 word, organism supplementary concept word, protocol supplementary concept word, rare disease
 2 supplementary concept word, unique identifier, synonyms] 299852
 3 40 peripheral vascular disease.mp. or exp Peripheral Vascular Diseases/ 65062
 4 41 exp Stroke/ or stroke.mp. 378102
 5 42 exp Ischemic Attack, Transient/ 21618
 6 43 transient isch?emic attack.mp. 12655
 7 44 congenital heart disease.mp. or exp Heart Defects, Congenital/ 177949
 8 45 valvular heart disease.mp. or exp Heart Valve Diseases/ 136981
 9 46 rheumatic heart disease.mp. or exp Rheumatic Heart Disease/ 15031
 10 47 exp Heart Diseases/ 1245391
 11 48 (heart disease or cardiac disease).mp. [mp=title, book title, abstract, original title, name of
 12 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
 13 supplementary concept word, protocol supplementary concept word, rare disease supplementary
 14 concept word, unique identifier, synonyms] 214566
 15 49 alopecia areata.mp. or exp Alopecia Areata/ 5456
 16 50 vitiligo.mp. or exp Vitiligo/ 8980
 17 51 exp Eczema/ or eczema.mp. 24134
 18 52 psoriasis.mp. or exp Psoriasis/ 60070
 19 53 acne.mp. or exp Acne Vulgaris/ 21180
 20 54 hidradenitis suppurativa.mp. or exp Hidradenitis Suppurativa/ 3951
 21 55 lichen planus.mp. or exp Lichen Planus/ 11203
 22 56 rosacea.mp. or exp Rosacea/ 4729
 23 57 seborrheic dermatitis.mp. or exp Dermatitis, Seborrheic/ 3431
 24 58 allergic rhinitis.mp. or exp Rhinitis, Allergic/ 31617
 25 59 allergic conjunctivitis.mp. or exp Conjunctivitis, Allergic/ 4493
 26 60 exp Hearing Loss/ 76292
 27 61 (hearing loss or deaf*).mp. [mp=title, book title, abstract, original title, name of substance
 28 word, subject heading word, floating sub-heading word, keyword heading word, organism
 29 supplementary concept word, protocol supplementary concept word, rare disease supplementary
 30 concept word, unique identifier, synonyms] 112157
 31 62 exp Addison Disease/ or addison* disease.mp. 6034
 32 63 exp Adrenocortical Adenoma/ or adren* adenoma.mp. 3177
 33 64 exp Pheochromocytoma/ 16529

1 65 ph?eochromocytoma.mp. 23936
2 66 exp Cushing Syndrome/ or cushing* syndrome.mp. 15980
3 67 exp Diabetes Mellitus, Type 2/ or exp Diabetes, Gestational/ or exp Diabetes Mellitus/ or exp
4 Diabetes Mellitus, Type 1/ 492036
5 68 (diabetes or diabetic\$1).mp. [mp=title, book title, abstract, original title, name of substance
6 word, subject heading word, floating sub-heading word, keyword heading word, organism
7 supplementary concept word, protocol supplementary concept word, rare disease supplementary
8 concept word, unique identifier, synonyms] 809517
9 69 exp Parathyroid Diseases/ or (parathyroid dis* or hyperparathyroid* or
10 hypoparathyroid*).mp. 46799
11 70 exp Thyroid Diseases/ or thyroid dis*.mp. 166479
12 71 (hyperthyroid* or hypothyroid* or thyroiditis or graves disease).mp. [mp=title, book title,
13 abstract, original title, name of substance word, subject heading word, floating sub-heading word,
14 keyword heading word, organism supplementary concept word, protocol supplementary concept
15 word, rare disease supplementary concept word, unique identifier, synonyms] 100991
16 72 exp Pituitary Diseases/ or pituitary dis*.mp. 65344
17 73 exp Endocrine System Diseases/1099839
18 74 exp Vision Disorders/ 77726
19 75 (visual* impair* or blindness).mp. [mp=title, book title, abstract, original title, name of
20 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
21 supplementary concept word, protocol supplementary concept word, rare disease supplementary
22 concept word, unique identifier, synonyms] 59580
23 76 exp Cataract/ or cataract.mp. 71946
24 77 exp Diabetic Retinopathy/ 28637
25 78 (diabetic retinopathy or diabetic eye dis*).mp. [mp=title, book title, abstract, original title,
26 name of substance word, subject heading word, floating sub-heading word, keyword heading word,
27 organism supplementary concept word, protocol supplementary concept word, rare disease
28 supplementary concept word, unique identifier, synonyms] 39000
29 79 glaucoma.mp. or exp Glaucoma/ 79199
30 80 scleritis.mp. or exp Scleritis/ 2393
31 81 episcleritis.mp. 624
32 82 exp Uveitis/ or uveitis.mp. 41131
33 83 retinal detachment.mp. or exp Retinal Detachment/ 28930
34 84 exp Eye Diseases/ 624904
35 85 alcoholic liver disease.mp. or exp Liver Diseases, Alcoholic/ 18612
36 86 autoimmune hepatitis.mp. or exp Hepatitis, Autoimmune/ 7336

1	87	sclerosing cholangitis.mp. or exp Cholangitis, Sclerosing/7900	
2	88	primary biliary cirrhosis.mp. or exp Liver Cirrhosis, Biliary/	10999
3	89	chronic hepatitis.mp. or exp Hepatitis, Chronic/	73739
4	90	exp Hepatitis B, Chronic/ or hepatitis B.mp.	109029
5	91	exp Hepatitis C, Chronic/ or hepatitis C.mp.	99589
6	92	liver cirrhosis.mp. or exp Liver Cirrhosis/	113060
7	93	non-alcoholic fatty liver disease.mp. or exp Non-alcoholic Fatty Liver Disease/	27321
8	94	exp Liver Diseases/	613804
9	95	chronic pancreatitis.mp. or exp Pancreatitis, Chronic/	17127
10	96	c?eliac disease.mp. or exp Celiac Disease/	26440
11	97	food allergy.mp. or exp Food Hypersensitivity/	26232
12	98	cholelithiasis.mp. or exp Cholelithiasis/	40302
13	99	gallstones.mp.	20545
14	100	inflammatory bowel disease.mp. or exp Inflammatory Bowel Diseases/	114088
15	101	exp Crohn Disease/ or crohn* disease.mp.	62863
16	102	ulcerative colitis.mp. or exp Colitis, Ulcerative/	56412
17	103	proctitis.mp. or exp Proctitis/	4741
18	104	irritable bowel syndrome.mp. or exp Irritable Bowel Syndrome/	16860
19	105	lactose intolerance.mp. or exp Lactose Intolerance/	3661
20	106	peptic ulcer.mp. or exp Peptic Ulcer/	88964
21	107	chronic pelvic inflammatory dis*.mp. [mp=title, book title, abstract, original title, name of	
22		substance word, subject heading word, floating sub-heading word, keyword heading word, organism	
23		supplementary concept word, protocol supplementary concept word, rare disease supplementary	
24		concept word, unique identifier, synonyms]	135
25	108	exp Pelvic Inflammatory Disease/	11423
26	109	dysmenorrhea.mp. or exp Dysmenorrhea/	7392
27	110	endometriosis.mp. or exp Endometriosis/	31997
28	111	infertility.mp. or exp Infertility/	104859
29	112	assisted reproduction.mp. or exp Reproductive Techniques, Assisted/	81518
30	113	(in vitro fertili#ation or IVF).mp. [mp=title, book title, abstract, original title, name of	
31		substance word, subject heading word, floating sub-heading word, keyword heading word, organism	
32		supplementary concept word, protocol supplementary concept word, rare disease supplementary	
33		concept word, unique identifier, synonyms]	40612

1	114	leiomyoma.mp. or exp Leiomyoma/	25551
2	115	fibroids.mp.	5762
3	116	exp Menopause/ or menopause.mp.	75624
4	117	menorrhagia.mp. or exp Menorrhagia/	6342
5	118	exp Urinary Incontinence/ or exp Pelvic Floor Disorders/ or exp Pelvic Organ Prolapse/ or exp	
6		Fecal Incontinence/	55156
7	119	(pelvic floor dysfunction or pelvic floor disorder*).mp. [mp=title, book title, abstract, original	
8		title, name of substance word, subject heading word, floating sub-heading word, keyword heading	
9		word, organism supplementary concept word, protocol supplementary concept word, rare disease	
10		supplementary concept word, unique identifier, synonyms]	3030
11	120	(urinary incontinence or fecal incontinence).mp. [mp=title, book title, abstract, original	
12		title, name of substance word, subject heading word, floating sub-heading word, keyword heading	
13		word, organism supplementary concept word, protocol supplementary concept word, rare disease	
14		supplementary concept word, unique identifier, synonyms]	54896
15	121	pelvic organ prolapse.mp.	7917
16	122	exp Polycystic Ovary Syndrome/ or polycystic ovar* syndrome.mp.	22165
17	123	recurrent miscarriage.mp. or exp Abortion, Habitual/	9737
18	124	exp Blood Coagulation Disorders/ or coagulation disorder.mp.	104538
19	125	hemophilia.mp.	29136
20	126	exp Anemia, Sick Cell/ or sickle cell.mp.	32225
21	127	thalassemia.mp. or exp Thalassemia/	30381
22	128	thrombophilia.mp. or exp Thrombophilia/	30589
23	129	pernicious anemia.mp. or exp Anemia, Pernicious/	7018
24	130	exp Thrombocytopenia/ or primary thrombocytopenia.mp.	52629
25	131	venous thromboembolism.mp. or exp Venous Thromboembolism/	29575
26	132	deep vein thrombosis.mp.	31577
27	133	pulmonary embolism.mp. or exp Pulmonary Embolism/	59857
28	134	HIV.mp. or exp HIV Infections/	434875
29	135	AIDS.mp. or exp Acquired Immunodeficiency Syndrome/	233377
30	136	exp Immunocompromised Host/	27383
31	137	exp Immunosuppression Therapy/ or exp Immunosuppressive Agents/	388928
32	138	immunosuppress*.mp.	250351
33	139	exp Transplantation/	562203

1 140 transplant*.mp.829484
2 141 exp Alcohol-Related Disorders/ 120079
3 142 (alcohol misuse or alcohol abuse or alcohol dependence or alcoholism).mp. [mp=title, book
4 title, abstract, original title, name of substance word, subject heading word, floating sub-heading
5 word, keyword heading word, organism supplementary concept word, protocol supplementary
6 concept word, rare disease supplementary concept word, unique identifier, synonyms] 102885
7 143 exp Substance-Related Disorders/ 305479
8 144 (substance misuse or substance abuse or substance dependence).mp. [mp=title, book title,
9 abstract, original title, name of substance word, subject heading word, floating sub-heading word,
10 keyword heading word, organism supplementary concept word, protocol supplementary concept
11 word, rare disease supplementary concept word, unique identifier, synonyms] 62218
12 145 exp Anxiety/ or exp Anxiety Disorders/ 182212
13 146 anxiety.mp. 293708
14 147 panic disorder.mp. or exp Panic Disorder/ 11740
15 148 phobic disorder.mp. or exp Phobic Disorders/ 12318
16 149 phobia.mp. 9483
17 150 exp Stress Disorders, Post-Traumatic/ 39810
18 151 (post traumatic stress disorder or post-traumatic stress disorder or PTSD).mp. [mp=title,
19 book title, abstract, original title, name of substance word, subject heading word, floating sub-
20 heading word, keyword heading word, organism supplementary concept word, protocol
21 supplementary concept word, rare disease supplementary concept word, unique identifier,
22 synonyms] 37152
23 152 exp Mood Disorders/ 133816
24 153 exp Depression/ or exp Depression, Postpartum/ 151065
25 154 (depression or depressive disorder or mood disorder).mp. [mp=title, book title, abstract,
26 original title, name of substance word, subject heading word, floating sub-heading word, keyword
27 heading word, organism supplementary concept word, protocol supplementary concept word, rare
28 disease supplementary concept word, unique identifier, synonyms] 512446
29 155 dementia.mp. or exp Dementia/ 249440
30 156 eating disorder.mp. or exp "Feeding and Eating Disorders"/ 38866
31 157 (anorexia nervosa or bulimia nervosa).mp. [mp=title, book title, abstract, original title, name
32 of substance word, subject heading word, floating sub-heading word, keyword heading word,
33 organism supplementary concept word, protocol supplementary concept word, rare disease
34 supplementary concept word, unique identifier, synonyms] 21488
35 158 bipolar disorder.mp. or exp Bipolar Disorder/ 55305
36 159 exp "schizophrenia spectrum and other psychotic disorders"/ 160377

1 160 (schizophrenia or psychosis or psychotic disorder or schizoaffective disorder).mp. [mp=title,
2 book title, abstract, original title, name of substance word, subject heading word, floating sub-
3 heading word, keyword heading word, organism supplementary concept word, protocol
4 supplementary concept word, rare disease supplementary concept word, unique identifier,
5 synonyms] 184089

6 161 dissociative disorder.mp. or exp Dissociative Disorders/ 4851

7 162 obsessive compulsive disorder.mp. or exp Obsessive-Compulsive Disorder/ 21507

8 163 personality disorder.mp. or exp Personality Disorders/ 49545

9 164 self harm.mp. or exp Self-Injurious Behavior/ 84338

10 165 exp Mental Disorders/ 1400314

11 166 (mental disorder or psychiatric disorder).mp. [mp=title, book title, abstract, original title,
12 name of substance word, subject heading word, floating sub-heading word, keyword heading word,
13 organism supplementary concept word, protocol supplementary concept word, rare disease
14 supplementary concept word, unique identifier, synonyms] 22024

15 167 (serious mental illness or severe mental illness).mp. [mp=title, book title, abstract, original
16 title, name of substance word, subject heading word, floating sub-heading word, keyword heading
17 word, organism supplementary concept word, protocol supplementary concept word, rare disease
18 supplementary concept word, unique identifier, synonyms] 9183

19 168 exp Attention Deficit Disorder with Hyperactivity/ 33703

20 169 (attention deficit hyperactivity disorder or ADHD).mp. [mp=title, book title, abstract, original
21 title, name of substance word, subject heading word, floating sub-heading word, keyword heading
22 word, organism supplementary concept word, protocol supplementary concept word, rare disease
23 supplementary concept word, unique identifier, synonyms] 37625

24 170 exp Autism Spectrum Disorder/ 40143

25 171 (autism or autistic).mp. [mp=title, book title, abstract, original title, name of substance word,
26 subject heading word, floating sub-heading word, keyword heading word, organism supplementary
27 concept word, protocol supplementary concept word, rare disease supplementary concept word,
28 unique identifier, synonyms] 65738

29 172 cerebral palsy.mp. or exp Cerebral Palsy/ 31036

30 173 intellectual disabilit*.mp. or exp Intellectual Disability/ 114299

31 174 exp Down Syndrome/ or down* syndrome.mp. 32674

32 175 exp Brain Injuries/ or acquired brain injury.mp. 80562

33 176 exp Headache Disorders/ 39158

34 177 (cluster headache or tension headache or chronic headache or migraine).mp. [mp=title,
35 book title, abstract, original title, name of substance word, subject heading word, floating sub-
36 heading word, keyword heading word, organism supplementary concept word, protocol
37 supplementary concept word, rare disease supplementary concept word, unique identifier,
38 synonyms] 47919

1 178 exp Epilepsy/ 123445

2 179 (epilepsy or epileptic).mp. [mp=title, book title, abstract, original title, name of substance
3 word, subject heading word, floating sub-heading word, keyword heading word, organism
4 supplementary concept word, protocol supplementary concept word, rare disease supplementary
5 concept word, unique identifier, synonyms] 168992

6 180 idiopathic intracranial hypertension.mp. or exp Pseudotumor Cerebri/ 5277

7 181 multiple sclerosis.mp. or exp Multiple Sclerosis/ 96126

8 182 peripheral neuropathy.mp. or exp Peripheral Nervous System Diseases/ 173401

9 183 exp Parkinson Disease/ or parkinson* disease.mp. 128663

10 184 exp Neurodegenerative Diseases/ 356554

11 185 (huntington* disease or huntington* chorea).mp. [mp=title, book title, abstract, original
12 title, name of substance word, subject heading word, floating sub-heading word, keyword heading
13 word, organism supplementary concept word, protocol supplementary concept word, rare disease
14 supplementary concept word, unique identifier, synonyms] 20536

15 186 motor neurone disease.mp. 1097

16 187 exp Sleep Wake Disorders/ 105644

17 188 (sleep disorder or narcolepsy or obstructive sleep apn?ea).mp. [mp=title, book title,
18 abstract, original title, name of substance word, subject heading word, floating sub-heading word,
19 keyword heading word, organism supplementary concept word, protocol supplementary concept
20 word, rare disease supplementary concept word, unique identifier, synonyms] 42731

21 189 spina bifida.mp. or exp Spinal Dysraphism/ 12140

22 190 exp Fatigue Syndrome, Chronic/6267

23 191 (chronic fatigue syndrome or myalgic encephalomyelitis).mp. [mp=title, book title, abstract,
24 original title, name of substance word, subject heading word, floating sub-heading word, keyword
25 heading word, organism supplementary concept word, protocol supplementary concept word, rare
26 disease supplementary concept word, unique identifier, synonyms] 6552

27 192 fibromyalgia.mp. or exp Fibromyalgia/ 13499

28 193 exp Chronic Pain/ 21039

29 194 exp Complex Regional Pain Syndromes/ 5902

30 195 exp Myofascial Pain Syndromes/ 6785

31 196 (chronic pain or pain syndrome).mp. [mp=title, book title, abstract, original title, name of
32 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
33 supplementary concept word, protocol supplementary concept word, rare disease supplementary
34 concept word, unique identifier, synonyms] 67401

35 197 exp Back Pain/ or chronic back pain.mp. 44796

36 198 osteoarthritis.mp. or exp Osteoarthritis/106483

1 199 exp Osteoporosis/ 61530

2 200 (osteoporosis or osteopenia).mp. [mp=title, book title, abstract, original title, name of
3 substance word, subject heading word, floating sub-heading word, keyword heading word, organism
4 supplementary concept word, protocol supplementary concept word, rare disease supplementary
5 concept word, unique identifier, synonyms] 102970

6 201 scoliosis.mp. or exp Scoliosis/ 28584

7 202 exp Spinal Diseases/ 137686

8 203 exp Fractures, Compression/ 3022

9 204 (compression fracture or collapsed vertebra*).mp. [mp=title, book title, abstract, original
10 title, name of substance word, subject heading word, floating sub-heading word, keyword heading
11 word, organism supplementary concept word, protocol supplementary concept word, rare disease
12 supplementary concept word, unique identifier, synonyms] 2523

13 205 intervertebral disc degeneration.mp. or exp Intervertebral Disc Degeneration/ 8566

14 206 sciatica.mp. or exp Sciatica/ 7238

15 207 spinal stenosis.mp. or exp Spinal Stenosis/ 9721

16 208 spondylosis.mp. or exp Spondylosis/ 11295

17 209 spondylolisthesis.mp. or exp Spondylolisthesis/ 7552

18 210 amputation.mp. or exp Amputation/ 52820

19 211 amputee.mp. 3034

20 212 paralysis.mp. or exp Paralysis/ 117463

21 213 exp Hemiplegia/ or hemiplegia.mp. 16665

22 214 exp Paraplegia/ or paraplegia.mp. 22286

23 215 quadriplegia.mp. or exp Quadriplegia/ 10148

24 216 exp Disabled Persons/ 72228

25 217 (disabled or disabilit*).mp. [mp=title, book title, abstract, original title, name of substance
26 word, subject heading word, floating sub-heading word, keyword heading word, organism
27 supplementary concept word, protocol supplementary concept word, rare disease supplementary
28 concept word, unique identifier, synonyms] 368071

29 218 chronic kidney disease.mp. or exp Renal Insufficiency, Chronic/ 165323

30 219 h?emodialysis.mp. or exp Renal Dialysis/ 147868

31 220 exp Urinary Calculi/ 38075

32 221 (urinary tract stone* or kidney stone*).mp. [mp=title, book title, abstract, original title,
33 name of substance word, subject heading word, floating sub-heading word, keyword heading word,
34 organism supplementary concept word, protocol supplementary concept word, rare disease
35 supplementary concept word, unique identifier, synonyms] 7526

1	222	exp Asthma/ or asthma.mp.	193826
2	223	exp Lung Diseases/ or chronic lung disease.mp.	1172810
3	224	bronchiectasis.mp. or exp Bronchiectasis/	15266
4	225	exp Pulmonary Disease, Chronic Obstructive/	65000
5	226	(chronic obstructive pulmonary disease or COPD).mp. [mp=title, book title, abstract, original	
6		title, name of substance word, subject heading word, floating sub-heading word, keyword heading	
7		word, organism supplementary concept word, protocol supplementary concept word, rare disease	
8		supplementary concept word, unique identifier, synonyms]	76565
9	227	cystic fibrosis.mp. or exp Cystic Fibrosis/	56480
10	228	interstitial lung disease.mp. or exp Lung Diseases, Interstitial/	88055
11	229	pulmonary fibrosis.mp.	34669
12	230	pulmonary hypertension.mp. or exp Hypertension, Pulmonary/	57397
13	231	exp Sarcoidosis/ or sarcoidosis.mp.	33257
14	232	exp Tuberculosis/ or tuberculosis.mp.	274528
15	233	exp Ehlers-Danlos Syndrome/ or ehlers-danlos.mp.	4735
16	234	rheumatoid arthritis.mp. or exp Arthritis, Rheumatoid/	162479
17	235	exp Sjogren's Syndrome/	14277
18	236	(sjogren* syndrome or sjogren* disease).mp. [mp=title, book title, abstract, original title,	
19		name of substance word, subject heading word, floating sub-heading word, keyword heading word,	
20		organism supplementary concept word, protocol supplementary concept word, rare disease	
21		supplementary concept word, unique identifier, synonyms]	19871
22	237	exp Raynaud Disease/ or raynaud*.mp.	10222
23	238	systemic sclerosis.mp. or exp Scleroderma, Systemic/	27173
24	239	scleroderma.mp.	29499
25	240	primary systemic vasculitis.mp. or exp Systemic Vasculitis/	18247
26	241	marfan* syndrome.mp. or exp Marfan Syndrome/	8688
27	242	spondyloarthritis.mp. or exp Spondylarthritis/	31559
28	243	psoriatic arthritis.mp. or exp Arthritis, Psoriatic/	12555
29	244	ankylosing spondylitis.mp. or exp Spondylitis, Ankylosing/	21291
30	245	systemic lupus erythematosus.mp. or exp Lupus Erythematosus, Systemic/	80550
31	246	autoimmune disease.mp. or exp Autoimmune Diseases/	545468
32	247	frailty.mp. or exp Frailty/	23160
33	248	exp COVID-19/ or long covid.mp.	199512

1 249 post COVID syndrome.mp. 288

2 250 exp Obesity/ 251605

3 251 (obese or obesity).mp. [mp=title, book title, abstract, original title, name of substance word,
4 subject heading word, floating sub-heading word, keyword heading word, organism supplementary
5 concept word, protocol supplementary concept word, rare disease supplementary concept word,
6 unique identifier, synonyms] 419142

7 252 polypharmacy.mp. or exp Polypharmacy/ 12907

8 253 turner* syndrome.mp. or exp Turner Syndrome/ 9757

9 254 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
10 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
11 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
12 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
13 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
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23 232 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
24 246 or 247 or 248 or 249 or 250 or 251 or 252 or 253 14494082

25 255 (questionnaire* or survey* or interview* or focus group* or case stud* or observ* or
26 ethnograph* or hermeneutic* or narrative* or phenomenolog* or grounded theory or process
27 evaluation or implementation study or implementation research or view* or experienc* or opinion*
28 or attitude* or perception* or perceive* or belie* or feel* or know* or understand* or barrier* or
29 facilitator* or enabler* or obstacle*).tw. 9977739

30 256 exp Qualitative Research/ or (qualitative or mixed method*).tw. 332065

31 257 255 or 256 10059034

32 258 9 and 20 and 254 and 257 2187

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1 Medline search strategy for LTCs economic evidence review (chapter 8)

2 **Ovid MEDLINE(R) ALL <1946 to August 17, 2022>**

3 n=3077, searched on 17/08/22

- 4 1. exp Breast Feeding/
- 5 2. breastfeed*.mp.
- 6 3. breastfed.mp.
- 7 4. breast-feed*.mp.
- 8 5. breast-fed.mp.
- 9 6. breast feed*.mp.
- 10 7. breast fed.mp.
- 11 8. infant feed*.mp.
- 12 9. exp Milk, Human/
- 13 10. Lactation/
- 14 11. lactat*.mp.
- 15 12. support.mp.
- 16 13. Social Support/
- 17 14. advice.mp.
- 18 15. advis*.mp.
- 19 16. help*.mp.
- 20 17. supportive adj2 relationship.mp
- 21 18. counsel*.mp.
- 22 19. educat*.mp.
- 23 20. consult*.mp.
- 24 21. Health Promotion/
- 25 22. Health Education/
- 26 23. Economics/
- 27 24. exp "Costs and cost analysis"/
- 28 25. "Cost allocation"/
- 29 26. Cost-benefit analysis/
- 30 27. "Cost control"/
- 31 28. "Cost savings"/

- 1 29. "Cost of illness"/
- 2 30. "Cost sharing"/
- 3 31. "deductibles and coinsurance"/
- 4 32. Medical savings accounts/
- 5 33. Health care costs/
- 6 34. Direct service costs/
- 7 35. Drug costs/
- 8 36. Employer health costs/
- 9 37. Hospital costs/
- 10 38. Health expenditures/
- 11 39. Capital expenditures/
- 12 40. Value of life/
- 13 41. exp economics, hospital/
- 14 42. exp economics, medical/
- 15 43. Economics, nursing/
- 16 44. Economics, pharmaceutical/
- 17 45. exp "fees and charges"/
- 18 46. exp budgets/
- 19 47. (low adj cost).mp.
- 20 48. (high adj cost).mp.
- 21 49. (health?care adj cost\$).mp.
- 22 50. (fiscal or funding or financial or finance).tw.
- 23 51. (cost adj estimate\$).mp.
- 24 52. (cost adj variable).mp.
- 25 53. (unit adj cost\$).mp.
- 26 54. (economic\$ or pharmacoeconomic\$ or price\$ or pricing).tw.
- 27 55. or/1-11
- 28 56. or/12-22
- 29 57. or/23-54
- 30 58. 55 and 56 and 57
- 31 59. exp animals/ not humans.sh.

1 60. 58 not 59

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1 Appendix 2: Study characteristics, risk of bias assessments and
2 behaviour-change techniques for mixed-methods synthesis (chapter
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Table 13. Study characteristics for mixed-methods synthesis (Chapter 4)

Author Year	RCT paper(s)	Country Setting/target population	Intervention description	Methods		
				Study objective	Participants and data collection	Data analysis
Ahmed <i>et al.</i> 2012 ¹⁰¹	Ahmed <i>et al.</i> 2020 ²⁶⁷	USA Hospital	Interactive web-based breastfeeding monitoring system	To develop an interactive web-based breastfeeding monitoring system (<i>LACTOR</i>) 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 Fischer's exact tests Content analysis
Andaya <i>et al.</i> 2012 ⁹³	Bonuck <i>et al.</i> 2014 ²²³	USA Urban Primary health care 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 <i>et al.</i> 2014 ¹⁰⁰				To examine women's perceptions of early infant feeding experiences and identified early postpartum barriers to breastfeeding		
Bronner <i>et al.</i> 2001 ¹⁰⁵	Gross <i>et al.</i> 1998 ²⁶⁸	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 Supplemental Nutrition Program for Women, Infants and Children (WIC) agencies.	Convenience sample of programme managers/co-ordinators (n=409) and peer counsellors (n=254) Survey	Descriptive statistics
Chapman <i>et al.</i> 2004 ¹⁰⁶	Chapman <i>et al.</i> 2004 ²⁶⁹	USA Urban Hospital and community	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

		Low-income Latina women				
Cramer <i>et al.</i> 2017 ¹⁰²	McLachlan <i>et al.</i> 2016 ²²⁷	Australia Urban and rural Community Areas with low breastfeeding rates	Two interventions 1 early home-based visiting by a maternal and child health nurse to women identified at risk of breastfeeding cessation 2 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
Ridgway <i>et al.</i> 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 <i>et al.</i> 2002 ¹⁰⁷	Dennis <i>et al.</i> 2002 ²⁷⁰	Canada Urban Community hospitals	Telephone support by volunteer with breastfeeding 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 <i>et al.</i> 2012 ¹⁰³	Hoddinott <i>et al.</i> 2012 ²²⁶	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)	Quantitative Telephone call log and workload diaries. Qualitative Interviews with women (n=40) with follow-up (n=11) and staff (n=17)	Descriptive statistics Framework analysis

				telephone support after hospital discharge.	Ward observations Recorded telephone calls (n=16) Steering group meetings notes (n=9) Trial case notes (n=69) Telephone interviews (n=372).	
Nankunda <i>et al.</i> 2006 ⁹⁵	Tylleskar <i>et al.</i> 2011 ¹⁰⁹	Uganda Rural Community and healthcare settings	Peer counselling Minimum of 5 home visits form late pregnancy up to 6 months postnatal Intervention delivered in 3 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 <i>et al.</i> 2010a 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 <i>et al.</i> 2010b 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 Fischer's exact test Coding of open-ended responses
Rujumba <i>et al.</i> 2020 ⁹⁹				To explore the barriers, facilitators 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 <i>et al.</i> 2010 ⁹⁴	Tylleskar <i>et al.</i> 2011 ¹⁰⁹	South Africa Community	Peer counselling Minimum of 5 home visits form late	To report the experience of three Community Health Worker supervisors who were	Semi-structured interviews (n=3)	Framework analysis

		Poor areas with high HIV prevalence	pregnancy up to 6 months postnatal Intervention delivered in 3 areas and adapted to local circumstances	responsible for supporting infant feeding peer counsellors.		
Nkonki <i>et al.</i> 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 <i>et al.</i> 2012 ⁹⁸	Sikander <i>et al.</i> 2015 ²⁷¹	Pakistan Rural community Low literacy, with low rates of exclusive breastfeeding	7 psycho-educational sessions integrated into the routine work of lady health workers (LHWs)	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

Abbreviations: LHW= Lady Health Workers; WIC=Supplemental Nutrition Program for Women, Infants and Children;

Table 14. Quality appraisal of included studies (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 <i>et al.</i> 2012 ¹⁰¹	Yes, a few steps were taken	Yes –several steps were taken	Yes- fairly thorough attempt	Reasonably well grounded/sup ported	Good/fair breadth but very little depth	A lot	Medium	Medium
Andaya <i>et al.</i> 2012 ⁹³	Yes- fairly thorough attempt	Yes- fairly thorough attempt	Yes- fairly thorough attempt	Reasonably well grounded/sup ported	Limited breadth or depth	Somewhat	Medium	Medium
Bronner <i>et al.</i> 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 <i>et al.</i> 2004 ¹⁰⁶	Yes, several steps were taken	Unclear	Yes, a few steps were taken	Reasonably well grounded/sup ported	Limited breadth or depth	A little	Medium	Medium
Cramer <i>et al.</i> 2017 ¹⁰²	Yes –several steps were taken	Yes –several steps were taken	Yes- fairly thorough attempt	Reasonably well grounded/sup ported	Good/fair depth but very little breadth	Not at all	High	Medium

Daniels <i>et al.</i> 2010 ⁹⁴	Yes –fairly thorough attempt	Yes- a few steps were taken	Yes- several steps were taken	Reasonably well grounded/sup ported	Good/fair depth but	Not at all	Low	Low
Dennis <i>et al.</i> 2002 ¹⁰⁷	Yes- fairly thorough attempt	Yes –fairly thorough attempt	Yes –fairly thorough attempt	Fairly well grounded/sup ported	Good/fair breadth but very little depth	Somewhat	Medium	Medium
Hoddinott <i>et al.</i> 2012 ¹⁰³	Yes- fairly thorough attempt	Yes- fairly thorough attempt	Yes- fairly thorough attempt	Reasonably well grounded/sup ported	Good/fair breadth and depth	A lot	High	High
Nankunda <i>et al.</i> 2006 ⁹⁵	Unclear	Yes –fairly thorough attempt	Unclear	Fairly well grounded/sup ported	Good/fair breadth and depth	Somewhat	Low	Medium
Nankunda <i>et al.</i> 2010a ⁹⁶	Yes, several steps were taken	Yes –several steps were taken	Yes- fairly thorough attempt	Fairly well grounded/sup ported	Good/fair breadth but very little depth	Not at all	Medium	Medium
Nankunda <i>et al.</i> 2010b ¹⁰⁴	Yes- fairly thorough attempt	Yes- fairly thorough attempt	Yes- fairly thorough attempt	Reasonably well grounded/sup ported	Good/fair breadth and depth	A lot	High	High
Nkonki <i>et al.</i> 2010 ⁹⁷	Yes- fairly thorough attempt	Yes- fairly thorough attempt	Yes- fairly thorough attempt	Fairly well grounded/sup ported	Good/fair depth but very little breadth	Not at all	High	High
Rahman <i>et al.</i> 2011 ⁹⁸	Yes, a few steps were taken	Yes, a few steps were taken	Yes- fairly thorough attempt	Reasonably well grounded/sup ported	Good/fair depth but very little breadth	Not at all	High	Medium
Ridgway <i>et al.</i> 2016 ¹⁰⁸	Unclear	Yes, a few steps were taken	Yes, a few steps were taken	Reasonably well	Limited breadth or depth	Not at all	Medium	Medium

				grounded/sup ported				
Rujumba <i>et al.</i> 2020 ⁹⁹	Yes- several steps were taken	Yes- several steps were taken	Yes- fairly thorough attempt	Reasonably well grounded/sup ported	Good/fair breadth and depth	A lot	High	High
Teich <i>et al.</i> 2014 ¹⁰⁰	Yes- fairly thorough attempt	Yes- fairly thorough attempt	Yes- fairly thorough attempt	Reasonably well grounded/sup ported	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)	Implementation research articles included in WP2 review	BCTs identified in Cochrane study articles
Ahmed 2020	Ahmed 2012	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 behavior 3.1. Social support (unspecified) 3.2. Social support (practical) 4.1. Instruction on how to perform the behavior 4.2. Information about antecedents 7.1. Prompts/cues 9.1. Credible source 10.4. Social reward
Bonuck 2014a, 2014b	Andaya 2012	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	Chapman 2004	<ul style="list-style-type: none"> 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 behavior 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	Dennis 2002	<ul style="list-style-type: none"> 1.2. Problem solving 3.1. Social support (unspecified) 3.2. Social support (practical)
Gross 1998	Bronner 2001	<ul style="list-style-type: none"> 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	Hoddinott 2012	<ul style="list-style-type: none"> 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
McLachlan 2016	<ul style="list-style-type: none"> Cramer 2017 Ridgeway 2016 	<ul style="list-style-type: none"> 1.1. Goal setting (behaviour) 1.2. Problem solving 3.1. Social support (unspecified) 15.1. Verbal persuasion about capability
Sikander 2015	Rahman 2012	<ul style="list-style-type: none"> 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 behavior 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	Nankunda 2006 Rujumba 2020 Nankunda 2010 Nankunda 2010a Nkonki 2010 Daniels 2010	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
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Appendix 3: Characteristics of included economic evaluation studies

Table 16. Characteristics of included economic evaluation studies (chapter 5)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Barnes 2017 (Barnes et al., 2017) 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 Provider: Professional (two FNP) Mode of delivery: Face-to-face with groups Intensity: High (44	Usual care Description: Offers every family a program of screening tests, immunizations, 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 with medium or high risk. The universal program includes a neonatal examination, a new baby re- view at about 14 days, a 6- to 8-week baby examination and a review by the time the child is 1 year	Inclusion criteria: Expectant mothers 16-20 weeks' gestation, expected delivery date within ~10 weeks, aged either (i) <20 years at last menstrual period with one or more previous live births, or (ii) 20-24 years at last menstrual period with no previous live births and with low educational qualifications Exclusion criteria: Women who had previously received FNP and those with psychotic mental illness Sample size: Total n = 166 (IG: 99; CG: 67) Baseline characteristics: Baseline characteristics of participants appear balanced. Participants appear	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) Data sources: <i>Outcome of effect:</i> within trial (EQ-5D-5L valued using UK Tariffs) <i>Resource use:</i> within trial <i>Unit costs:</i> 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 (i) completers (attended ≥17 sessions) and (ii) program 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	Base case results: ICER = -£247,485 per QALY gained, ICER = £111,334 per gain in AAPI-2 score, ICER = -£2,382 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 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 NW quadrant and the probability of cost-effectiveness remaining <20% 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.

	contacts) Duration: From first trimester of pregnancy until infants were 12 months old	old and at 2 to 2.5 years old.	in keeping with target population.	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 highest and lowest number of observed values across all groups and sites.		
Brown 2020 (Brown et al., 2020)	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 entry for description 2) Communicating Healthy Beginnings Advice by Telephone (CHAT) trial - see Wen 2017 entry for description 3) Prevention of Overweight in Infancy (POI) trial - see Tan 2020 entry for description Provider: Professional	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 Baseline characteristics: 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 5 trials (3 eligible for this review) Perspective: Provider/funder Currency, price year: AUD \$, 2018 Time horizon: Birth to infant aged 2 years Discount rate: 5% for costs Primary outcome: Intervention cost Secondary outcomes: Not applicable Data sources: <i>Outcome of effect:</i> not applicable <i>Resource use:</i> within trial <i>Unit costs:</i> national sources 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%	Base case results: From most to least costly: HB \$1135 (\$1059-\$1189); POI-combined \$602 (\$577-\$624); POI-FAB alone \$429 (\$409-\$449); CHAT-Telephone \$394 (\$373-\$382); CHAT-SMS \$80 (\$77-\$82) Interventions varied widely in terms of resource use and costs. 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.	Not applicable: Intervention costs reported with a comparison, OECD setting. Provider perspective, time horizon from birth up to infant age 2 years

	Mode of delivery: Face-to-face and/or Telephone/SMS Intensity: Moderate-High (8-10 contacts) Duration: From late pregnancy/birth to infant age 2 years (POI 18 months; 2 years on request)					
Delgado 2018 (Delgado et al., 2018) 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 United Kingdom 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." Provider:	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 Sample size: A total of 95 mothers visited the café during the one-year data collection period Baseline characteristics: Not applicable; however, 95% of mothers attending came from the WIC clinic catchment area, indicating low-income status	Type of economic evaluation: Cost description Perspective: Provider (State funder) Currency, price year: USD \$, 2010 Time horizon: Birth to infant aged 8 Weeks Discount rate: 3.5% for delivery costs across 5-years Primary outcome: Cost per mother Secondary outcomes: Cost per session Data sources: <i>Outcome of effect:</i> not applicable <i>Resource use:</i> programme data <i>Unit costs:</i> 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"	Base case results: Cost per mother = \$105; cost per session = \$22.53 Findings from sensitivity analyses: Cost per mother ranged from \$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.

	Professional (lactation specialist) and lay person (peer counsellor) Mode of delivery: Face-to-face in groups Intensity: Low-Moderate (2-8 contacts) Duration: From birth to infant age 8 weeks					
DelliFraine 2011 (DelliFrane et al., 2011) USA Nationwide Hospital setting	BFHI accredited hospitals Support: Breastfeeding plus Description: BFHI steps 1-9 for organisations to promote successful breastfeeding 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	Usual care Description: Non-BFHI accredited hospitals. No further information provided	Inclusion criteria: All baby-friendly hospital and birthing sites in the United States 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) Exclusion criteria: Baby-friendly hospital and birthing sites in the United States in 2009 without data available in the public data files Sample size: Total n = 124 (IG: 62; CG: 62) Baseline	Type of economic evaluation: Cost analysis of two alternatives Perspective: Payer Currency, price year: USD \$, 2007 Time horizon: One year Discount rate: Not applicable Primary outcome: Mean cost per nursery plus labour and delivery Secondary outcomes: Not applicable Data sources: <i>Outcome of effect:</i> not applicable <i>Resource use:</i> data from the 2007 American Hospital Association <i>Unit costs:</i> national sources Measurement of uncertainty: Not reported Consideration of heterogeneity: Not reported Sensitivity analyses: Not reported	Base case results: Differential cost of \$35 per nursery plus labour and delivery For the primary outcome, no statistically significant difference in mean cost per delivery identified (\$2205 vs \$2170) for Baby-friendly hospitals compared to 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 one year.

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.

<p>Frick 2012</p> <p>USA</p> <p>2 hospitals (1 university and 1 community hospital) serving urban areas in Baltimore, Maryland, USA</p> <p>Two hospitals (1 university and 1 community hospital)</p>	<p>Usual care plus a structured programme of education and support + usual care</p> <p>Support: Breastfeeding only</p> <p>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)</p> <p>Provider: Professional and paraprofessional with a community nurse and peer counsellor</p> <p>Mode of delivery: Face-to-face and phone</p> <p>Intensity: High</p> <p>Duration: Birth to 24 weeks' postpartum</p>	<p>Usual care</p> <p>Description: Usual care included access to a lactation consultant in hospital and phone access after discharge home</p>	<p>Inclusion criteria: Mother English-speaking, with phone access and living within 25 miles of the hospital, intending to breastfeed, family eligible for WIC program, singleton term infant (>37 weeks' gestation)</p> <p>Exclusion criteria: Infants or mothers with positive drug screen, infants with craniofacial abnormalities, infants admitted to NICU</p> <p>Sample size: Total N=328 Intervention N=168 Control N=160</p> <p>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.</p>	<p>Type of economic evaluation: CA</p> <p>Perspective: Societal perspective – limited to payer and family</p> <p>Currency, price year: \$USD, 2009 adjusted to 2011 prices</p> <p>Time horizon: Infant age 12 weeks</p> <p>Discount rate: N/A</p> <p>Primary outcome: Base Case Per Person Costs of the Program (Personnel and transportation costs only)</p> <p>Data sources:</p> <p><i>Outcome of effect:</i> within trial</p> <p><i>Resource use:</i> within trial</p> <p><i>Unit costs:</i> within trial and national sources</p> <p>Measurement of uncertainty: Varied labour costs to upper and lower confidence interval limits for time (assuming max. and min. expenditures, respectively).</p> <p>Consideration of heterogeneity: None reported</p> <p>Sensitivity analyses: (1) Costs at upper limit, (2) Costs at lower limit.</p>	<p>Base case results: Cost = US\$296.54 (274.12-320.97)</p> <p>Findings from sensitivity analyses: (1) Cost at upper limit = US\$320.97, (2) Cost at lower limit = US\$274.12</p>	<p>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.</p>
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<p>Haider 2014 (Haider et al., 2014)</p> <p>USA</p> <p>22 counties in the State of Michigan</p> <p>Community healthcare setting</p>	<p>Peer counsellor (PC) breastfeeding support programme</p> <p>Support: Breastfeeding only</p> <p>Description: Breastfeeding education and support to low socio-economic status women through the use of 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.</p> <p>Provider: Lay person (peer counsellor)</p> <p>Mode of delivery: Face-to-face and telephone</p> <p>Intensity: High - aim for monthly home visits or telephone calls, depending on type of support needed</p>	<p>Unclear</p> <p>Description: Women had requested the PC support programme but did not receive it due to high demand and low capacity</p>	<p>Inclusion criteria: Women who requested the breastfeeding support programme, individuals for whom Medicaid claims data were available and who were recruited into the program prenatally</p> <p>Exclusion criteria: Not reported</p> <p>Sample size: Total n = 846 (IG: 274; CG: 572)</p> <p>Baseline characteristics: Appear balanced at baseline</p>	<p>Type of economic evaluation: Cost outcome description of two alternatives</p> <p>Perspective: Payer</p> <p>Currency, price year: USD \$, price year not reported</p> <p>Time horizon: From birth to infant age 12 months</p> <p>Discount rate: Not applicable</p> <p>Primary outcome: Mean expenditures on health utilization per infant</p> <p>Secondary outcomes: Programme cost per mother</p> <p>Data sources:</p> <p><i>Outcome of effect:</i> breastfeeding rates</p> <p><i>Resource use:</i> data from Medicaid administrative data</p> <p><i>Unit costs:</i> not applicable (total expenditure from Medicaid administrative data)</p> <p>Measurement of uncertainty: 95% confidence intervals reported</p> <p>Consideration of heterogeneity: Regression model adjusted for potential confounders</p> <p>Sensitivity analyses: Not reported</p>	<p>Base case results: Adjusted differential expenditure of 770 (-927, 2467) on health utilization per infant</p> <p>For the primary outcome, no statistically significant difference in mean expenditures on health utilization per infant for women receiving PC support compared to those who requested support but did not receive it.</p>	<p>Not applicable: Payer perspective, differential cost reported with gross costing methods used. OECD setting, time horizon from birth to infant age 12 months.</p>
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Duration: Third trimester of pregnancy up to maximum infant age 12 months

<p>Hanafin 2018</p> <p>Ireland</p> <p>Country-wide</p> <p>Community healthcare setting</p>	<p>PHN-facilitated Breastfeeding Groups + usual care</p> <p>Support: Breastfeeding only</p> <p>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.</p> <p>Provider: Professional (lactation consultants)</p> <p>Mode of delivery: Face-to-face</p> <p>Intensity: High</p> <p>Duration: Antenatal through to postnatal duration of breastfeeding</p>	<p>No comparator</p> <p>Description: Not applicable</p>	<p>Inclusion criteria: N/A</p> <p>Exclusion criteria: N/A</p> <p>Sample size: N/A</p> <p>Baseline characteristics: N/A</p>	<p>Type of economic evaluation: CBA - Social Return on Investment</p> <p>Perspective: Societal</p> <p>Currency, price year: Euro €, price date and year of conversion unclear</p> <p>Time horizon: Costs and benefits are calculated and presented in terms of average annual figures for a group</p> <p>Discount rate: Outcomes beyond one year were discounted at 5% for those 2-5 years</p> <p>Primary outcome: Net present value social return on investment (SROI) ratio in Euro € per annum for the PHN-facilitated breastfeeding groups</p> <p>Data sources:</p> <p><i>Outcome of effect:</i> within study and literature</p> <p><i>Resource use:</i> within study and literature</p> <p><i>Unit costs:</i> within study and literature</p> <p>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.</p> <p>Consideration of heterogeneity: No consideration of heterogeneity</p> <p>Sensitivity analyses: Sensitivity analysis assessed changes to valuations of key benefits: increased intelligence, improved lifetime earnings, reduced cancer incidence.</p>	<p>Base case results: SROI ratio in Euro€ per annum for the PHN-facilitated breastfeeding groups €15.85:1</p> <p>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</p>	<p>Not applicable: Cost of one alternative provided, no ICER reported. OECD-setting, societal perspective, time horizon from birth to lifetime.</p>
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<p>Hayes 2014 (Hayes et al., 2014; Wen et al., 2012)</p> <p>Australia</p> <p>Socially and economically disadvantaged areas of Sydney</p> <p>Community setting with home visits</p>	<p>Healthy Beginnings (HB) + usual care</p> <p>Support: Breastfeeding plus</p> <p>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 hrs with the mother/infant and addressed 4 key areas: infant feeding practices, infant nutrition and active play, family physical activity and nutrition, as well as social support).</p> <p>Provider: Professional (community nurse)</p> <p>Mode of delivery: Face-to-face with individuals via home visits</p> <p>Intensity: Moderate (8 contacts)</p> <p>Duration: From pregnancy until infant age 2 yrs</p>	<p>Usual care</p> <p>Description: usual childhood nursing service, comprising 1 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.</p>	<p>Inclusion criteria: ≥16 years old, expecting first child, between weeks 24-34 of pregnancy, able to communicate in English, and lived in the local area</p> <p>Exclusion criteria: Women were excluded from the study if they had severe medical conditions as evaluated by their physicians,</p> <p>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: 166; CG: 158))</p> <p>Baseline characteristics: Baseline characteristics appear balanced for age, household income and education level, excepting marital status (p=0.046) with a lower percentage</p>	<p>Type of economic evaluation: CEA (trial-based)</p> <p>Perspective: Provider (health funder)</p> <p>Currency, price year: AUD \$, 2012</p> <p>Time horizon: Within trial - pregnancy to infant aged 2 years</p> <p>Discount rate: 5% for costs and benefits accrued beyond the first 12 months of follow-up</p> <p>Primary outcome: Incremental cost per unit BMI avoided</p> <p>Secondary outcomes: Incremental cost per 0.1 BMI-z score reduction</p> <p>Data sources: <i>Outcome of effect:</i> within trial <i>Resource use:</i> retrospective costing of trial data <i>Unit costs:</i> national sources</p> <p>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</p> <p>Consideration of heterogeneity: Not reported</p> <p>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 min to 20 min</p>	<p>Base case results: ICER = \$4,230 per unit BMI avoided; ICER = \$631 per 0.1 BMI-z score reduction</p> <p>Difficult to gauge cost-effectiveness, as no understanding of health providers' WTP for the prevention of BMI gain.</p> <p>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 HB being cost-effective (66% vs 30%) at a suggested WTP threshold of \$500 for a 0.1 BMI z-score reduction</p>	<p>Partially applicable: OECD setting. Provider perspective, cost per unit BMI avoided reported, within-trial time horizon from birth to infant age 2 years.</p>
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			(90% vs 96%) of women being married/de-facto in the intervention group			
Hoddinott 2009 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	Type of economic evaluation: CA Perspective: Provider (e.g., NHS & PSS), Patient i.e., Mother Currency, price year: GBP £, 2005/2006 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: <i>Outcome of effect:</i> within trial <i>Resource use:</i> within trial <i>Unit costs:</i> 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.

			existing number of breastfeeding groups per 1000 births. Considered intervention and control groups to be comparable.			
Hoddinott 2012	Feeding support team with proactive telephone support + usual care Support: Breastfeeding only Description: Proactive telephone calls Provider: Professional and para-professional staff (two band 4 staff (a nursery nurse and a maternity care assistant) and a band 7 (midwife) team leader Mode of delivery: Telephone Intensity: Moderate (median of 8 contacts) Duration: From hospital discharge up to 14 days post discharge	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 answer-phone messaging available.	Inclusion criteria: Women admitted to the ward who lived in 3 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 Sample size: Total n = 69 (IG: 35; CG: 34) Baseline characteristics: Concerns about baseline imbalances with women in IG a year older on average, more living	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 Data sources: <i>Outcome of effect:</i> within-trial data <i>Resource use:</i> within-trial data <i>Unit costs:</i> 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	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.

			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.			
Mavranouzouli 2022 (Mavranouzouli et al., 2022) 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 eight weeks after birth." Provider: Lay person and professional Mode of delivery: Face-to-face	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	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 Baseline characteristics: For modelling purposes, maternal mean age was 30 years for both groups	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: <i>Outcome of effect:</i> age- and gender-specific UK population-based EQ-5D-derived utility values used <i>Resource use:</i> expert advice for the intervention, systematic review evidence for probability estimates on health care resource use <i>Unit costs:</i> national sources Measurement of uncertainty: 10,000 iterations of incremental costs and effects generated to determine level of sampling	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	Directly applicable: UK setting, provider perspective, cost per QALY gained reported, time horizon from birth up to 1 year or lifetime, depending on condition.

Intensity: Moderate (6 contacts: four individual and two group-based)

Duration: Initiated antenatally and provided postnatally. No indication of duration

health visitors as part of routine postnatal care visits."

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.

takes place e.g., incidence of breast cancer.

<p>Morrell 2000 (Morrell et al., 2000a & 2000b)</p> <p>England</p> <p>Recruitment from one maternity hospital</p> <p>Community healthcare setting</p>	<p>Community postnatal support worker + usual care</p> <p>Support: Breastfeeding plus</p> <p>Description: Community postnatal support worker with 8 weeks' training provided home-based practical and emotional social support</p> <p>Provider: Lay (postnatal support workers)</p> <p>Mode of delivery: Face-to-face</p> <p>Intensity: High (up to 10 contacts)</p> <p>Duration: the first 28 days after birth (maximum of 3 h/visit)</p>	<p>Usual care</p> <p>Description: Standard UK care includes postnatal home visits from midwives and health visitors</p>	<p>Inclusion criteria: English-speaking women, ≥ 17 years, who gave birth at the study hospital</p> <p>Exclusion criteria: Baby spent >48 h on the SCBU</p> <p>Sample size: Total n = 623 (IG: 311; CG: 312)</p> <p>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.</p>	<p>Type of economic evaluation: Cost analysis (conducted alongside a RCT)</p> <p>Perspective: Provider (NHS and PSS)</p> <p>Currency, price year: GBP £, 1996</p> <p>Time horizon: From birth up to infant aged 6 months</p> <p>Discount rate: Not applicable</p> <p>Primary outcome: Mean incremental costs at six months</p> <p>Secondary outcomes: Mean incremental costs at six weeks</p> <p>Data sources: <i>Outcome of effect:</i> within trial (but not included in economic evaluation) <i>Resource use:</i> within trial <i>Unit costs:</i> local and national sources</p> <p>Measurement of uncertainty: Nonparametric bootstrap centile confidence intervals were estimated for the difference in mean scores between the groups</p> <p>Consideration of heterogeneity: Not as part of the economic evaluation.</p> <p>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.</p>	<p>Base case results: Mean incremental costs at six months 178.61 (79.6 - 272.4); Mean incremental costs at six weeks £179.58 (125-85 - 232.34). Authors note that "There were no savings to the NHS over six months after the introduction of the community postnatal support worker service."</p> <p>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 six weeks.</p>	<p>Partially applicable: UK setting, provider perspective, intervention costs reported only, time horizon limited to within -trial (birth to infant age 6 months).</p>
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<p>Mottl-Santiago 2020</p> <p>USA</p> <p>Boston, MA</p> <p>Community healthcare setting</p>	<p>Birth Sisters Best Beginnings for Babies program (Doula support) + usual care</p> <p>Support: Breastfeeding plus</p> <p>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.</p> <p>Provider: Lay (Doula peer support)</p> <p>Mode of delivery: Face-to-face</p> <p>Intensity: High – Up to 12 contacts</p> <p>Duration: 24 weeks' gestation through to 6-8 weeks postpartum.</p>	<p>Usual care</p> <p>Description: Usual prenatal, intrapartum and postpartum maternity care</p>	<p>Inclusion criteria: Being a pregnant Woman 16 to 24 gestational age, First Time Mother, Singleton, Public insurance, no known fetal anomaly. Described as "a healthy population of nulliparous pregnant women"</p> <p>Exclusion criteria: < 18 years of age, high risk pregnancy defined by care in the high-risk prenatal clinic</p> <p>Sample size: Total N=411, Intervention N=207, Control N=204</p> <p>Baseline characteristics: No group differences observed at baseline</p>	<p>Type of economic evaluation: CBA (study-based)</p> <p>Perspective: Payer</p> <p>Currency, price year: USD \$, 2018</p> <p>Time horizon: From mid-pregnancy to 6-8 weeks postpartum</p> <p>Discount rate: N/A</p> <p>Primary outcome: Average incremental cost per additional person served over the three years</p> <p>Secondary outcomes: Return on investment</p> <p>Data sources:</p> <p><i>Outcome of effect:</i> within trial</p> <p><i>Resource use:</i> within trial</p> <p><i>Unit costs:</i> local sources</p> <p>Measurement of uncertainty: Payments were winsorized to address outliers.</p> <p>Consideration of heterogeneity: Variations in impact for different populations</p> <p>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.</p>	<p>Base case results: Incremental cost=\$433, ROI: 18%</p> <p>Findings from subgroup analyses: Variation in target population, ROI changed for social risk (70%), Medical risk (276%), Medical and social risk (471%).</p> <p>Findings from sensitivity analyses: Variations in wages, programme costs ranged from \$769-\$1604.</p>	<p>Not applicable: Payer perspective taken. OECD setting, Incremental costs reported and return on investment.</p>
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<p>Paranjothy 2017</p> <p>UK</p> <p>England and Wales</p> <p>Community healthcare setting</p>	<p>Mam-Kind intervention + usual care</p> <p>Support: Breastfeeding only</p> <p>Description: Mam-Kind is a motivational interviewing-based breastfeeding peer-support intervention to support breastfeeding maintenance.</p> <p>Provider: Lay (Mam-Kind buddy)</p> <p>Mode of delivery: Face-to-face</p> <p>Intensity: High - mean 16 contacts (0-44)</p> <p>Duration: Birth to 6 weeks' postpartum</p>	<p>No comparator</p> <p>Description: Not applicable</p>	<p>Inclusion criteria: Pregnant women considering breastfeeding</p> <p>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.</p> <p>Sample size: Total N=70 (no control group)</p> <p>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)</p>	<p>Type of economic evaluation: Cost-outcome descriptions</p> <p>Perspective: Societal</p> <p>Currency, price year: GBP £, 2016</p> <p>Time horizon: Bottom-up approach: Pregnancy up to 10 weeks' postpartum; top-down approach: 6 months</p> <p>Discount rate: N/A</p> <p>Primary outcome: Total intervention costs</p> <p>Secondary outcomes: Intervention cost per participant</p> <p>Data sources:</p> <p><i>Outcome of effect:</i> within trial</p> <p><i>Resource use:</i> within trial</p> <p><i>Unit costs:</i> within trial and national sources</p> <p>Measurement of uncertainty: N/A</p> <p>Consideration of heterogeneity: N/A</p>	<p>Base case results: Total intervention costs = £33,595, Intervention cost per participant = £480</p>	<p>Not applicable: UK-based study, societal perspective, costs for one alternative reported.</p>
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Pramono 2021b 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. Provider: Professional Mode of delivery: Face-to-face Intensity: High	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: <i>Outcome of effect:</i> within study and literature <i>Resource use:</i> within study and literature <i>Unit costs:</i> 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.	Base case results: SROI = AUD\$55.38:1 Findings from sensitivity analyses: SROI ranged from AUD\$16-111:1	Not applicable: OECD setting, societal perspective, no cost per QALY gained reported.
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<p>Pugh 2002</p> <p>USA</p> <p>City of Baltimore, Maryland</p> <p>Community healthcare setting</p>	<p>Breastfeeding Support Program + usual care</p> <p>Support: Breastfeeding only</p> <p>Description: Breastfeeding support visits by community health nurse/peer counsellor team. Support offered daily in hospital, and at home during weeks 1, 2, 4 and at team's discretion. Telephone support from peer counsellor twice weekly through to week 8 and monthly through to month 6.</p> <p>Provider: Professional and lay (community health nurse/peer counsellor team)</p> <p>Mode of delivery: Face-to-face and telephone</p> <p>Intensity: High</p> <p>Duration: From birth to infant age 6 months</p>	<p>Usual care</p> <p>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, 1 hospital visit from a LC.</p>	<p>Inclusion criteria: Low-income women receiving financial medical assistance</p> <p>Exclusion criteria: Not reported</p> <p>Sample size: Total N=41 Intervention N=21 Control N=20</p> <p>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."</p>	<p>Type of economic evaluation: Cost -outcome description of two alternatives</p> <p>Perspective: Provider and Family</p> <p>Currency, price year: USD \$ Not reported - used cost data from the National Compensation Survey, which was authored in 1998 and accessed on 25th Jan 2002. November 1999 was used as reference point when valuing the cost of concentrate/powder for formula feeding.</p> <p>Time horizon: Birth to 6 months postpartum</p> <p>Discount rate: N/A</p> <p>Primary outcome: Incremental cost per mother (contact time and travel)</p> <p>Secondary outcomes: Incremental cost per mother (Formula milk and Intervention + Mother's time to feed)</p> <p>Data sources:</p> <p><i>Outcome of effect:</i> within trial</p> <p><i>Resource use:</i> within trial</p> <p><i>Unit costs:</i> within trial, local and national sources</p> <p>Measurement of uncertainty: Measure of uncertainty (standard error) reported around incremental costs</p> <p>Consideration of heterogeneity: N/A</p> <p>Sensitivity analyses Calculation of project costs using project records to ascertain what staff were paid, taking into account training and in-service education.</p>	<p>Base case results: Incremental cost per mother (contact time and travel) = US\$646 (SE 251); Incremental cost per mother (Formula milk and Intervention + Mother's time to feed) = US\$646 (SE 251)</p> <p>Findings from SA: Alternative costing scenario suggest incremental costs would be sensitive to change in method of valuing staff time.</p>	<p>Partially applicable: OECD setting, provider and family perspective with costs reported separately, within-trial time horizon from birth to 6 months, incremental costs reported.</p>
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Spiby 2015 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 method 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 & 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: <i>Outcome of effect:</i> within study and literature <i>Resource use:</i> within study and literature <i>Unit costs:</i> 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.
Stevens 2006 Canada City of Toronto Hospital and community setting	Home breastfeeding support Support: Breastfeeding only Description: Planned early discharge from hospital (24-36 hrs postpartum) and up to 3 home visits by community nurse LCs. Content of support unclear. Provider: Professional (LC) Mode of delivery:	Standard care Description: Standard discharge from hospital (48-60 hrs postpartum) with in-hospital breastfeeding support.	Inclusion criteria: Live, singleton, term or near term infant delivered in 12 h before recruitment; women ≥ 21 years residing in defined study area, intending to breastfeed and with satisfactory home circumstances (assessed by postpartum nurses) Exclusion criteria: Non-English-speaking	Type of economic evaluation: Cost analysis (conducted alongside a RCT) Perspective: Health care 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 Data sources: <i>Outcome of effect:</i> within trial, % of mothers exclusive breastfeeding in past 24 hrs (not incorporated into economic evaluation but used herein to estimate cost per additional	Base case results: Health care provider and family (Incremental cost for term newborns = \$119, incremental cost for near term newborns = \$1352) Health care provider only (Incremental cost for term newborns = \$17, incremental cost for near term newborns = \$-309) Estimated ICER = \$78.70 per additional term infant exclusively breastfed at 5-12	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.

	<p>Face-to-face with individual with home visits</p> <p>Intensity: Low (3 contacts)</p> <p>Duration: From birth until infants age one week</p>		<p>women, caesarean delivery, postpartum complications, morbidities chronic illness or disabilities; infants with congenital abnormalities or morbidities</p> <p>Sample size: Total n = 138 (IG: 72; CG: 66)</p> <p>Baseline characteristics:</p> <p>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).</p>	<p>infant exclusively breastfed at 5-12 days taking a provider perspective)</p> <p><i>Resource use:</i> within trial</p> <p><i>Unit costs:</i> national sources</p> <p>Measurement of uncertainty: Not reported</p> <p>Consideration of heterogeneity: incremental costs and outcomes reported separately for term infants and near term infants</p> <p>Sensitivity analyses: Not reported</p>	<p>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.</p>	<p>Outcomes reported separately, but allowed for an estimation of the cost per additional infant exclusively breastfed at 5-12 days.</p>
<p>Tan 2020 (Tan et al., 2020; Taylor et al., 2018)</p> <p>New Zealand</p> <p>City of Dunedin</p>	<p>Combination of Sleep + Food Activity Breastfeeding (FAB) programme + usual care</p> <p>Support: Breastfeeding plus</p> <p>Description: Participants received</p>	<p>Usual care Description: Standard maternity care and well-child care from a maternity care professional and a well-child provider of their choice.</p>	<p>Inclusion criteria: All mothers booked into the maternity hospital invited to participate at 28-30 weeks' gestation with an 'opt out' recruitment strategy.</p> <p>Exclusion criteria:</p>	<p>Type of economic evaluation: CUA and CEA (trial-based and modelled)</p> <p>Perspective: Provider (health sector)</p> <p>Currency, price year: AUD \$, 2018</p> <p>Time horizon: Extrapolation of 5 yr. within trial data to 15 yrs.</p> <p>Discount rate: 5% for costs and benefits accrued beyond one yr.</p> <p>Primary outcome: Incremental cost per QALY</p>	<p>Base case results: ICER = \$94,667 per QALY gained, ICER = \$5,164 per BMI avoided at age 15 years, ICER = \$6,678 per BMI avoided at age 5 years</p> <p>For the primary outcome, the intervention was not considered to be cost-</p>	<p>Partially applicable: Non-OECD setting, provider perspective, cost per QALY gained reported.</p>

Community setting	<p>infant sleep education and advice on food, physical activity and breastfeeding.</p> <p>Provider: Professional (Lactation consultant provided the FAB intervention)</p> <p>Mode of delivery: Face-to-face with individuals</p> <p>Intensity: Moderate for breastfeeding support (5 sessions) but overall high for the broader combination intervention at 10 parent contacts</p> <p>Duration: Not reported</p>	<p>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.</p> <p>Sample size: Total n = 405 (IG: 196; CG: 209)</p> <p>Baseline characteristics: No baseline imbalance apparent.</p>	<p>gained</p> <p>Secondary outcomes: Incremental cost per BMI avoided at age 15 years, Incremental cost per BMI avoided at age 5 yrs</p> <p>Data sources:</p> <p><i>Outcome of effect:</i> QALYs to age 15 years modelled using utility weights associated with child weight status</p> <p><i>Resource use:</i> assumed same resource use for children under 5 years in the intervention and control groups; health care costs modelled from 5 years up to age 15 years using the EPOCH microsimulation model, which predicts health care costs using a top down method</p> <p><i>Unit costs:</i> local and national sources for programme costs</p> <p>Measurement of uncertainty: 10,000 replications of incremental costs and benefits generated to determine level of sampling uncertainty around the mean ICERs</p> <p>Consideration of heterogeneity: Not reported</p> <p>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.</p>	<p>effective.</p> <p>Findings from sensitivity analyses: Sensitivity analyses not conducted, as the ICER for the Combination intervention was not considered cost-effective.</p>
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<p>Wen 2017 (Killedar et al., 2022; Wen et al., 2017; Wen et al., 2021)</p> <p>Australia</p> <p>Recruitment from seven hospitals in four health districts in the metropolitan area of Sydney</p> <p>Community setting</p>	<p>Telephone (IG1) or SMS (IG2) support + usual care</p> <p>Support: Breastfeeding plus</p> <p>Description: The intervention was informed by the Health Belief Model providing 6 staged intervention booklets corresponded to key stages of child feeding and movement. The booklets were mailed to the intervention groups.</p> <p><i>IG1:</i> One 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 to 60 minutes long.</p> <p><i>IG2:</i> One week after mailing, a set of SMS messages were sent to participants twice a week for 4 weeks to reinforce the information.</p>	<p>Usual care</p> <p>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, 9 months of 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 to child and family health centres available to all families.</p>	<p>Inclusion criteria: Women aged 16 years or older, 24-34 weeks' gestation, able to communicate in English, had a mobile telephone, and lived in recruitment areas.</p> <p>Exclusion criteria: Severe medical condition, could not give informed consent, expecting multiple births and those with babies with known major fetal anomalies.</p> <p>Sample size: Total n = 1155 (IG1: 386; IG SMS: 384; CG: 385)</p> <p>Baseline characteristics: No baseline imbalance. Participants included 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 (IG1: 9%, IG2: 9%, CG: 8%), 25-34 (IG1: 59%, IG2:</p>	<p>Type of economic evaluation: CEA (trial based - conducted alongside a 3-arm RCT)</p> <p>Perspective: Provider (local government)</p> <p>Currency, price year: AUD \$, 2018</p> <p>Time horizon: Pregnancy to infant aged 2 years</p> <p>Discount rate: 5% for costs and benefits accrued beyond the first 12 months of follow-up</p> <p>Primary outcome: Incremental cost per unit BMI avoided</p> <p>Secondary outcomes: Incremental cost per 0.1 BMI-z units avoided</p> <p>Data sources: <i>Outcome of effect:</i> within trial <i>Resource use:</i> within trial <i>Unit costs:</i> national sources</p> <p>Measurement of uncertainty: Joint uncertainty in costs and out-comes was determined using bootstrapping with replacement</p> <p>Consideration of heterogeneity: Not reported</p> <p>Sensitivity analyses: Adopted a limited societal perspective with the inclusion of productivity losses for the mother.</p>	<p>Base case results: ICER = \$10,664.89 per unit BMI avoided (IG1 vs CG), ICER = \$5154.14 per unit BMI avoided (IG2 vs CG). SMS + usual care was more cost-effective than telephone support + usual care when compared to usual care alone. Difficult to gauge cost-effectiveness, as no understanding of health providers' WTP for the prevention of BMI gain.</p> <p>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.</p>	<p>Partially applicable: OECD setting. Provider perspective, incremental cost per unit BMI avoided reported. Time horizon within trial from birth to infant age 2 years.</p>
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	Provider: Professional (child and family health nurse) Mode of delivery: Telephone calls (IG1) or SMS (IG2) with individuals Intensity: Moderate (6 contacts) Duration: From third trimester of pregnancy until infants were 10 months old		63%, CG: 64%), >35 (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%).			
Wouk 2017 US State of North Carolina (NC)	Lactation Consultant service + usual care Support: Breastfeeding only Description: IBCLC support Provider: Professional (IBCLC) Mode of delivery: Face-to-face Intensity: Duration:	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: US \$, 2010 data Time horizon: One year Discount rate: N/A Primary outcome: Cost savings for averted cases of lower respiratory tract infection, gastroenteritis, necrotizing enterocolitis Secondary outcomes: Cost of service Data sources: <i>Outcome of effect:</i> Literature and state/national sources <i>Resource use:</i> Expert opinion for costing the intervention; literature and state sources for health service use <i>Unit costs:</i> Not reported Measurement of uncertainty: Consideration of heterogeneity: Sensitivity analyses:	Base case results: Cost savings of \$7.1m; cost of service= £4.77m	Not applicable: OECD setting, payer perspective, lack of detail with aggregate costs (cost savings) reported.

Abbreviations: BFHI= Baby Friendly Hospital Initiative; BMI= Body Mass Index; CBA= Cost-benefit analysis; CEA= Cost-effectiveness analysis; CG= Control Group; CUA= Cost-utility analysis; HB= Healthy Beginnings; IBCLC= International board-certified lactation consultant; ICER= Incremental cost-effectiveness ratio; IG= Intervention Group; FNP= Family Nurse Partnership; NICE= National Institute for Health and Care Excellence; OECD= Organisation for Economic Cooperation and Development; PSS= Personal social services; QALY=Quality-adjusted life year; RCT= Randomised Control Trial; 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; WTP= Willingness to Pay

Appendix 4: Study characteristics and risk of bias assessments for breastfeeding support interventions for women with LTCs (chapter 6).

Characteristics of included studies

Table 17. Characteristics of included studies for breastfeeding support interventions for women with long-term conditions (Chapter 6)

Study	Country	Participant characteristics	Participants' condition	Total sample	Intervention	Comparator
Aldana-Parra <i>et al.</i> ^{186, 272}	Colombia	Not reported	Obesity (defined as BMI \geq 28.1) and no diabetes	90	EBF counselling by certified counsellor; antenatal and postnatal; at least 4 contacts; face-to-face	Based on the institutional and national policy for breastfeeding.
Bartu <i>et al.</i> ¹⁷⁹	Australia	Median age SG = 27 (IQR 17 to 39) Median age CG = 25 (IQR 18 to 41). 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; 8 contacts; face-to-face; also included mental health and stress management support, and immunization discussion.	A telephone contact at two months and a home visit at six months
Steube <i>et al.</i> ^{161, 189, 273, 274}	USA	Mean age (+ SD) SG = 30.3 (6.6) Mean age (+ SD) CG = 30.0 (6.0). Ethnicity SG: Hispanic: 5(10%) non- Hispanic 45(90%); Black/African American: 22(44%). Ethnicity CG: Hispanic: 6(12%) non- Hispanic:	GDM (excluding women with overt diabetes, indexed by a baseline A1c of 6.5 mg/dL or more)	100	Group sessions which included some breastfeeding support by IBCLC; 13 contacts but IBCLC was only available at 4; antenatal and postnatal; face-to-face; phone, 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.

Study	Country	Participant characteristics	Participants' condition	Total sample	Intervention	Comparator
		44(88%); Black/African American: 30(60%)				
Carlsen <i>et al.</i> 180, 275	Denmark	Mean age SG = 31.3 (SD 4.5). Mean age SG = 31.8 (SD 4.1). 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 9 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 <i>et al.</i> 175, 276-279	USA	Median age SG = 23 (IQR 21 to 28) Median age CG = 25 (IQR 22 to 31). 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 and above	206	Specialized peer counsellors by peers who received additional training on breastfeeding and obesity; at least 15 contacts; antenatal and postnatal; face-to-face and phone; 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
Ehrlich <i>et al.</i> 176, 190	USA	Age SG: 21-24y: 3.1% 25-29y: 18.8% 30+: 78.1% Age CG: 21-24y: 4.0% 25-29y: 20.8%	GDM	197	Diet, breastfeeding and exercise support by dietitians and IBCLCs; 15-26 contacts antenatal and postnatal; face-to-face and	Usual care including printed material on GDM and infant safety.

Study	Country	Participant characteristics	Participants' condition	Total sample	Intervention	Comparator
		30+: 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%			phone; also provided advice and support to lose weight via diet and exercise	
O'Brien <i>et al.</i> ^{181, 280} (also includes unpublished data provided by author)	Ireland	Not reported	Overweight and obesity defined as BMI of 25 and over	224	Multi-component intervention which targets prospective mothers and their support partner. Included antenatal education class; postnatal group clinics and video calls all by an IBCLC; at least 8 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 <i>et al.</i> ¹⁶⁸	Australia	Not reported	Not specifically targeted intervention for LTC but includes data for obese	765	Weekly lactation consultant phone call; 4 contacts; postnatal	Standard postnatal care (no details)

Study	Country	Participant characteristics	Participants' condition	Total sample	Intervention	Comparator
			mothers and mothers with depression.			
Fiks <i>et al.</i> ¹⁷⁷	USA	Mean age SG = 25.8 (SD 5.2). Mean age SG = 27.3 (SD 5.6). 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 >25)	87	Private peer Facebook group facilitated by a psychologist with 2 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.
You <i>et al.</i> ¹⁸⁵	China	Median age SG = 33.0 (30.0-37.0) Median age CG = 34.0 (31.0-37.0). 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 6 contacts; antenatal and postnatal; face-to-face, phone and digital	Usual care for lactation support during the antenatal and postnatal period (no details)
Ijumba <i>et al.</i> ¹⁶⁹	South Africa	Not reported by HIV status. Overall median age = 23.	HIV	At least 3957 but	Community health workers (CHW) who visited women to support infant feeding and	CHWs who visited women to provide information on

Study	Country	Participant characteristics	Participants' condition	Total sample	Intervention	Comparator
		Ethnicity not reported		not all were HIV +ve	other aspects of antenatal and newborn care; 7-9 visits; face-to-face; access to social welfare grants	obtaining social welfare grants and not breastfeeding
Lewkowitz <i>et al.</i> ¹⁷⁰	USA	Age SG: Aged 18-34 = 93% Aged 35 + = 7% Age CG: Aged 18-34 = 91.5% Aged 35 + = 8.5% Women had to be African-American to take part.	Socioeconomically Disadvantaged African American Women with Overweight or Obesity defined as BMI 25.0-45.0	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 which had 1 session on breastfeeding. Additional breastfeeding support was available on request.
MacVicar <i>et al.</i> ¹⁸²	UK	Age SG: 20-35: 5(71%) >35: 2(29%) Age CG: 20-35: 4(57%) >35: 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; 5 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 <i>et al.</i> ¹⁷¹	Australia	Mean age SG = 31.6 (SD 5.1). Mean age SG = 29.5 (SD 7.8). Ethnicity SG: Born in Australia = 100%	Overweight and obese mothers with a BMI 25-35 kg/m ²	24	Lactation support from IBCLC; at least 3 contacts; antenatal and postnatal; phone and face-to-face; dietary intervention included antenatal sessions by a dietician	Dietary intervention and standard antenatal care (no details)

Study	Country	Participant characteristics	Participants' condition	Total sample	Intervention	Comparator
		Control SG: Born in Australia = 91%				
Reifsnider <i>et al.</i> ^{173, 263, 281}	USA	Age was not reported. All women were Hispanic. SG Mother's nation of birth: Mexico = 57.4%; US = 42.6%; Other = 0. CG Mother's nation of birth: Mexico = 56.9%; US = 39.7%; Other = 3.5%	Low-income Hispanic women with obesity: pre pregnant BMI >25	174	Home visiting from promotoras and support from lactation consultant if needed; antenatal and postnatal; at least 7 contacts; also included infant growth and development; sleep; and play/exercise	Standard WIC services
Namale-Matovu <i>et al.</i> ¹⁷²	Uganda	All groups had a mean age of 34. Ethnicity not reported.	HIV positive and under-going appropriate anti-retroviral treatment	218	Arm B: enhanced peer support. Family members and a hospital-based peer supported women to EBF.; postnatal; 5 training sessions plus peer support as needed; also considered wider PMTCT.	Standard PMTCT messages on HIV and infant feeding with counselling and support from PMTCT counsellors face-to-face; postnatal; 5 sessions.

Study	Country	Participant characteristics	Participants' condition	Total sample	Intervention	Comparator
					Arm C: enhanced peer support + clinic based coaching by an infant feeding counsellor; face-to-face; postnatal; 5 sessions; also considered wider PMTCT and suitable foods for infants	
Pezley <i>et al.</i> ¹⁷⁸	USA	Mean age SG = 30.9 (3.3) Mean age SG = 29.7 (4.7). Ethnicity SG: non-Hispanic = 100% Ethnicity SG: non-Hispanic = 89%	Mild-moderate depression (as defined with PHQ score 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; 6 lessons and at least 2 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; 9 sessions; no breastfeeding support
Rasmussen <i>et al.</i> ¹⁷⁴	USA	Mean age SG = 27.3 (8.6) Mean age CG = 26.6 (9.1). Ethnicity not reported.	Obesity (defined as BMI >29 pre-pregnancy)	50	Breastfeeding support from nurses in hospital plus pre- and post-partum calls with lactation consultant; visiting restrictions in hospital; at least 4 contacts; face-to-face and phone; 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. 1 pre-partum call from a lactation consultant.

Study	Country	Participant characteristics	Participants' condition	Total sample	Intervention	Comparator
Reimers <i>et al.</i> 183, 282	South Africa	Median age SG = 3 28.4 (27.5-29.2) Median age CG = 28.8 (27.5-30.0). Ethnicity not reported.	HIV +ve	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; 4 training sessions and on-going buddy support; also considered compliance with treatment, immunizations and baby monitoring	No details provided
Rotheram-Borus <i>et al.</i> 184	South Africa	Mean age SG = 26.5 (5.5) Mean age CG = 26.5 (5.5). Ethnicity not reported.	HIV +ve	1200	Peer mentor meetings which included CBT, PMTCT, wider child support and breastfeeding; face-to-face; antenatal and postnatal; 8 contacts	Standard clinic care of PMTCT services (does not seem to include breastfeeding)
Samburu <i>et al.</i> 187	Kenya	Mean age SG = 22.5 (0.5). Mean age CG = 22.4 (0.5). Ethnicity not reported.	HIV +ve	52 (NB this is a sub-sample from a larger cluster RCT which also included HIV -ve women)	Home based counselling by 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	Routine services including antenatal and postnatal care, delivery, general nutrition, hygiene and nutrition. Routine visits by community health workers.

Study	Country	Participant characteristics	Participants' condition	Total sample	Intervention	Comparator
					rooms at the primary care centre.	
Suryavanshi <i>et al.</i> ¹⁸⁸	India	Median age SG = 25 (IQR 22 to 29) Median age CG = 25 (IQR 22 to 29). Ethnicity not reported.	HIV +ve	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 which includes promotion of EBF, HIV testing and treatment.

Abbreviations: BMI = body mass index; CG = control group; EBF = exclusive breastfeeding GDM = gestational diabetes mellitus; IBCLC = international board-certified lactation consultant; IQR= interquartile range; LTC = long term condition; PMTCT = prevention of mother to child transmission; SD= Standard deviation; SG = support group WIC = special supplemental nutrition program for women, infants and children.

Risk of bias assessments

Table 1818. Risk of bias assessments for included studies for breastfeeding support interventions for women with long-term conditions (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 <i>et al.</i> ¹⁷⁷	Low	Low	High	High	Low	Unsure	High
Stuebe <i>et al.</i> ¹⁶¹	Low	Unsure	High	Unsure	High	Unsure	High
Suryavanshi <i>et al.</i>	Low	Unsure	High	Unsure	High	Unsure	High
Samburu <i>et al.</i> ¹⁸⁷	Low	Unsure	High	High	High	High	Low
Rotheram-Borus <i>et al.</i> ¹⁸⁴	Low	Unsure	High	High	Low	Unsure	High
Reimers <i>et al.</i> ¹⁸³	Unsure	Unsure	High	High	High	High	High
Rasmussen <i>et al.</i> ¹⁷⁴	Low	Unsure	High	High	High	High	High
O'Brien <i>et al.</i> ¹⁸¹	Unsure	Unsure	High	High	Low	Unsure	High
Pezley <i>et al.</i> ¹⁷⁸	Low	Low	High	High	High	Unsure	Unsure
Namale-Matovu <i>et al.</i> ¹⁷²	Low	Unsure	High	High	High	Unsure	High
Reifsnider <i>et al.</i> ¹⁷³	Low	Unsure	High	High	Low	Unsure	High
Martin <i>et al.</i> ¹⁷¹	Low	Low	High	High	High	High	High
MacVicar <i>et al.</i> ¹⁸²	Low	Low	High	High	High	Unsure	Unsure
Lewkowitz <i>et al.</i> ¹⁷⁰	Low	High	High	High	High	Unsure	Unsure
Ijumba <i>et al.</i> ¹⁶⁹	Low	Unsure	High	High	Low	High	Unsure
You <i>et al.</i> ¹⁸⁵	Low	Unsure	High	High	Low	Unsure	High
Fan <i>et al.</i> ¹⁶⁸	Low	Low	High	High	Low	Unsure	Unsure
Ehrlich <i>et al.</i> ¹⁷⁶	Unsure	Unsure	High	High	Unsure	Unsure	Unsure
Chapman <i>et al.</i> ¹⁷⁵	Low	Unsure	High	High	Low	High	Low
Carlsen <i>et al.</i> ¹⁸⁰	Low	Unsure	High	High	High	High	Unsure

Bartu <i>et al.</i> ¹⁷⁹	Low	Low	High	High	Low	High	Unsure
Aldana-Parra <i>et al.</i> ²⁷²	Unsure	Low	High	High	Unsure	Unsure	Unsure

Appendix 5. Data and analysis for breastfeeding support interventions for women with LTCs (chapter 6).

Forest Plots for interventions examining effectiveness of breastfeeding support for women with LTCs.

Primary outcomes

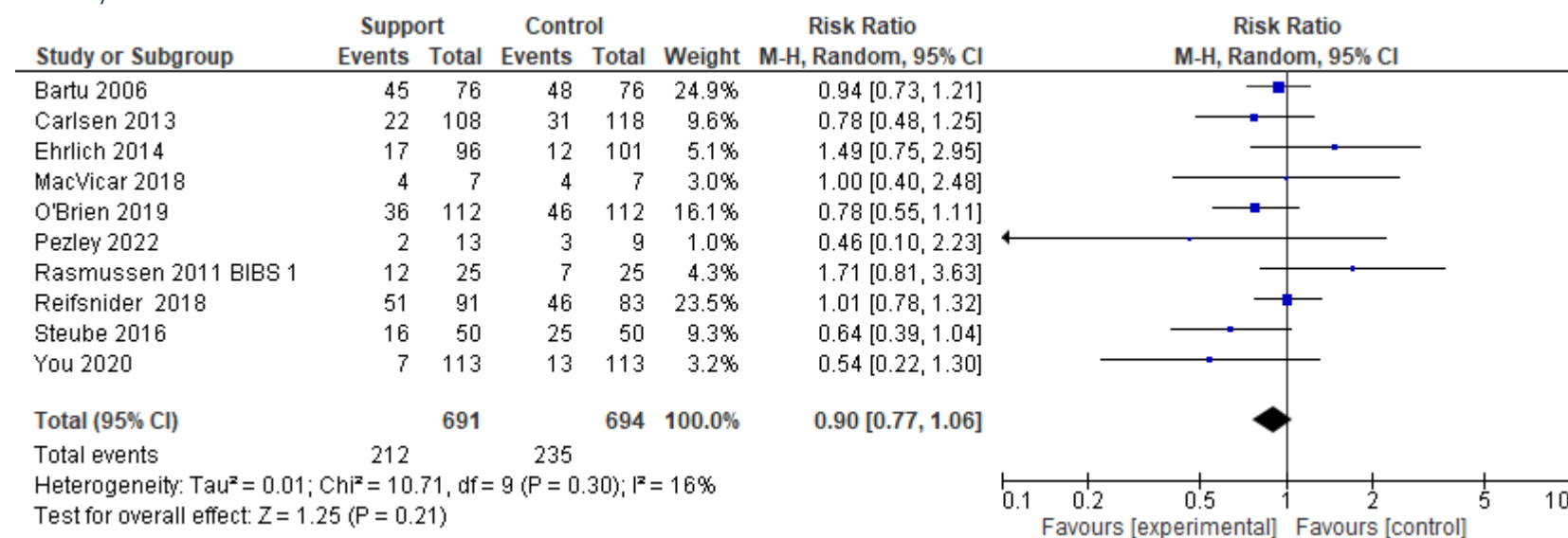


Figure 9. Breastfeeding support versus usual care, outcome: Not any breastfeeding at 4-8 weeks.

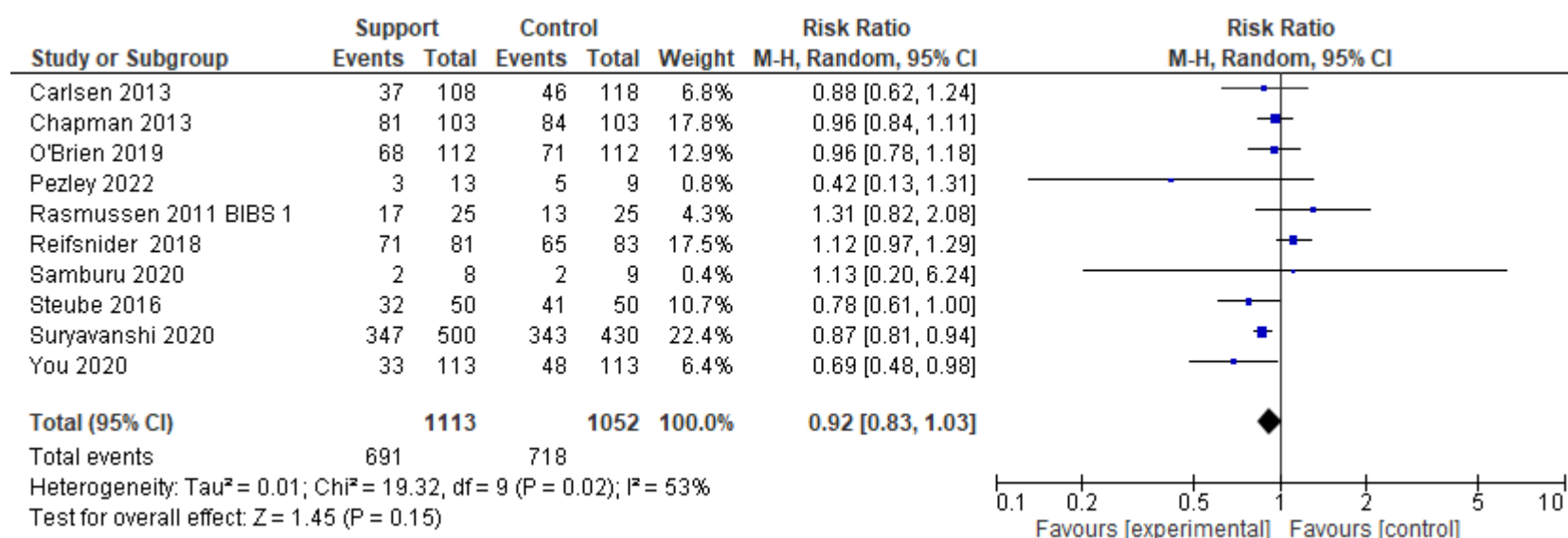


Figure 10. Breastfeeding support versus usual care, outcome: Not exclusive breastfeeding at 4-8 weeks

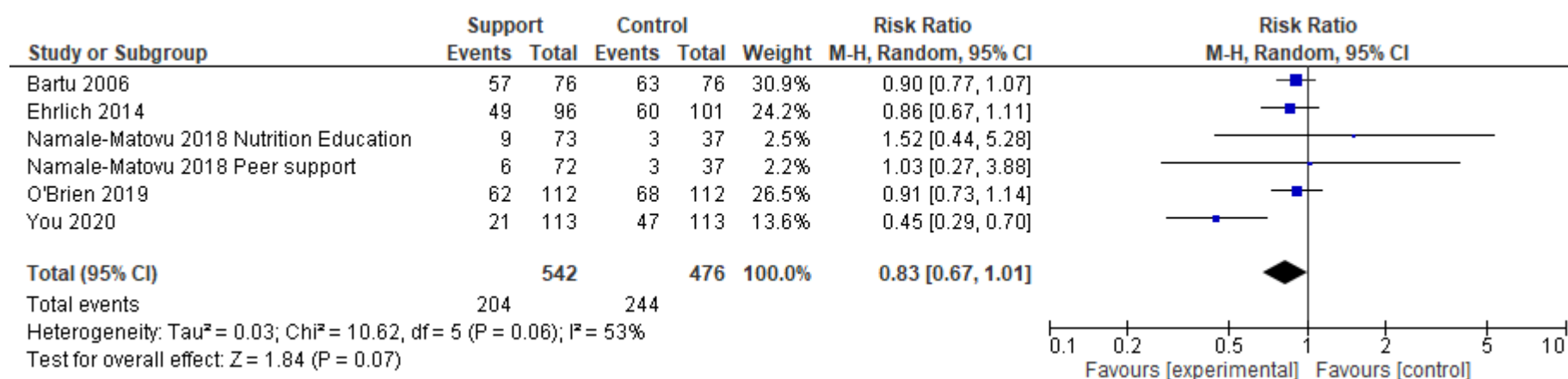


Figure 11. Breastfeeding support versus usual care, outcome: Not any breastfeeding at 6 months.

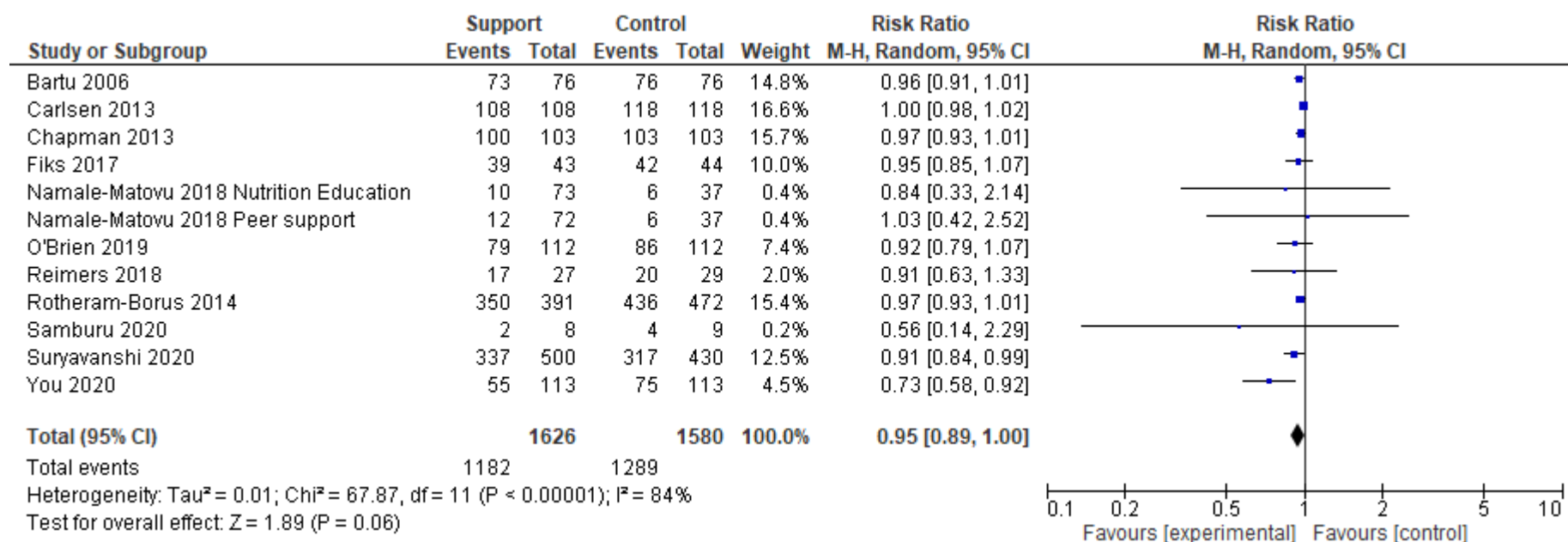


Figure 12. Breastfeeding support versus usual care, outcome: Not exclusive breastfeeding at 6 months.

Additional outcomes

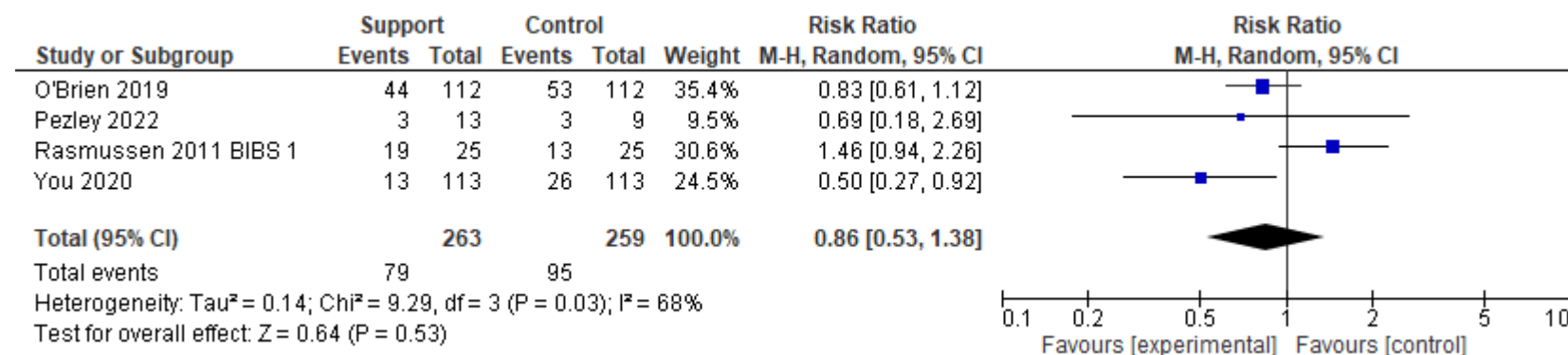


Figure 13. Breastfeeding support versus usual care, outcome: Not any breastfeeding at 3-4 months.

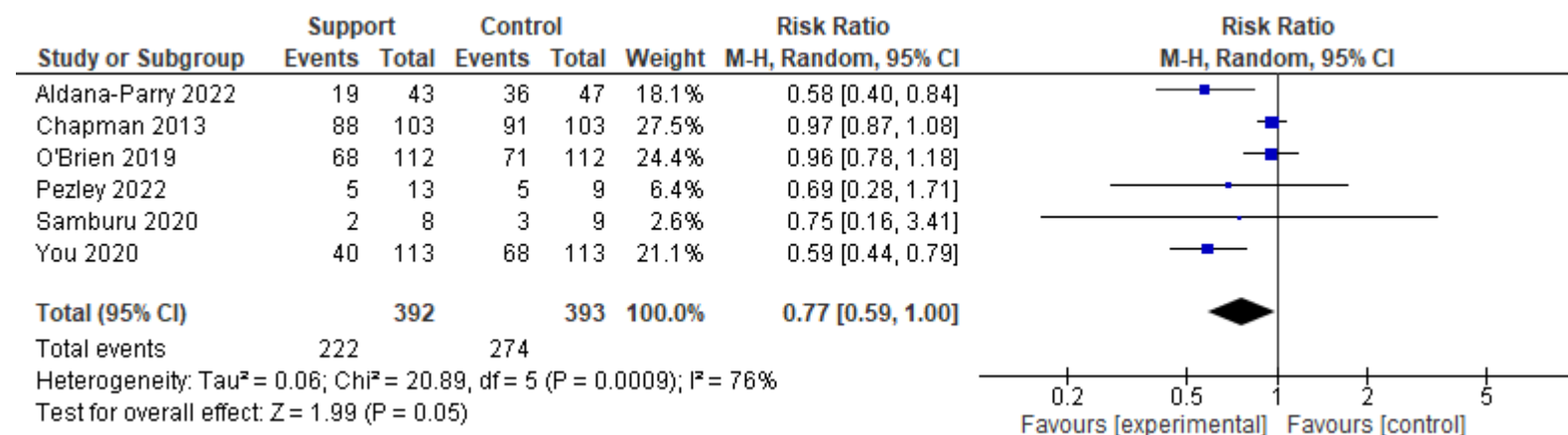


Figure 14. Breastfeeding support versus usual care, outcome: Not exclusive breastfeeding at 3-4 months

Sensitivity Analysis

Primary outcomes

Table 19. Sensitivity analyses for stopping any breastfeeding at 4-8 weeks

Outcome	Risk Ratio	95% Confidence Interval
Studies excluded due to high risk of bias for allocation concealment	0.90	0.77, 1.04
Studies excluded with >20% loss to follow-up	1.02	0.62, 1.67
Cluster RCTs for which a design effect could not be calculated excluded	0.94	0.80, 1.09

Studies for women with HIV excluded	NA	NA
Results of primary analysis	0.90	0.77, 1.06

Table 20. Sensitivity analyses for stopping exclusive breastfeeding at 4-8 weeks

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

Table 21. Sensitivity analyses for stopping any breastfeeding at 6 months

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

Table 22. Sensitivity analyses for stopping exclusive breastfeeding at 6 months

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

Additional outcomes

Table 23. Sensitivity analyses for stopping any breastfeeding at 3-4 months

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

Table 24. Sensitivity analyses for stopping exclusive breastfeeding at 3-4 months

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

Funnel Plots

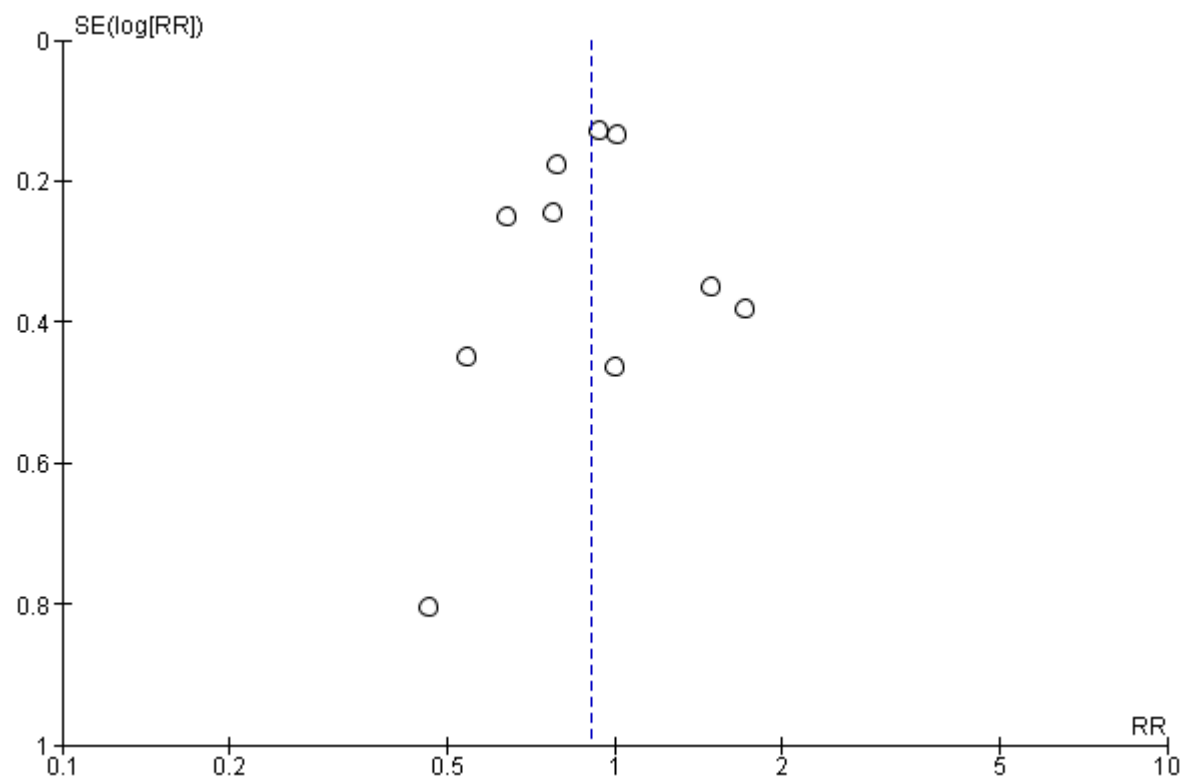


Figure 15. Funnel plot of comparison: 1 Breastfeeding support versus usual care, outcome: Not any breastfeeding at 4-8 weeks.

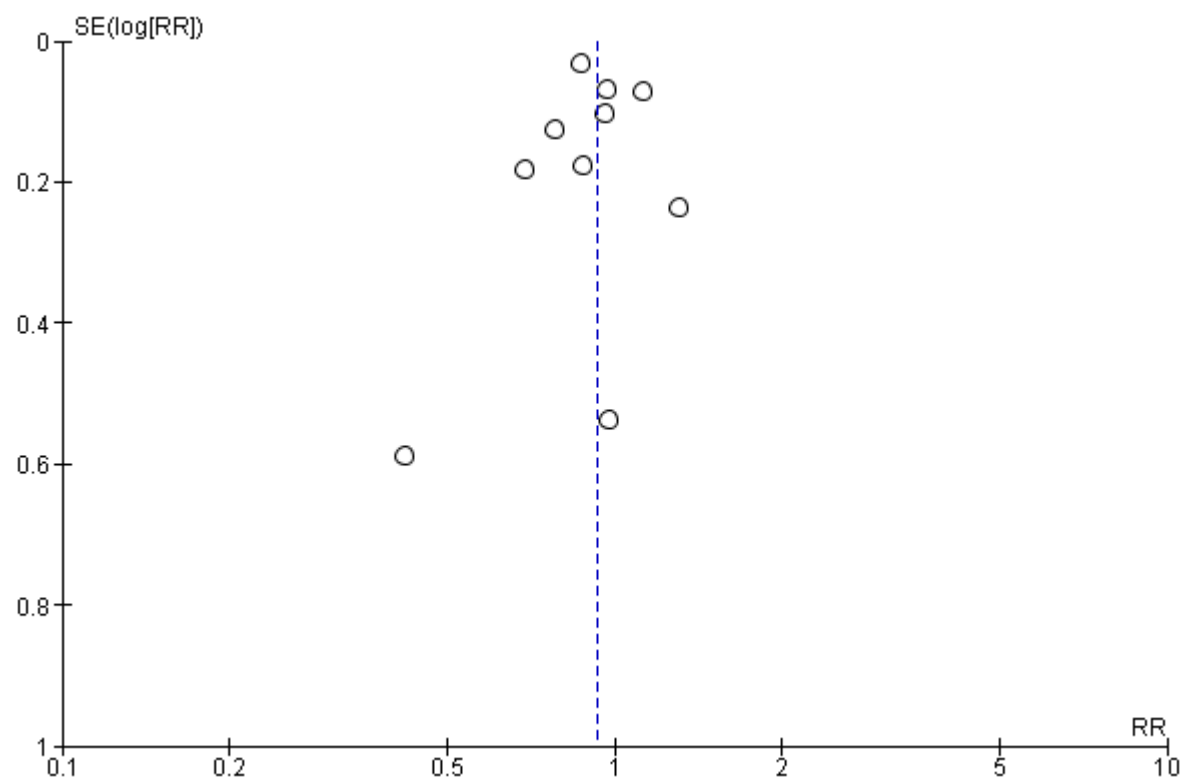


Figure 16. Funnel plot of comparison: 1 Breastfeeding support versus usual care, outcome: Not exclusive breastfeeding at 4-8 weeks.

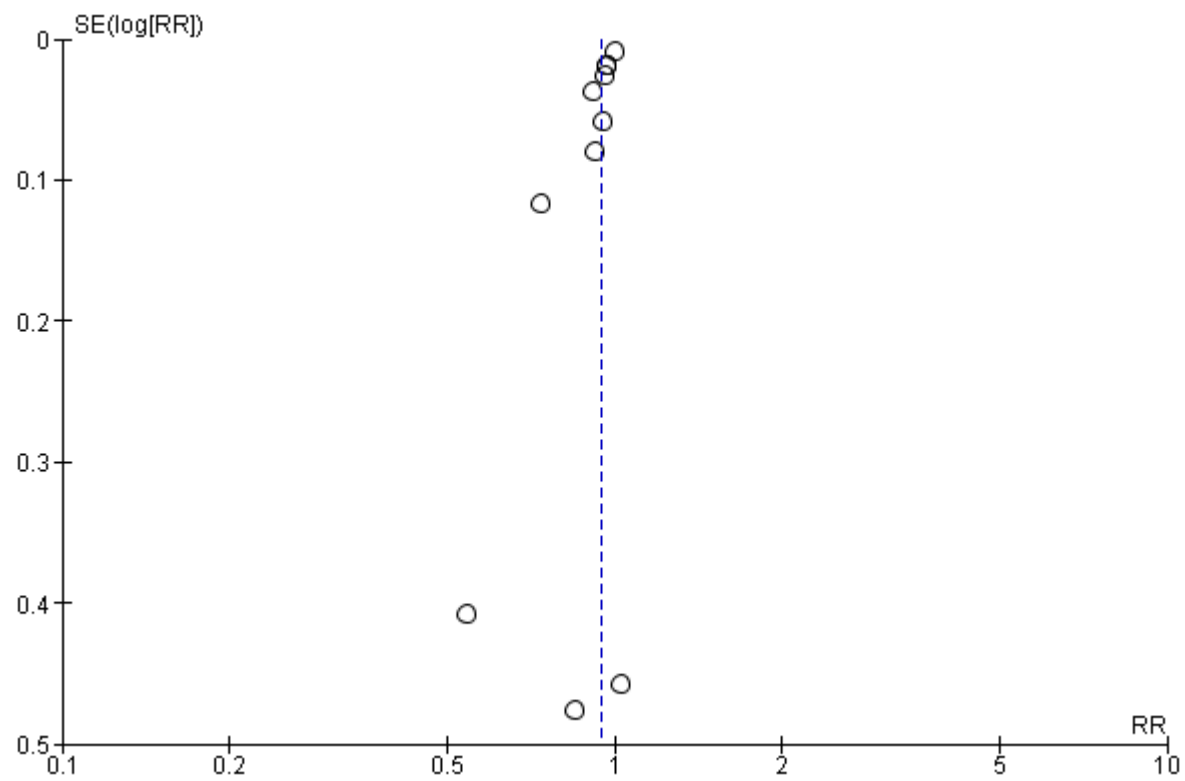


Figure 17. Funnel plot of comparison: 1 Breastfeeding support versus usual care, outcome: Not exclusive breastfeeding at 6 months.

Appendix 6: Study characteristics and risk of bias assessments for long-term conditions mixed-methods synthesis (chapter 7)

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

Table 2525. Characteristics of studies for mixed-methods synthesis for long-term conditions (Chapter 7)

Study ID Country Setting	Aims	Study design Data collection and analysis method(s)	Sample size Population description	Main study conclusions
Acheampong <i>et al.</i> ¹⁹³ 2018 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 with 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 <i>et al.</i> ¹⁹⁴ 2021 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 <i>et al.</i> ¹⁹⁵ 2015 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 <i>et al.</i> ¹⁹⁶ 2022 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 greater than or equal to 25 that were planning to breastfeed or express milk for their infant	While participants in this sample recognized 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.
Fadnes <i>et al.</i> ²¹³ 2010 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 <i>et al.</i> ²¹⁴ 2016 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 0-23 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+, 18-years or older who had a child under 24 months.	This represents a missed opportunity for health workers to support optimal IYCF practices within Option B+.

Garner <i>et al</i> ¹⁹⁷ 2014 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 <i>et al</i> ¹⁹⁸ 2016 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
Hicks <i>et al</i> ²⁰⁹ 2018 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 <i>et al</i> ¹⁹⁹ 2018 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 semi-structured interviews utilising interview guide Grounded theory analysis	25 Mothers with opioid use disorder enrolled in a treatment program	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, minimizing stigma, and maximizing resilience.
Israel-Ballard <i>et al</i> ²⁰⁰ 2014 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 AFSS assessments, greatly simplifying both the government's and counsellor's tasks.
Jagiello <i>et al</i> ²⁰¹ 2015 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.

Keely <i>et al</i> ²⁰² 2015 UK Population based	To explore the views and experiences of obese women who initiated breastfeeding when their babies were born and intended to continue exclusively breastfeeding until at least 16 weeks later, but who were no longer exclusively breast-feeding, or had stopped breast-feeding 6-10 weeks later.	Qualitative research Semi-structured 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/m2.	Midwives should be mindful of the presence of additional factors alongside maternal obesity, such as caesarean delivery, physical difficulties when breast-feeding, 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 breast-feeding support groups and services and encouraged to access these services when appropriate.
Laws <i>et al</i> ²¹² 2016 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 ED.	While genetic screening is offered to pregnant women who have a known family history of a genetic disorder, many genetic disorders 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 breastfeeding difficulties.

MacVicar <i>et al</i> ²⁰³ 2017 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, modifiers 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.
MacVicar <i>et al</i> ²¹⁵ 2018 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 randomised controlled trial and maternal questionnaire Descriptive statistics	14 Mothers who were on opioid substitution medication therapy during pregnancy, had an intention to breastfeed, were greater than 36-weeks' gestation and over 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 randomised controlled trial to evaluate clinical efficacy is recommended.
Matsunaga <i>et al</i> ²¹⁰ 2021 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 were 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 <i>et al</i> ²¹⁶ 2021 Canada	1) To determine the likelihood of full breastfeeding at 3 months postpartum in women with and without diabetes in pregnancy (DiP); 2) 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 Semi-structured 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, over 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.
Nieuwoudt ²⁰⁴ <i>et al</i> 2018 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 upon their upbringing, experiences of infant feeding, and values as these related to their experiences.	Qualitative research Semi-structured 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 breastfeeding 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 <i>et al</i> ²⁰⁶ 2009 South Africa Community based	The aim of the study was to explore the perceptions and experiences of infant-feeding peer counselling in 3 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 <i>et al</i> ²⁰⁵ 2012 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 Semi-structured 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.
O'Reilly <i>et al</i> ²⁰⁷ 2022 Ireland Population and hospital based	This study aimed to (a) explore the barriers and enablers to breastfeeding in women with high body mass indices, and (b) map specific behaviours suitable for intervention across the antenatal to postpartum periods.	Qualitative research Semi-structured interviews Reflexive thematic analysis	61 Women with a BMI over 25kg/m ² who had exclusively breastfed for 6 months or more 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 body mass indices were similar to those for the broader population; however, the physicality and associated social bias of high body mass indices 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 body mass indices.

Powell <i>et al</i> ²⁰⁸ 2018 USA Population based	This study aimed to explore the facilitators and barriers to breastfeeding among women with physical disabilities.	Qualitative research Semi-structured 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 <i>et al</i> ²¹¹ 2006 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 BF.	Quantitative, cross-sectional study Questionnaire survey conducted via email or telephone interview Chi-square tests	120 Health care 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.

Abbreviations: AFASS= Acceptable, feasible, affordable, sustainable, safe; BMI= Body mass index; DiP= Diabetes in pregnancy; EBF= Exclusive breastfeeding; GDM= Gestational diabetes mellitus; IYCF=Infant and young child feeding; NICU= Neonatal intensive care unit; PMTCT= Prevention of mother to child transmission; WHO= World Health Organisation.

CASP Qualitative summary

Table 26. CASP Qualitative summary for mixed-methods synthesis (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. ¹⁹³	Yes	Yes	Yes	Yes	Yes	Partial	Yes	Yes	Yes	Partial
Andrews et al. ¹⁹⁴	Yes	Yes	Partial	Yes	Partial	Partial	No	Yes	Yes	Yes
Dieterich et al. ¹⁹⁶	Yes	Yes	Yes	Yes	Yes	Partial	Yes	Partial	Partial	Yes
Demirci et al. ¹⁹⁵	Yes	Yes	Can't answer	Partial	Partial	Partial	Partial	Yes	Partial	Yes
Fadnes et al. ²¹³	Yes	Yes	Yes	Yes	Can't answer	No	Yes	Yes	Yes	Yes
Flax et al. ²¹⁴	Yes	Yes	Yes	Yes	Yes	No	Partial	Yes	Yes	Yes
Garner et al. ¹⁹⁷	Yes	Yes	Partial	Yes	Yes	Partial	Partial	Yes	Yes	Partial
Hazemba et al. ¹⁹⁸	Yes	Yes	Partial	Yes	Partial	No	Yes	Yes	Partial	Partial
Howard et al. ¹⁹⁹	Yes	Yes	No	Yes	Yes	No	No	Partial	Yes	Partial
Israel-Ballard et al. ²⁰⁰	Yes	Yes	Can't answer	Yes	Partial	No	Partial	No	No	No

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?
Jagiello & Azulay Chertok et al. ²⁰¹	Yes	Yes	Yes	Yes	Partial	No	Yes	Yes	Yes	Yes
Keely et al. ²⁰²	Yes	Yes	Yes	Yes	Yes	No	Partial	Partial	Partial	Yes
Laws et al. ²¹²	Yes	Yes	Partial	Partial	Partial	No	Partial	No	Partial	Partial
MacVicar et al. ²⁰³	Yes	Yes	Yes	Yes	Partial	Partial	Yes	Partial	Partial	Yes
MacVicar et al. ²¹⁵	Yes	Yes	Yes	Partial	Yes	No	Partial	Partial	Partial	Yes
Misita et al. ²¹⁶	Yes	Yes	Yes	Yes	Yes	No	Partial	Partial	Partial	Partial
Nieuwoudt & Manderson ²⁰⁴	Yes	Yes	Partial	Partial	Yes	Partial	Yes	Partial	Partial	Yes
Nor et al., 2009 ²⁰⁶	Yes	Yes	Partial	Partial	Partial	Partial	Partial	Yes	Partial	Yes
Nor et al., 2012 ²⁰⁵	Partial	Yes	Partial	Partial	Partial	No	Partial	Yes	Partial	Partial
O'Reilly et al. ²⁰⁷	Yes	Yes	Partial	Partial	Yes	Yes	Yes	Yes	Partial	Yes
Powell et al. ²⁰⁸	Yes	Yes	Partial	Partial	Yes	No	Yes	Yes	Yes	Yes

AXIS summary

Table 2727. *AXIS Summary for mixed-methods synthesis (Chapter 7)*

		Hicks et al. ²⁰⁹	Laws et al. ²¹²	Matsunga et al. ²¹⁰	Rasmussen et al. ²¹¹
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	NA	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, confidence intervals)	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?	NA	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

		Hicks et al. ²⁰⁹	Laws et al. ²¹²	Matsunga et al. ²¹⁰	Rasmussen et al. ²¹¹
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 long-term conditions	Availability of breastfeeding support for mothers with long-term conditions	The role and practice of breastfeeding support for mothers with long-term conditions	Suggested strategies to improve breastfeeding support for mothers with long-term conditions
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 (Chapter 8)

Study ID and setting	Intervention	Comparator	Participant characteristics	Methods of economic analysis	Summary of results	Applicability
Avram 2020 (Avram et al., 2020) 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: <i>Outcome of effect:</i> literature-based (systematic reviews and retrospective cohort studies) <i>Resource use:</i> literature-based costs <i>Unit costs:</i> not reported Measurement of uncertainty: 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 \$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 (Bick et al 2019, Bick et al 2020a, Bick et al 2020b) 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 8-16 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 >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: <i>Outcome of effect:</i> within study <i>Resource use:</i> within study <i>Unit costs:</i> 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.
Desmond 2008 (Desmond et al., 2008) 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 six months Provider: Lay breastfeeding counsellor Mode of delivery: Face-to-face Intensity: High (Minimum 14 visits) Duration: From late	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: Seven months Discount rate: N/A Primary outcome: Cost per increased month of EBF Secondary outcomes: not reported Data sources: <i>Outcome of effect:</i> within-trial <i>Resource use:</i> within-trial <i>Unit costs:</i> local and national sources Measurement of uncertainty: N/A Consideration of heterogeneity: N/A Sensitivity analyses: Scenario analyses	Base case results: ICER = \$88 per increased month of EBF Findings from scenario analyses: Simplified scenario \$29 per increased month of EBF, full scenario \$48 per increased month of EBF	Not applicable: Non-OECD setting. Provider perspective, cost per DALY averted reported, time horizon from birth up to seven months.

	pregnancy to 6 months postpartum			reported for different levels of intervention		
Mottl-Santiago 2020 (Mottl-Santiago 2020) 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 8 two-hour prenatal home visits; continuous support through labour and birth, and up to 4 two-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 winsorized 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.

Maredza 2013 (Maredza et al., 2013) 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: Para-professional (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: <i>Outcome of effect:</i> literature and expert opinion <i>Resource use:</i> Literature <i>Unit costs:</i> 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.
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Abbreviations: 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; ICER= incremental cost-effectiveness ratio; OECD= organisation for economic cooperation and development.

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 key criteria to consider for those considering to adopt and adapt 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 review⁸³ 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 interventions²²³⁻²²⁹ 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 hrs of discharge and regular phone 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, 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 phone 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 phone or SMS during this three-month period and beyond it 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.

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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. Cooperation between intervention providers and recipients
 11. Socio-demographic 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 with the same person delivering the intervention antenatally and postnatally so that women don't 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 multi-morbidities 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 three-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 long-term conditions. 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 multi-morbidities in the multi-disciplinary team including GPs. Supporting women with multi-morbidities to breastfeed should be included in routine breastfeeding training updates;
- services should be co-ordinated with infant feeding advisor as the key point of contact for the multi-disciplinary 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/enablers to implementing breastfeeding support interventions derived from synthesising process evaluations of effective interventions (Chapter 4) which 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 and enablers to 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 lacks 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 two 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)
- socio-economic and structural factors e.g., 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 multi-disciplinary 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 for diverse populations e.g., lack of language support, lack of accessible venues, staff attitudes (stereotyping)
- lack of feedback to staff e.g., 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 multi-disciplinary 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.	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	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 multi-disciplinary team
Revise roles as needed to support the intervention- e.g., 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 delivers and recipients
 - Intervention fidelity
 - Breastfeeding rates - exclusive and any with clear definitions and consider further sub-divisions at:
 - First feed within one hour after birth
 - Discharge from hospital
 - Six to eight weeks
 - Six 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.