NHS
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This protocol has regard for the HRA guidance and is in line with the PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 statement

FULL TITLE OF THE STUDY

Co-production of an NHS-tailored implementation and evaluation strategy framework to support women in the UK to breastfeed with a focus on reducing health inequities: evidence synthesis with stakeholder engagement.

SHORT STUDY TITLE / ACRONYM

Breastfeeding evidence synthesis

PROTOCOL VERSION NUMBER AND DATE

Protocol Version 2 – 18 April 2022

RESEARCH REFERENCE NUMBERS

IRAS Number:	N/A
SPONSORS Number:	UOD-SHS-2021-010
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This study is funded by the National Institute for Health Research (NIHR), Health Services and Delivery Research (HS&DR) Programme (NIHR130995). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Date:
18/04/2022

Signature:

.....

Name: (please print):

Alison McFadden

.....

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KEY STUDY CONTACTS

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Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	NIHR Health Services and Delivery Research Programme
Key Protocol Contributors	N/A
Committees	N/A

STUDY SUMMARY

Study Title	Co-production of an NHS-tailored implementation and evaluation strategy framework to support women in the UK to breastfeed with a focus on reducing health inequities: evidence synthesis with stakeholder engagement.
Internal ref. no. (or short title)	Breastfeeding evidence synthesis
Study Design	Evidence synthesis with embedded stakeholder engagement
Study Participants	Published studies that include: • Healthy pregnant women and pregnant women with long-term conditions considering or intending to breastfeed • Healthy women and women with long-term conditions who are breastfeeding healthy babies • Any participants involved in delivering breastfeeding support interventions (including breastfeeding women, families, service providers, managers, commissioners and policymakers)
Planned Size of Sample (if applicable)	N/A
Follow up duration (if applicable)	N/A
Planned Study Period	February 2021 – January 2023 (24 months)

Research Question/Aim(s)	Aim: The aim of the research is to improve health outcomes and reduce health inequalities for women and children in the UK by increasing breastfeeding rates. We will achieve this by synthesising global and UK evidence to derive, in partnership with key stakeholders, an NHS-tailored implementation and evaluation strategy framework to address contextual barriers and inform the transferability, development and evaluation of cost-effective breastfeeding support interventions in the UK. Objectives: 1. To update the Cochrane review "Support for healthy breastfeeding mothers with healthy term babies" to identify effective breastfeeding support interventions; 2. To conduct a theoretically informed mixed methods synthesis of process evaluations of UK relevant interventions; 3. To conduct an economic evaluation of interventions to enable women to breastfeed; 4. To conduct a systematic review to identify effective interventions which provide breastfeeding support for women with long-term conditions. 5. To conduct a a theoretically informed mixed methods synthesis of process evaluations of breastfeeding support interventions for women with long-term conditions; 6. To conduct an economic evaluation of interventions to enable women with long-term conditions to breastfeed; 7. To co-create an NHS-tailored implementation and evaluation strategy framework to address contextual barriers and inform transferability of cost-effective interventions to increase breastfeeding for all women in the UK; 8. To contribute to methodological development on a) involving stakeholders in co-creation of systematic reviews and b) synthesising process evaluations as part of systematic reviews of effectiveness to support the transferability and applicability of global evidence to local health service contexts.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**

(Names and contact details of ALL organisations providing funding and/or support in kind for this study)	
NIHR Health Services and Delivery Research Programme, Researcher-led (Evidence Synthesis)	**hsdrinfo@nihr.ac.uk**

ROLE OF STUDY SPONSOR AND FUNDER

The UK Policy Framework for Health and Social Care research requires that all healthcare research involving human participants, their organs, tissues or data must have an identified Sponsor who takes responsibility for the initiation, management and financing of a study. On behalf of Sponsor (UoD) we review the study documents and conduct the risk assessment of the study to make sure any risks are identified and mitigated against.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering Committee (SSC)

Membership to be confirmed.

The role of the SSC is to provide overall supervision for the project on behalf of the Project Sponsor and Project Funder and to ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice.

The constitution of the SSC and terms of reference will be in accordance with NIHR Research Governance Guidelines (5th February 2019).

Project Management Group (PMG)

The PMG comprises the study co-investigators and the project manager. The role of the PMG is to support the Chief investigator in the day-to-day management of the project. The PMG will meet monthly with e-mail communication as required.

Stakeholder Working Group (SWG)

Full membership to be confirmed

The stakeholder working group will comprise 12 members representing three third sector organisations (Breastfeeding Network; Association of Breastfeeding Mothers; La Leche League), policymakers, NHS and public health service commissioners and frontline practitioners. The group will influence the research by meeting three times during the study, once face-to-face (if Covid restrictions allow) and twice virtually with further e-mail contact as required. Each meeting will have specific tasks that will feed into the design and conduct of the work packages of this evidence synthesis (see WP descriptions below). Stakeholders will also be invited to co-facilitate the co-creation workshops. Six stakeholders have agreed to participate: J. Baines, health visitor and infant feeding lead in a deprived area of North

Manchester; J. Orgles, midwife and breastfeeding co-ordinator in Harrogate who is also involved in Unicef Baby friendly Initiative assessments; S. Ross, general practitioner in Glasgow; E. Pickett, Association of Breastfeeding Mothers; S. Fisher, Breastfeeding Network.

An additional stakeholder working group will be convened as part of the 'study within a project' (SWAP) to ensure the work can be taken to breastfeeding support for women with multiple long-term conditions (MLTCs). This will consist of 6 members comprised of healthcare professionals and third sector organizations (including a General Practitioner, Pharmacist, Specialist Nurse, Specialist Midwife and Medical Consultants. Membership to be confirmed.

Parent's Panel and PPI focus groups

The parents' panel will comprise 6-8 parents recruited through the participating third sector organisations, and will include women who are or have recently (within last 3 years) breastfed a child. We will aim to include at least two fathers of breastfed babies. The parents' panel will meet three times over the course of the research, mirroring the stakeholder working group meetings. They will address the same co-creation tasks as the stakeholder working group to ensure that the evidence synthesis is influenced by the views of parents. In addition to the parents' panel, PPI focus group discussions will be conducted to reach parents from socially-disadvantaged backgrounds who may be less likely to participate in larger group meetings and who represent groups that are least likely to breastfeed. We have commitment from 'Auntie Pam's in Dewsbury, a peer support organisation familiar with co-creation, recruit participants for the focus groups in the local area to encourage involvement of healthy disadvantaged and marginalised women, including younger women and parents from lower socioeconomic and ethnic minority groups.

An additional parents' panel will be convened as part of the 'study within a project' (SWAP). This will consist of 6 members comprised of women with MLTCs and their carers.

KEY WORDS: Breastfeeding support; Evidence synthesis; Stakeholder engagement; Inequalities; Economic evaluation; Implementation

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STUDY FLOW DIAGRAM

	Study months	1-3 (Feb-Apr 21)	4-9 (May-Oct 21)	10-12 (Nov-Jan 22)	13-15 (Feb-Apr 22)	16-21 (May-Oct 22)	22-24 (Nov-Jan23)
Stakeholder engagement Strand incorporating PPI	Stakeholder working group	Identify/confirm membership Agree terms of reference	S1 Face-to-face	S1a and e-mail communication	E-mail communication SWAP: Confirm membership	S2 Virtual + online tasks SWAP: S1 and S2	S3 Workshops + Virtual meeting
	PPI: Parents' panel and focus group discussions	Identify/confirm membership Agree terms of reference	P1 Face-to-face FGD1	P1a and e-mail communication	E-mail communication SWAP: Confirm membership	P2 Virtual + online tasks FGD2 SWAP: P1 and P2	P3 Workshops + Virtual meeting FGD3
WP1	Update Cochrane Review						
SWAP: WP1	Systematic review of effective interventions						
WP2	Theoretically-informed mixed methods synthesis						
SWAP: WP2	Theoretically-informed mixed methods synthesis						
WP3	Economic evaluation						
SWAP: WP3	Economic evaluation						
WP 4	Co-produce implementation and evaluation strategy framework						
Study outputs					Updated Cochrane review	Integrative reviews Economic evaluations	NHS-tailored implementation and evaluation strategy framework

Project team meeting: face-to-face*					X														
Tele-conference		X	X	X		X	X	X	X	X	X	X	X	X	X	X		X	
Study steering committee					X						X						X		

STUDY PROTOCOL

Co-production of an NHS-tailored implementation and evaluation strategy framework to support women in the UK to breastfeed with a focus on reducing health inequities: evidence synthesis with stakeholder engagement.

1 BACKGROUND

An evidence-based tailored implementation and evaluation framework for breastfeeding support is needed because the UK has among the lowest breastfeeding rates worldwide [1]. There is a marked social gradient whereby women from socio-economically deprived groups, those with lower education levels and adolescent women have the lowest breastfeeding rates [2] but have most to gain from the health benefits conferred by breastfeeding. While overall, breastfeeding initiation rates in the UK are high, there is rapid decrease in continued breastfeeding in the early weeks following birth [2] and this is when support services have potential to make a difference.

Around 80% of women in the UK stop breastfeeding before they intended and this causes distress [2] and can lead to poor mental health [3, 4]. Women report feeling unsupported by healthcare professionals and their social networks, especially in the early weeks following birth [5]. This is exacerbated by the reduction of breastfeeding support services in many areas of the UK; anecdotal evidence suggests that at least 44% of local authority areas in England were affected by recent cuts to breastfeeding services [6]. Recent survey data [7] suggested that coverage of breastfeeding peer support across the UK is variable and not accessed by socially-disadvantaged women. Practitioners report that postnatal care services in hospital and at home are stretched and midwives and health visitors report difficulties providing breastfeeding support [8].

Breastfeeding has the greatest known impact of any preventative intervention [9] and the positive impact of breastfeeding on short-, medium- and long-term outcomes for women and babies across the lifespan are well established. This has been demonstrated across settings and population groups, including high income countries such as the UK, although the balance of benefits and risks differs from setting to setting. 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 [1]. High quality evidence demonstrates that, for children, breastfeeding contributes to reduced risk of mortality due to infectious diseases [10], reduced rates of hospitalisation for preventable disease such as gastroenteritis and respiratory disease [11], otitis media [12], reduced rates of childhood diabetes and obesity [13], and reduced rates of dental disease [14, 15]. There is evidence suggesting that not being breastfed has an adverse impact on intelligence quotient (IQ), and educational and behavioural outcomes for children [16-18]. For women, there is good quality evidence that breastfeeding is associated with decreased risks of breast and ovarian cancer, and diabetes [19].

Importantly, for many health outcomes, there appears to be a dose-response with the greatest benefit resulting from breastfeeding exclusively, with no added food or fluids, for around six months, with breastfeeding continuing thereafter as an important component of the infant's diet for the first year of life and beyond [20].

Breastmilk is the most significant factor in the development of the infant gut microbiota [21] which affects gene expression and has lifelong effects on health and wellbeing. For example, the microbiome is implicated in the prevention of allergies, diabetes and obesity. The gut microbiota differs between breastfed and formula fed infants during infancy and into adulthood [22]. Exclusive and longer duration of breastfeeding leads to a stable, less diverse microbiome [23] but with greater gene expression [24]. In the early weeks of life alteration of the microbiota can lead to increased susceptibility to a variety of metabolic and immunological diseases and can influence brain function [25]. Therefore, this ultimately leads to further health benefits of exclusive breastfeeding and impact of effective provision of support for women who wish to breastfeed. It has been hypothesised that there is a relationship between

maternal psychosocial distress and milk microbiota further underlining the importance of breastfeeding support [26].

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 £242 billion and in the UK estimates were that £23.6 million additional treatment costs each year could be saved by increased breastfeeding [27]. A further cost to the NHS is the increasing number of prescriptions for specialist formula to treat cow's milk protein allergy [28]. The environmental impact of not breastfeeding i.e. feeding with infant formula is significant, for example plastics, and resources used by the dairy industry [29, 30].

There is strong global evidence from systematic reviews that breastfeeding support is effective in increasing partial and exclusive breastfeeding [31-34]. However, these reviews include evidence from high, middle and low income countries together, with most of the high income country evidence coming from the USA. The extent to which global evidence, including that from other high-income countries, is transferable to the UK setting is unclear. Evidence to date from UK based trials is limited and has not demonstrated efficacy of interventions [35, 36]. Interventions included in trials worldwide are vastly heterogeneous and under-theorised, although there are examples of reporting the theoretical underpinnings of peer support [37, 38]. We are aware of feasibility studies in the UK of peer support interventions [37, 39] and an ongoing trial of babies judged to have tongue-tie [40]. There is some evidence that multi-component interventions are more likely to be effective than single components ones, but the particular combination of components in different contexts is unknown.

There is therefore a critical need to determine the characteristics and components of breastfeeding support interventions that are likely to be effective and cost effective in a UK and NHS setting. This is particularly the case for populations where breastfeeding rates are low including young mothers, women of low socio-economic status, women with multiple long-term conditions and those from marginalised groups such as Gypsy/Travellers. The proposed research will co-create a framework, tailored to the UK and NHS context that will provide prioritised strategies to guide implementation and evaluation of context-driven, theoretically-informed breastfeeding support interventions and pathways.

2 RATIONALE

Breastfeeding plays a significant role in improving population health and reducing health inequities in the UK. It is therefore important to find out what works to support women to meet their infant feeding goals, to breastfeed for longer, and to increase rates of exclusive breastfeeding. 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 appears to be increasingly struggling to meet demand, and life-expectancy is stalling, cost-effective public health interventions targeted to disadvantaged communities are vital.

This proposed research is needed and timely to ensure that scarce resources are invested wisely. Given the background of stretched funding and recent reduction in access to breastfeeding support, it is critical for the NHS that interventions are cost-effective and likely to realise a return on investment. Furthermore, interventions that are theoretically-informed and context driven are more likely to be successful and transferable. The evidence-based tailored implementation and evaluation framework for breastfeeding support is needed now to inform decision-makers on how to implement cost-effective interventions in the NHS.

This research involves updating the Cochrane review on effective interventions to support healthy breastfeeding mothers with healthy term babies [31], which is considered to be the key source of global evidence on breastfeeding support; it was the most downloaded updated review in the Cochrane library in 2017 and has over 300 citations in Google Scholar. However, the previous update, funded by WHO, was completed rapidly and covered the primary outcomes only. The current review includes over 100

trials; we are aware of at least 7 more trials published between 2016 and 2018 and a scoping search of Medline found 16 trials published since January 2018. It is therefore timely to conduct a full update to amend the protocol so that the review is fit for purpose for the 21st century. We plan to include support interventions provided through digital technologies and interventions targeted to women who experience caesarean birth. This will ensure this review is applicable to a wider population of women who are importantly at increased risk of not breastfeeding [41]. Moreover, as this review is focused on healthy women, there is a knowledge gap of breastfeeding support for women with MLTCs. The SWAP will therefore include a separate systematic review of breastfeeding support interventions for women with long-term conditions.

The evidence syntheses, economic evaluation and framework could support service commissioners in England, Health Boards in Scotland and Wales and the Health and Social Service Boards in Northern Ireland respond to policy goals. While policy varies across the 4 countries, all highlight the need to improve breastfeeding support which, despite some localised examples of good practice, does not meet women's needs [42-45]. In England, the NHS Long Term Plan [46] proactively approaches prevention highlighting issues such as obesity and is committed to reducing inequity. The need to improve health through increasing breastfeeding rates in Scotland was identified in the "Best Start" Plan for Maternity and Neonatal Care [43]. Crucial to this is improvement of feeding advice and support as the Scottish Maternity Care Experience Survey identified that only 60% of women felt that health professionals gave support and encouragement about feeding and only 53% felt health professionals gave consistent advice about feeding their baby [47]. In Wales the Five Year Maternity Vision [44] identifies improving support for breastfeeding as a priority and the accompanying Breastfeeding Action Plan [48] sets out the approach in more detail. In addition the Healthy Weight Strategy [49] identifies improving breastfeeding rates as a priority for reducing obesity in the early years.

3 RESEARCH QUESTION/AIM(S)

The aim of the research is to improve health outcomes and reduce health inequalities for women and children in the UK by increasing breastfeeding rates. We will achieve this by synthesising global and UK evidence to derive, in partnership with key stakeholders, an NHS-tailored implementation and evaluation strategy framework to address contextual barriers and inform the transferability, development and evaluation of cost-effective breastfeeding support interventions in the UK.

3.1 Objectives

1. To update the Cochrane review "Support for healthy breastfeeding mothers with healthy term babies" to identify effective interventions to enable women to breastfeed;
2. To conduct a theoretically-informed mixed methods synthesis of process evaluations of UK relevant interventions to support women to breastfeed;
3. To synthesise economic evaluations of interventions to enable women to breastfeed;
4. To conduct a systematic review to identify effective interventions which provide breastfeeding support for women with long-term conditions.
5. To conduct a a theoretically informed mixed methods synthesis of process evaluations of breastfeeding support interventions for women with long-term conditions;
6. To conduct an economic evaluation of interventions to enable women with long-term conditions to breastfeed;
7. To co-create an NHS-tailored implementation and evaluation strategy framework to address contextual barriers and inform transferability of cost-effective interventions to increase breastfeeding for all women in the UK.
8. To contribute to methodological development on a) involving stakeholders in co-creation of systematic reviews and b) synthesising process evaluations as part of systematic reviews of

effectiveness to support the transferability and applicability of global evidence to local health service contexts.

3.2 Outcome

Key outputs are the updated Cochrane review, a Systematic Review of breastfeeding support interventions for women with long-term conditions; two theoretically-informed integrative reviews of process evaluations of effective interventions (one for healthy women and one for women with long-term conditions), two economic evaluations of effective breastfeeding interventions (one for healthy women and one for women with long-term conditions); and a co-created NHS/public health-tailored implementation and evaluation strategy framework to inform policy, practice and research in relation interventions to support women and babies in the UK to breastfeed.

The main beneficiaries of these outputs are; policymakers in the 4 UK countries who are responsible for maternal and young child public health, wellbeing, and nutrition; health/public health service providers and commissioners; third sector organisations who advocate for and provide services to breastfeeding mothers, babies and families including peer support; women, babies and their families who are recipients of breastfeeding support; researchers who are interested in development and evaluation of complex service interventions and co-creation of evidence synthesis research. There is a global audience interested in the findings of the Cochrane review. The NHS-tailored implementation and evaluation strategy framework while developed specifically for the UK context may will be of interest to practitioners and researchers in other high income settings with similar breastfeeding challenges.

As part of the stakeholder engagement activities in this study we will co-create pathways to impact to identify relevant knowledge exchange and dissemination activities. This might include, for example, lay and professional summaries, policy briefings, short animations and infographics which can be disseminated through the community of interested stakeholders developed from the workshops in WP4. We will work with the participating third sector organisations to reach a wide service-user and practitioner audience through websites, social media channels and blogs. The updated Cochrane review will be published in the Cochrane Library and we will work with the Cochrane Pregnancy and Childbirth Group to disseminate it through podcasts (the current review podcast is available in 7 languages) and an infographic. Alongside the findings published in NIHR Journals, we will publish the the Systematic Review of interventions to support women with long-term conditions to breastfeed; the two theoretically-informed integrative reviews of process evaluations of effective interventions to support women and babies in the UK to breastfeed, the two reviews of economic evaluations of effective breastfeeding interventions, and the account of the co-creation approach in open access journals e.g. Maternal and Child Nutrition, BMC Public Health. We will publish the findings in professional journals such as The Practising Midwife and the Journal of Health Visiting. We will present the research at relevant academic and professional conferences e.g. Public Health England and UNICEF-UK Baby-Friendly Initiative annual conferences.

The ultimate impact of this work will be that breastfeeding mothers and babies in the UK will be offered cost-effective support interventions which will increase breastfeeding rates, particularly among communities who have low breastfeeding rates. In the longterm increased breastfeeding rates will improve population health outcomes, reduce health inequities and reduce societal and health service costs and environmental impact of formula feeding. In the shorter-term, the NHS-tailored implementation and evaluation strategy will support health service commissioners to commission cost-effective breastfeeding support services.

4 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

The study comprises four linked work packages (WP) underpinned by a cross-cutting strand of stakeholder engagement. The SWAP mirrors these work packages. The study design is evidence synthesis and economic evaluation with embedded stakeholder involvement, including PPI. The 18-month study will use the principles of participatory research comprising co-creation to ensure study outputs are relevant to the NHS context. There will be a focus throughout the work on reducing inequities in breastfeeding by ensuring the NHS-tailored implementation and evaluation strategy framework is informed by the needs of women and babies from communities that have low breastfeeding rates.

4.1 Stakeholder Engagement cross-cutting work strand (all objectives), months 1-18.

To ensure joint ownership throughout and at key decision points [50] , three key tasks will be completed in the stakeholder work strand: a) convene a co-creation stakeholder working group to inform the study design and execution, and to ensure the research outcomes and outputs are relevant to policy and practice across the UK; b) convene a co-creation parent's panel, supported by focus group discussions with socially-disadvantaged women to ensure the experiential insights of women and their families inform all stages of the research; c) hold co-creation workshops towards the end of the study to refine the draft implementation and evaluation strategy framework.

Our approach to stakeholder involvement is that of '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 [51]. Involvement and co-creation are essential to enhance the quality and relevance of evidence synthesis and ensure effective implementation [52, 53]. Stakeholders and parents will be involved in the study using a combination of approaches and formats, for example, by working in partnership with researchers throughout, by being a co-investigator (PB); being involved by invitation throughout the study as a working group/panel member or an open invitation to contribute by attending co-creation workshops.

a) Stakeholder working group

The stakeholder working group will comprise 12 members representing three third sector organisations (Breastfeeding Network; Association of Breastfeeding Mothers; La Leche League), policymakers, NHS and public health service commissioners and frontline practitioners. The group will influence the research by meeting three times during the study, once face-to-face and twice virtually with further e-mail contact as required. Each meeting will have specific tasks that will feed into the design and conduct of the work packages of this evidence synthesis (see WP descriptions below). Stakeholders will also be invited to co-facilitate the co-creation workshops. Six stakeholders have agreed to participate and provided letters of support (see uploads): J. Baines, health visitor and infant feeding lead in a deprived area of North Manchester; J. Orgles, midwife and breastfeeding co-ordinator in Harrogate who is also involved in Unicef Baby friendly Initiative assessments; S. Ross, general practitioner in Glasgow; E. Pickett, Association of Breastfeeding Mothers; S. Fisher Breastfeeding Network.

The SWAP will consist of an additional stakeholder working group to ensure the work can be taken to breastfeeding support for women with MLTCs. This will consist of 6 members comprised of healthcare professionals and third sector organizations (including a General Practitioner, Pharmacist, Specialist Nurse, Specialist Midwife and Medical Consultants. Membership to be confirmed.

b) Parents' panel and PPI focus group discussions

The parents' panel will comprise 6-8 parents recruited through the participating third sector organisations, and will include women who are or have recently (within last 3 years) breastfed a child. We will aim to include at least two fathers of breastfed babies. The parents' panel will meet

three times over the course of the research, mirroring the stakeholder working group meetings. They will address the same co-creation tasks as the stakeholder working group to ensure that the evidence synthesis is influenced by the views of parents. In addition to the parents' panel, focus group discussions will be conducted to reach parents from socially-disadvantaged backgrounds who may be less likely to participate in larger group meetings and who represent groups that are least likely to breastfeed. We have commitment from 'Auntie Pam's in Dewsbury, a peer support organisation familiar with co-creation, to help recruit to focus groups in the local area to encourage involvement of healthy disadvantaged and marginalised women, including younger women and parents from lower socioeconomic and ethnic minority groups.

An additional parents' panel will be convened as part of the SWAP. This will consist of 6 members comprised of women with MLTCs and their carers.

i) Co-creation stakeholder workshops

Towards the end of the project (WP4a), we will hold 4 workshops, one in each of the UK countries, where the implementation and evaluation strategy framework will be co-created with all relevant sectors to ensure it is grounded in the reality of policy and practice in the NHS and is appropriate for use in each of the 4 UK countries.

Stakeholder Engagement activities

During the first three months of the study, we will confirm membership of the stakeholder working group and parents' panel and through e-mail communication and teleconferences, agree the ground rules for both groups. The ground rules will cover expectations, roles and responsibilities, and behaviours [50]. For the parent's panel, training needs in relation to evidence syntheses that could optimise contribution will be identified so that brief training can be planned. An initial visit to 'Auntie Pams' will introduce the study and explain the timing and target participants for the three focus groups discussions.

Meeting 1, month 4: virtual meeting with the stakeholder working group (S1) the parents' panel (P1) and focus group discussion (FGD1).

The first face-to-face meetings have four purposes: 1) to develop trust and build good working relationships; 2) to develop eligibility criteria and use them to assess which interventions are potentially relevant to supporting women in the UK to breastfeed (see WP2a); 3) to identify important questions/issues to inform WPs 2 and 3; and 4) to agree a draft knowledge exchange plan to disseminate the findings of the study. We will hold the stakeholder and the parents' panel meetings separately as our PPI work informing this proposal suggested that some parents may prefer to work in a parents' only group, and to ensure that parents' voices are not overshadowed by other stakeholders.

To achieve the first purpose, time will be spent getting to know each other, learning about past experiences, and discussing motivations and expectations regarding participating in the evidence synthesis. This will also involve creating a safe and supportive space to facilitate open reflection on how we are working together (Hickey et al 2018). Members of both the stakeholder working group and the parents' panel will be asked for their preferences in terms of reflecting on the approaches used to enable stakeholder involvement in the study such as keeping reflective diaries following each activity, or dedicating time during meetings. See WP2a for details of how we will develop eligibility criteria to assess UK-relevant interventions. As well as developing these criteria, we will identify important questions and issues to inform the conduct of the mixed methods review (WP2b) and review of economic evaluations (WP3). This might include for example views on important outcomes, and contextual factors to be considered in data extraction, and issues related to why women stop breastfeeding or combine breast and formula feeding. We will provide brief training on user-involvement in the conduct of evidence syntheses for parents to optimise their understanding and contribution. We will also discuss knowledge exchange activities to optimise the reach and impact of the study findings.

Following meetings S1 and P1, we will combine the eligibility criteria co-created by stakeholders and parents and translate these into a topic guide for FGD1. The purpose of the focus group discussion is checking that the eligibility criteria are relevant and important to women from communities that have low breastfeeding rates. We will aim to recruit 6-8 participants to each FGD and to maintain continuity of participants across the five FGDs as far as is possible. All FGDs will be face-to-face and facilitated by a member of the research team.

Meeting 2, months 10-12, online tasks and virtual/face-to-face meeting with stakeholder working group (S2), parents (P2) and FGD2
The purpose of the online tasks and virtual meeting is the co-creation of a prioritised set of implementation strategies to address contextual factors identified in WP2b - see WP2c for detailed description of the tasks. The online tasks will be conducted using the secure University of Dundee survey tool.

Similar to FGD1, on completion of S2 and P2, findings will be translated into a topic guide for FGD2. The purpose is to sense check that contextual factors being addressed and the prioritised implementation strategies have potential to address factors that are important and relevant to women and babies from disadvantaged communities.

Co-creation stakeholder workshops, months 16-18
See WP4a for a detailed description of the workshops. Members of the stakeholder working group and the parents' panel will be invited to attend one or more workshops and offered the opportunity to support the research team with the facilitation of the workshop activities. As described in WP4a below, the workshops will engage a wider range of stakeholder input across all four UK countries.

Meeting 3, months 16-18, virtual/face-to-face meeting with stakeholders (S3), parents (P3) and FGD3
This meeting has two purposes: 1) to co-create the final NHS/public health-tailored implementation and evaluation strategy framework; and 2) co-create a reflexive account of the strengths and limitations of the approaches used. See WP4b and c for a description of how this will be achieved.

The framework and study recommendations will be translated into a topic guide for FGD3, during which participants will also be asked to reflect on their involvement in the study.

4.1 SWAP

The SWAP will have two meetings with the stakeholders and two meetings with parents' panels to discuss the findings in regard to women with MLTCs. More specifically, because we anticipate that the majority of the evidence identified will be focused on women with one long-term condition, these meetings will consider how findings can be applied to women with MLTCs. Meeting 1 will take place at month 2 and meeting 2 will take place at month 5. They will be conducted using Microsoft Teams.

4.2 WP1: Update Cochrane Review (objective 1), months 1-9.

Two key tasks will be completed in WP1: a) updating the Cochrane review "Support for healthy breastfeeding mothers with healthy term babies"; b) identifying a long list of effective interventions to take forward to WPs 2 and 3.

WP1a) *Update Cochrane review Support for healthy breastfeeding mothers with healthy term babies"*
A revised protocol for updating the review "Support for healthy breastfeeding mothers with healthy term babies" was approved by the Cochrane Pregnancy and Childbirth Group (PCG) in July 2019. Since the previous version of the review [31], several changes have been made. Due to the significant heterogeneity of interventions in previous versions of the review (which analysed all interventions together), and in the light of evidence that suggests multi-component interventions are more effective than single component ones, we will take a more nuanced approach to analysis in this update. The review objectives have been revised to reflect this.

The primary review aim is to describe forms of breastfeeding support which have been evaluated in controlled studies, the timing of the interventions and the settings in which they have been used. The review objectives are

1. To examine the effectiveness of:
    a) Single component breastfeeding support interventions delivered to healthy mothers with healthy term babies;
    b) multifaceted breastfeeding interventions which include breastfeeding support and are delivered to healthy mothers with healthy term babies
    c) multifaceted maternal and newborn health interventions which include breastfeeding support and are delivered to healthy mothers with healthy term babies

2. To examine the effectiveness of the following characteristics of single and multiple component breastfeeding interventions:
    a) type of support (e.g. face-to-face, telephone, digital technologies, group or individual support, proactive or reactive)
    b) timing of support (e.g. antenatal and postnatal, postnatal only)
    c) intensity of support (i.e. number of postnatal contacts)
    d) person delivering intervention (e.g. health professional, lay person)

3. To examine the impact of the following on the effectiveness of support:
    a) background breastfeeding rates
    b) conducted in high-income, or low- and middle-income country

Inclusion Criteria.
To ensure that the review can meet the needs of UK women in 2022 and beyond, we have widened the inclusion criteria to include: 1) interventions for healthy women undergoing caesarean section (CS); and 2) interventions provided by digital technologies. To ensure studies that were previously excluded for these reasons are now included, all previously excluded studies will be screened.

The new inclusion criteria are:
Population: Participants are healthy pregnant women considering or intending to breastfeed or healthy women who are breastfeeding healthy babies. This includes healthy women who had a caesarean section (e.g. for malpresentation, post-term pregnancy, previous caesarean section, maternal choice). Healthy women and babies are considered those who do not require additional medical care (e.g. women with diabetes, pre-term or low birthweight infants). Therefore studies which focus specifically on women or babies with additional care needs will be excluded.

Intervention: Contact with an individual or individuals (either professional or lay) offering support which is supplementary to the standard care offered in that setting. '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. It could also include staff training to improve the supportive care given to women. Interventions could be in hospital and/or community settings. It could be offered to groups of women or one-to-one, and it could be offered proactively or reactively. It could be provided face-to-face, using digital technologies or over the telephone, and it could involve any schedule of contacts. Interventions can occur in the postnatal period alone or also include an antenatal component. Interventions taking place in the antenatal period alone will be excluded from this review.

Comparator: Standard care or no intervention or alternative non-breastfeeding intervention.

The previous version of the review was last updated in 2016 as part of a programme for work commissioned by the World Health Organization to inform the develop of the guideline: *Protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services [54]*. This work had to be completed in a short time period and it was not possible to consider secondary outcomes. This update will consider all primary and secondary outcomes.

Outcomes: Primary outcomes:

1. Stopping any breastfeeding before six months postpartum.
2. Stopping exclusive breastfeeding before six months postpartum.
3. Stopping any breastfeeding before four to six weeks postpartum.
4. Stopping exclusive breastfeeding before four to six weeks postpartum.

Secondary outcomes:

1. Stopping breastfeeding before two, three, nine and 12 months postpartum.
2. Stopping exclusive breastfeeding before two, and three, 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. Post-natal depression

Study design: Randomised controlled trials or cluster-randomised controlled trials.

Language: Studies published in any language. Support will be sought from Cochrane for translation.

The review update will be conducted following Cochrane Pregnancy and Childbirth group methods [55]

Searches
We will identify new studies using the Cochrane Pregnancy and Childbirth Group's (CPG) Trial Register. This is a database of completed and ongoing trials compiled by the editorial base through searching CENTRAL, MEDLINE, EMBASE, CINAHL, Clinical Trials Registries, and relevant journals and conference proceedings. We will search all trials categorised as lactation. Supplementary search methods will include: screening reference lists of included studies; contacting experts and searching websites of key organisations.

Study Selection
The results of the searches will be exported into Covidence software[56]. Two reviewers will first independently screen the titles and abstracts and then the full-texts against the eligibility criteria. Any disagreements will be resolved by a third reviewer. A record of the study selection process will be presented in a PRISMA flow diagram.

Data Extraction
Data will be extracted for all eligible studies by two reviewers. Any discrepancies will be resolved through discussion and consultation with a third reviewer. Data will be extracted into customisable forms using Covidence.

Risk of Bias Assessment
Two reviewers will independently assess risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions [55]. This process will be carried out in Covidence. Any discrepancies will be resolved through discussion and consultation with a third reviewer.

Data Synthesis
Pairwise Meta-analysis
We will first perform a pairwise meta-analysis in Review Manager Software (RevMan) for the following three comparisons: 1) single component breastfeeding support versus standard care or placebo; 2) multifaceted breastfeeding intervention versus standard care or placebo; 3) multifaceted maternal and newborn health intervention which includes breastfeeding support versus standard care or placebo. We anticipate heterogeneity in terms of the populations and interventions so a random effects model will be used [55].

We are aware that a number of cluster-randomised trials will be included in the meta-analyses. To account for the effects of clustering, we will adjust the sample sizes using an estimate of the intracluster correlation coefficient [57].

We are aware that a number of trials have multiple intervention groups. We will split the control group in half in terms of numbers and event rates for dichotomous data and split the control group in half in terms of numbers for continuous data [55].

Network meta-analysis
If feasible, we will aim to synthesise data on the effect of interventions through a network meta-analysis (NMA). By using a NMA, comparisons of a range of interventions and their comparators or components of interventions can be compared statistically. While a meta-analysis provides a more objective and precise estimate of an intervention's overall effectiveness than estimates derived from individual studies alone [55]; a NMA is able to extend this analysis to allow for indirect and mixed treatment comparisons. Bayesian methods will be used to combine evidence from the network, integrating statistical estimation within a probabilistic modelling framework. Guidance from the NICE Decision Support Unit on evidence synthesis and indirect comparisons will be adhered to[58-61]. We will use Covidence to manage data extracted from individual studies and export to WinBUGS to conduct the NMA.

Assessment of heterogeneity
We will consider an I^2 of greater than 30% to suggest the presence of statistical heterogeneity that needs exploration through sub-group analyses [55].

Subgroup Analyses
For the primary outcomes, we will adopt a two-stage approach to sub-group analyses. First, we will assess pre-specified sub-group differences using pairwise meta-analyses. Secondly, if feasible, we will also explore sub-group differences using network meta-analysis through subgroup analyses of indirect and mixed comparisons. For the primary outcomes we will assess pre-specified sub-group differences in pairwise comparisons and, if feasible, indirect and mixed treatment comparisons. The following is a list of potential sub-group analyses. We will work with our stakeholder working group and parent's panels to select the 3 or 4 most important and relevant analyses to conduct prior to data analysis.

- Subgroup i) Person providing support (i.e. professional versus lay person versus both)
- Subgroup ii) Type of support (i.e. face-to-face versus digital technology versus phone)
- Subgroup iii) Timing of support (i.e. antenatal and postnatal versus postnatal alone).
- Subgroup iv) Background breastfeeding rates (low versus medium versus high)
- Subgroup v) Intensity of support (fewer than 6 contacts versus 6 or more contacts)
- Subgroup vi) Income status of country (HIC versus LMIC)
- Subgroup vii) level of intervention (i.e. intervention targeted women versus intervention targeted healthcare staff)

Sensitivity Analysis
We will carry out a sensitivity analysis for the primary outcomes to look at the possible impact of methodological quality. Studies will be divided into sub-groups according to whether they were at low risk of bias as opposed to high or unclear risk of bias for allocation concealment, and whether or not attrition is higher than 20%

Assessment of Reporting Biases
We will assess for reporting biases (e.g. publication bias) by generating funnel plots for each outcome with at least ten studies and examine these visually.

Assessment of the quality of the evidence using the GRADE approach
The Grading of Recommendations Assessment, Development and Evaluation (GRADE) is an approach to assessing the quality and certainty of evidence. This will enable users of the review to make a judgement on the strength of evidence which will inform recommendations. We will follow the approach outlined in the GRADE handbook and use the GRADEpro Guideline Development to generate Summary of Findings Tables [62].

WP1b) identify a list of effective interventions that are potentially relevant to supporting women to breastfeeding in the UK

When we have completed the study selection process in WP1a, the research team will identify a long list of effective interventions to take forward to WP2 and 3.

Outputs for WP1: Updated Cochrane review submitted to the Cochrane Pregnancy and Childbirth Editorial Group; long list of effective breastfeeding support interventions.

4.2 SWAP

Whilst the SWAP is aimed at providing support for women with MLTCs, we believe that much of the evidence on breastfeeding support will be focused on women with single long-term conditions. We will therefore conduct a systematic review to identify effective interventions which provide breastfeeding support for women with single long-term conditions. A review protocol will be published in PROSPERO and the review will follow the methods described in the Cochrane Handbook and used in WP1. We anticipate that heterogeneity may be greater in this review and if that is found to be the case, meta-analysis will not be performed, and a narrative synthesis will be conducted instead. The aim of the narrative synthesis would be to identify effective interventions and their characteristics.

4.3 WP2: Theoretically-informed mixed methods synthesis (objective 2), months 4-12.

3 key tasks will be completed: a) co-create eligibility criteria for process evaluations of UK-relevant interventions identified in WP1b; b) conduct a theoretically-informed synthesis of policy and implementation research relating to interventions identified in WP2a; c) co-create a prioritised set of implementation strategies to address contextual factors identified in WP2b.

WP2a): co-development of eligibility criteria for process evaluations of UK-relevant interventions
The main objective of WP2a is to establish which interventions, are relevant and potentially transferable to a UK context. UK-based interventions will be progressed directly to WP2b. The transferability to UK settings of non-UK-based interventions will be assessed by the stakeholders during meetings S1 and P1, and in FGD1.

The process and criteria to assess transferability of interventions will be informed by the Population-Intervention-Environment-Transfer model of Transferability (PIET-T) [63]. The PIET-T model focuses on the perspective of the decision-maker who seeks to transfer an intervention from a primary context to a target context, and provides a conceptual basis and systematised criteria to support the assessment of transferability. Given that transferability is dependent on the conditions of the primary and target context, the assessment process will focus on the identification of similarities and differences between the two contexts. Criteria from the PIET-T model will be employed to determine which information is relevant for the target context and for comparison with existing information about the primary context. The research team will provide information on the evidence established in the primary context of included non-UK-based interventions to the stakeholder working group and parents' panel, who will then consider this in relation to their own experience and practice contexts to decide which non-UK-based interventions might be suitable and/or transferable to UK settings.

The subset of selected interventions will define the scope of the eligibility criteria and inform the development of the search strategy for WP2b.

WP2b) *Theoretically-informed synthesis of policy and implementation research relating to interventions identified in WP2a*
This systematic review will employ a mixed methods approach [64] to respond to the following questions: What is known about the contextual factors affecting the implementation of interventions to support women to breastfeed?: What are the behaviour change techniques in use in effective interventions? These questions will be specifically addressed with reference to the UK context. Therefore, the scope of the review question will be limited to contextual factors (barriers/facilitators) of interventions considered in WP2a as suitable and/or potentially transferable (i.e. where adaptations may be needed) for use in UK settings.

Inclusion criteria
Population: Any participants involved in either delivering or receiving any of the identified breastfeeding support interventions, including breastfeeding women and babies and their families, service providers, managers, commissioners and policymakers.
Phenomenon of Interest: Any contextual factors (barriers/facilitators) affecting the implementation of effective interventions considered relevant to UK settings in WP2a. Any behaviour change techniques in these interventions [65]. By BCT, we mean an observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour; that is, a technique is proposed to be an 'active ingredient' (e.g., feedback, self-monitoring, reinforcement)
Design: No restrictions will be applied.
Evaluation: 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. Papers only reporting on impact evaluation results (i.e. effectiveness of interventions) will be excluded.
Research type: Qualitative and quantitative studies, either standalone or in mixed methods designs, will be included.

Search strategy
A comprehensive search strategy will be developed, employing combinations of search filters, free text words and index terms relating to implementation research and the selected interventions, including variations and permutations used in similar reviews, with no restriction on date or language. The following bibliographic databases will be searched for primary studies: MEDLINE, EMBASE, PsycINFO, Social Policy and Practice, CINAHL, Nursing and Allied Health Sources, Applied Social Sciences Index and Abstracts, and SCOPUS. Citations and references in all included papers and any relevant reviews identified will be screened for eligible primary studies. Supplementary searches will also be conducted based on the name of the intervention and lead author of papers identified in WP1b. Additional sources will be used for citation searching (Sciences and Social Sciences Citation Index) and grey literature (Healthcare Management Information Consortium, Conference Proceedings Citation Index and Sociological Abstracts, websites of relevant organisations).

Quality appraisal
Quality appraisal of included studies will be conducted using a self-developed tool derived from a set of criteria previously used in other NIHR funded work to assess the quality of process evaluations [66]. The methodological quality of each included study will be independently appraised by two reviewers. Disagreements will be resolved by discussion and involvement of a third reviewer until consensus is reached. Acknowledging ongoing debates around the inherent difficulty of appraising all aspects of quality of qualitative research and the role of quality appraisal in systematic reviews that include qualitative research, studies will not be excluded based on the quality/adequacy of the reporting. Instead, the quality of studies will be taken into consideration during data synthesis by exploring whether any particular finding or group of findings are dependent, either exclusively or disproportionately, on one or more studies classed as 'low-quality' or 'inadequately reported'.

Data extraction
Data extraction will be conducted by two reviewers using a self-developed and piloted data extraction and quality assessment tool. Alongside items relating to the quality appraisal criteria noted above, the tool will contain a broad range of items relating to: study aims, objectives and/or research questions; study setting, timeframe and location; population, sample and recruitment/sampling strategies; intervention characteristics and implementation strategy; behaviour change techniques, methodological approach and study design; data collection and data analysis methods; study results; and conclusions. Any discrepancies will be resolved by discussion and involvement of a third reviewer where necessary.

Data synthesis

The review will comprise three interrelated syntheses: a synthesis of quantitative process evaluation studies (synthesis 1); a synthesis of qualitative process evaluation studies (synthesis 2); and a cross-study synthesis to integrate qualitative and quantitative process evaluation data (synthesis 3).

Synthesis 1: Narrative methods [67] will be used to synthesise quantitative findings from included process evaluations, as any attempts to pool primary data are unlikely to be meaningful in the context of this review. Two reviewers will independently assess the tabulated characteristics of the included quantitative studies and will discuss which domain would be more salient/relevant to use as the basis to organise the included studies. A conceptual framework will then be developed, discussed, refined and agreed upon by the review team. An overarching narrative will then describe, bring together and critically reflect on the primary study findings.

Synthesis 2: A data driven approach to thematic synthesis [68] will be used to synthesise qualitative findings from included process evaluations. This will involve 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. As we will adopt an inductive approach to data analysis, the analytical concerns of this synthesis will not be established beforehand. During the initial descriptive stage of the data analysis process we expect to identify the main issues reported by primary studies alongside the range of aspects that frame them. These will then be critically discussed and mapped to the main emerging descriptive themes to then consider the focus of the analytical stage of the thematic synthesis. To ensure the robustness of the synthesis, various techniques to enhance trustworthiness will be undertaken, including: audit trail, multiple coding, reviewer triangulation and team discussions.

Synthesis 3: A theory driven approach to thematic synthesis [68] will be used to synthesise and bring together quantitative and qualitative findings from included primary studies. This synthesis will be informed by the Consolidated Framework For Implementation Research (CFIR) [69], 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. The main analytical focus of this synthesis will be to evaluate CFIR derived themes through interrogation of the literature using datasets from syntheses 1 and 2. First, findings from syntheses 1 and 2 will be assigned to one or more of the 39 contextual determinants described by the CFIR framework. Two reviewers will then independently review the categorisation of findings and their considerations will be discussed in subsequent review team meetings until a consensus is achieved and the final results are established.

WP2c) Co-creation of a prioritised set of implementation strategies to address contextual factors identified in WP2b

Stakeholders will engage in a modified Delphi process to generate consensus on a prioritised set of implementation strategies that would best address the specific contextual factors and behaviour change techniques used in these contexts identified in WP2b. This phase will be informed by the Expert Recommendations for Implementing Change (ERIC) [70], a stakeholder-based compilation of 73 discrete implementation strategies, which can be used both in isolation or combined as multifaceted strategies to address the contextual determinants of intervention implementation.

The process will involve 3 rounds, administered online using web-based surveys, where the stakeholder working group and the parents' panel will be presented with a summary of findings from WP2b and asked to consider and prioritise which ERIC strategies would best address each of them. In Round 1, stakeholders will be able to match one or more strategies to each specific contextual factor and note any concerns regarding the proposed strategies or suggest additional strategies. In Round 2, stakeholders will be asked to prioritise the strategies matched to each contextual factor, and note the rationale behind their choices and potential implications for the NHS. A refined list of implementation strategies will be developed based on feedback from Rounds 1 and 2. In Round 3, consensus will be sought on the final set of implementation strategies. Quantitative data will be analysed using descriptive statistics, employing specific tests to determine group and round differences and establish final

agreement. Open comments will be analysed qualitatively. Findings will inform the development of a draft implementation and evaluation strategy framework, which will be developed, tested and further refined in WP4.

Outputs of WP2: Theoretically-informed and stakeholder-based identification of effective interventions relevant to UK settings; a theoretically informed integrative review of process evaluations suitable for publication; a co-created set of prioritised implementation strategies to address contextual factors of effective interventions relevant to UK settings.

4.3 SWAP

The SWAP will include a mixed-methods synthesis of barriers and facilitators to breastfeeding support in women with LTCs and will utilise the methodology in WP2b of the original study and the inclusion criteria will be amended to include women with long-term conditions. We will be interested in the support needs of women, training and skills needed for healthcare providers, and how care can be effectively coordinated to ensure women receive consistent support and information. Again, due to the knowledge gap of support for women with MLTC, we will take our findings to the SWG and PP to consider.

4.4 WP3: Economic evaluation (objective 3), months 4-12

3 key tasks will be completed: a) synthesis of economic evaluations of breastfeeding support interventions that are relevant to the UK and NHS context; b) development of an economic decision model to assess the cost-effectiveness analysis of breastfeeding support interventions; c) value of information analysis.

WP3a) Synthesis of economic evaluations of breastfeeding support interventions

A systematic review of economic evidence for breastfeeding support interventions will be conducted. Guidance on searching for economic evidence and conducting reviews of economic evidence will be adhered to [55, 71, 72]. The overarching review question is: What is the incremental cost-effectiveness of breastfeeding support interventions for women in comparison to standard care, no intervention, or an alternative intervention in a UK setting?

Inclusion criteria

Population: The population will reflect that outlined for the Cochrane review, conducted as part of WP1.
Interventions: Breastfeeding support interventions that are identified in WP1b as suitable and/or potentially transferable for use in UK settings.
Outcomes: Economic-related outcomes will include resource use, costs and cost-effectiveness associated with supporting women to breastfeed.
Types of studies: All types of full economic evaluations (cost-minimisation, cost-effectiveness, cost-benefit and cost-utility), in addition to partial economic evaluations (cost analyses) will be eligible for inclusion.

Search strategy

We will conduct a supplementary search to the Cochrane review that will include additional search terms related to costs, as recommended by the Cochrane and Campbell Economics Methods Group, and in the following additional databases: American Economic Association's electronic bibliography (EconLit), EURONHEED, 2000 to current, Health Economic Evaluations database (HEED), available 1994 to end 2014, IDEAS economics database, NHS Economic Evaluation database (NHS EED), available 1994 to March 2015, Paediatric Economic Evaluation database (PEDE). The stakeholder working group will also provide additional advice on relevant sources to facilitate a search of grey literature. No language or date restrictions will be applied.

Selection of studies

Two reviewers will independently screen titles and abstracts against the inclusion criteria. All potentially relevant records will be brought forward for the full text sift. During the full text sift, two reviewers will

independently read all full papers and reports. Relevant papers will be progressed to full data extraction. Reasons for exclusion at this stage will be recorded. Any unresolved disagreements will be discussed with the project team.

Quality appraisal
Quality appraisal of included studies will be conducted using the CHEERS checklist for economic evaluations [73], which is used to assess partial and full economic evaluations. The quality appraisal will be conducted independently by two reviewers. Disagreements will be resolved by discussion and involvement of a third reviewer where necessary until consensus is reached. The potential impact of including any methodologically weak studies will be explored as part of the narrative synthesis.

Data extraction
Two review authors will independently extract and record data using a piloted data collection form. Alongside items outlined for extraction as part of the Cochrane review on evidence of effect, additional data will include resource use, costs and cost-effectiveness.

Data synthesis
A narrative synthesis will be developed summarising detailed characteristics and results of included economic evaluations. The narrative synthesis will inform the development of an economic decision model, cost analysis and subsequent cost-effectiveness analysis for WP3b.

WP3b) Economic model and cost-effectiveness analysis
A detailed health economic analysis plan for the cost-effectiveness analysis will be drawn up at the start of the project. We will adhere to guidelines set out in the Guide to the Methods of Technology Appraisal 2013 [74] and on good practice in decision-analytic modelling within health technology assessments [75]. Findings from WP1 and WP3a will be used to develop the structure and form of the decision-analytic model, which will allow for simulation of intervention effects, costs and cost-effectiveness, for the UK health services.

A cost analysis of the interventions and comparators identified within WP1b will be carried out using a micro-costing process. This will be informed from data on resource use identified in WP1a, WP3a and costs from standard data sources, for example, NHS Reference costs [76], at 2020 prices. Relevant guidance on estimating costs will be followed [77].

The findings from WP1 and WP3a will be used to source evidence for relevant parameters and used to populate the model. The primary outcome for the cost-effectiveness analysis will be cost per QALY gained, presented as incremental cost-effectiveness ratios. However, further analysis with other relevant outcomes will be explored, such as cost per month of exclusive breastfeeding. The stakeholder working group and the parents' panel will consider and prioritise the most relevant secondary outcomes for the cost-effectiveness analysis. The baseline model will be analysed from a NHS cost perspective, with further analysis using a societal perspective, if sufficient data are available. Both future costs and benefits will be discounted at 3.5% per annum in the baseline.

In addition to the base case economic analysis, which assesses the cost-effectiveness of breastfeeding support interventions versus control for healthy pregnant women with healthy babies, we will conduct further economic analyses to investigate how the cost-effectiveness of interventions changes for pre-specified subgroups of women. We will assess alternative scenarios based on known risk factors for experiencing health inequalities. These maternal characteristics will include: (i) adolescent mothers; (ii) mothers with a lower level of education; and, (iii) socially disadvantaged mothers. We will ask, does the return of investment differ for breastfeeding support interventions that target women who are at greater risk of health inequalities compared to those that are universal? The ability to conduct evaluation of these alternative scenarios will be dependent on the scope and inclusion criteria of the evidence identified for the health economic analysis matching these target populations.

Sensitivity analysis will be performed to assess the impact of key model assumptions and alternative estimates for key parameters (e.g. intervention effects, intervention costs, discount rate) on the cost-

effectiveness results for the baseline model. This will follow recommendations on exploring uncertainty in cost-effectiveness analysis [78, 79]. Cost-effectiveness acceptability and affordability curves will be reported to summarise any decision uncertainty in our estimates of cost-effectiveness and the affordability of providing breastfeeding support interventions as part of the care pathway for mothers in the UK.

WP3c) Value of information analysis
The economic model will be used further to perform a value of information analysis to quantify the main uncertainties for decision makers and determine future research priorities. The expected value of perfect information (EVPI) will be calculated, along with the expected value of partial perfect information (EVPPI), to identify the cost of removing uncertainty surrounding specific model parameters. This will help identify whether further research into breastfeeding support interventions is justified and, if so, the types of research and evaluation studies that funders should invest in. Sensitivity analysis will be performed to explore uncertainty around the estimates of EVPI and EVPPI.

Outputs of WP3: a systematic review of economic evidence suitable for publication; an incremental cost-effectiveness analysis of breastfeeding support interventions in comparison to standard care, no intervention, or alternative interventions relevant to a UK setting; a Value of Information analysis, which identifies the gaps in research evidence and informs decision makers on future research funding priorities.

4.4 SWAP

The SWAP will include a systematic review of economic evaluations of breastfeeding support interventions for women with single long-term conditions. The methodology will be similar to WP3. We will summarise evidence for resource use, costs and cost-effectiveness. A narrative synthesis will also be developed to set the findings in context of delivering to women with MLTC in the UK, considering evidence of worth based on resources available.

4.5 WP4: Develop an NHS-tailored implementation and evaluation strategy framework (objectives 4 and 5), months 13-18.

Three key tasks will be completed: a) develop, test and refine the implementation and evaluation strategy framework in 4 workshops across the UK; b) co-create the final version of the framework based on all evidence and stakeholder input from WPs 1–4a; c) co-create a reflexive account of the strengths and limitations of the methodological approaches used.

WP4a) develop, test and refine an implementation and evaluation strategy framework
Based on the findings of WPs 1-3, a draft implementation and evaluation framework will be developed by the research team. The framework will be built around the co-created set of prioritised implementation strategies from WP2c, taking into account the findings of the Cochrane review and economic evaluations so that cost-effectiveness is included.

Four workshops will be convened, one each in England, Scotland, Wales and Northern Ireland. The purpose of the workshops is to test and refine the draft framework based on the views, preferences and experiences of a wider group of stakeholders. Based on previous experiences of similar type workshops, around 30 participants are ideal to gain a wide range of views while also being realistic to facilitate effectively to ensure all voices are heard. Participants will represent 4 main constituencies: 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. We will ensure that workshop participants represent, or work with, service user

communities where breastfeeding rates are low to maintain our focus on inequities. Workshop attendees will form a community of interested stakeholders who can support dissemination.

The workshops will use consensus-building activities to test the draft implementation and evaluation framework in the context of participants' experiences of breastfeeding support in the NHS. The workshops will draw on Experience-Based Co-Design (EBCD) [80] and will align with INVOLVE guidance on co-producing a research project [81]. We hope that through the workshop activities, participants will own the implementation and evaluation framework. Consistent with EBCD, the workshops will be facilitated so that all voices and experiences are of equal legitimacy. During the workshops, participants will work mainly in small groups (6-8 people) with whole-group plenary sessions to sense check the findings of work packages 1-3, discuss how the draft implementation and evaluation framework could work in their practice and policy context; discuss the how the framework could be implemented highlighting gaps, feasibility issues, and refinements needed to adapt to national (England, Scotland, Wales or Northern Ireland) contexts.. Activities will include developing recommendations for how the framework could be used to design, commission and implement breastfeeding support interventions, including who will pay for any interventions, and how it could inform intervention development for future research. This will include considering reasons why women top breastfeeding or combine breast and formula feeding. Finally participants will prioritise actions needed, and by whom to disseminate and implement the outputs from the study. Workshops will be facilitated by members of the research team, the stakeholder working group and the parents' panel.

WP4b) co-create the final version of the framework
The findings from the 4 workshops will be synthesised by the research team and final virtual meetings with the stakeholder working group (S3) and parents' panel (P4) will be held to co-create the final version of the framework. While the framework will be based on core principles, we anticipate there may be adaptations for the 4 UK country contexts.

WP4 c) co-create with stakeholders, a reflexive account of the strengths and limitations of the methodological approaches used.
At the final meetings (S3 and P3) time for reflection on the study will be allocated. This will include the previous reflections/reflective diary content. A summary will form a reflexive account of the strengths and limitations of the approaches used and will form the basis of a publication.

Outputs of WP4: co-created NHS-tailored implementation and evaluation strategy framework; study recommendations for how the framework could be used to inform policy, practice and research; reflexive account of the methodological processes used to engage stakeholders in evidence syntheses that will form the basis of a methodological publication; a community of interested stakeholders to enhance dissemination and impact of the study findings.

5 ETHICAL AND REGULATORY CONSIDERATIONS

The project does not require Sponsor approval, NHS REC favourable opinion and NHS R&D permission as it does not involve the NHS patients/service users for research purposes. Work package 2 involves stakeholders and a parents' panel and has been approved by the University of Dundee School Research Ethics Committee (Ref: UOD-SHS-2021-010).

We will conduct the stakeholder engagement work following the principles of good clinical research practice and the General Data Protection Regulations.

5.1 Assessment and management of risk

Given the secondary nature of this research there is no potential risk/harm to the participants.

5.2 Peer review

The study was peer-reviewed as part of the NIHR HS&DR funding process – these reviews are available on request.

Prior to submission for funding, the grant application was peer-reviewed by the study team, the Associate Dean for Research and one independent member of staff in the School of Health Sciences.

5.3 Patient & Public Involvement

Public and Patient Involvement (PPI) is central to this proposal as service users i.e. breastfeeding women and babies and their families are key stakeholders. We are fully committed to equal partnership working in our approach to PPI and will provide training and have fully costed PPI participants' time and expenses following Involve guidance.

In developing this proposal, we consulted Breastfeeding Network members and received responses from 56 parents and 26 lay breastfeeding supporters. The responses indicated that this work is important and that there is a need for better evidence-based support for breastfeeding women and babies in the NHS. About half of respondents said they would be interested in joining a parents' panel and half said they would be interested in attending a workshop with health care practitioners and academics. The responses influenced the design of the study in the following ways: 1) we will run the parents' panel separately from the stakeholder working group; 2) the key forms of communication with the parent's panel will be virtual (e-mail and social media), except for the first meeting and the workshops); 3) parents will be reimbursed for their time and any expenses incurred.

Within the research team, co-applicant PB represents services users and has 25 years' experience of supporting breastfeeding mothers and families. She co-founded the Breastfeeding Network (BfN) a voluntary sector organisation with a focus on disadvantaged families.

We will convene a parents' panel of 6-8 service users (mothers and fathers) who will be fully-engaged in co-creation and co-production of the research, outputs and dissemination. We will recruit the parents through the through the participating third sector organisations, and will include women who are or have recently (within last 3 years) breastfed a child. We will aim to include at least two fathers of breastfed babies. We have had already identified one woman, a Gypsy/Traveller who is keen to be involved in the parents' panel. The parents' panel will meet three times over the course of the research, mirroring the stakeholder working group meetings. They will address same co-creation tasks as the stakeholder working group to ensure that the evidence synthesis is influenced by the views of parents (see project plan for further details of how this will be achieved). In addition to the parents' panel, focus group discussions will be conducted to reach parents from socially-disadvantaged backgrounds who may be less likely to participate in larger group meetings and who represent groups that are least likely to breastfeed. We have commitment from 'Auntie Pam's in Dewsbury, a peer support organisation familiar with co-production, to help recruit to focus groups in the local area to encourage involvement of healthy disadvantaged and marginalised women, including younger women and parents from lower socioeconomic and ethnic minority groups (see letter of support). In addition, the SWAP will contain an additional Parents' Panel with 6 participants comprising of women with MLTCs and their carers.

We will provide brief training in understanding systematic review methods and approaches to enable the parent panel members to contribute fully to the project. This will take place during the first face-to-face meeting of the panel in month four.

We have fully costed the PPI to take account of the time commitment as well as reimbursing travel and other out-of-pocket expenses.

In addition to the parents' panel, the stakeholder working group will include 3 members representing the key voluntary specific breastfeeding support organisations active in the UK (Breastfeeding Network; Association of Breastfeeding Mothers, La Leche League). These members will represent the views of breastfeeding women and their families. As for the parents' panel. we have fully costed both time and out-of-pocket expenses for these individuals.

In addition to the stakeholder work, we will also invite additional parents and breastfeeding advocates to attend the workshops in work package 4 and again this has been fully costed.

5.4 Protocol compliance

Protocol deviations can happen at any time; however, these will not carry any risks of harm to participants given the secondary nature of this research. Any protocol deviations from the approved protocol will be discussed with the funder and adequately documented and reported.

5.5 Data protection and patient confidentiality

As secondary research the conduct of is study will not raise any data protection and patient confidentially issues.

The stakeholder engagement component of this study will be managed in compliance with the requirements of the Data Protection Act 1998 but will not involve the collection, processing or storage of any personal data from stakeholders.

5.6 Indemnity

The University of Dundee is Sponsoring the study.

Insurance – The University of Dundee will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study.

Indemnity The Sponsors do not provide study participants with indemnity in relation to participation in the Study but have insurance for legal liability as described above

5.7 Access to the final study dataset

The final study dataset will consist entirely of secondary data of published primary studies, therefore, there will be no restrictions for study co-investigators to access to the final study dataset other than adhering to the publication and dissemination plans agreed upon by the study team and the steering group.

6 DISSEMINIATION POLICY

6.1 Dissemination policy

The data arising from the study is owned by the study team.

On completion of the study, the data will be analysed and tabulated and a final report prepared.

The final report can be accessed through NIHR journals.

In addition to the final report, the updated Cochrane review will be published by the Cochrane library. Other outputs from the study will be submitted to peer-reviewed journals for publication. A publication plan will be agreed that indicates co-authorship of each output.

6.2 Authorship eligibility guidelines and any intended use of professional writers

All study co-investigators will be granted authorship on the final study report.

Guidelines on authorship on the final study report and other manuscripts submitted for publication will follow authorship criteria as defined by The International Committee of Medical Journal Editors.

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11. APPENDICIES

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	2	18/04/2022	Alison McFadden	The protocol has been amended to incorporate; 1. A 6-month no-cost extension until 31/01/2023 2. A funded SWAP extending the study to cover women with long-term conditions.

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