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FULL TEXT – NOT FOR BLIND REVIEW

A realist review of one-to-one breastfeeding peer support experiments conducted in developed country settings.

Heather Trickey, Gill Thomson, Aimee Grant, Julia Sanders, Mala Mann, Simon Murphy and Shantini Paranjothy

Abstract

The World Health Organisation guidance recommends breastfeeding peer support (BFPS) as part of a strategy to improve breastfeeding rates. In the UK, BFPS is supported by NICE guidance and a variety of models are in use. The experimental evidence for BFPS in developed countries is mixed and traditional methods of systematic review are ill-equipped to explore heterogeneity, complexity and context influences on effectiveness. This review aimed to enhance learning from the experimental evidence base for one-to-one BFPS intervention. Principles of realist review were applied to intervention case studies associated with published experimental studies. The review aimed (1) to explore heterogeneity in theoretical underpinnings and intervention design for this category of BFPS intervention; (2) inform design decisions by identifying transferable lessons developed from cross-case comparison of context-mechanism-outcome (CMO) relationships; and, (3) inform evaluation design by identifying CMO relationships associated with experimental conditions. Findings highlighted poor attention to intervention theory and considerable heterogeneity in BFPS intervention design. Transferable mid-range theories to inform design emerged, which could be grouped into seven categories: (i) congruence with local infant feeding norms, (ii) integration with the existing system of health care, (iii) overcoming practical and emotional barriers to access, (iv) ensuring friendly, competent and proactive peers, (v) facilitating authentic peer-mother interactions, (vi) motivating peers to ensure positive within-intervention amplification, and (vii) ensuring positive legacy and maintenance of gains. There is a need to integrate realist principles into evaluation design to improve our understanding of what forms of BFPS work, for whom and under what circumstances.

Commented [HT1]: We have corrected the omission of Dr Mala Mann as a co-author on this paper, who conducted the literature searches and contributed to the discussion of strengths and limitations from this approach to evidence review.

Commented [HT2]: We have revised the description of the rationale for the study and the study aims to more clearly reflect the realist approach to review taken, as suggested by Reviewer 3

Introduction

International and UK national-level recommendations support the use of breastfeeding peer support (BFPS) to increase breastfeeding rates (WHO 2003; NICE 2005, 2008). The idea that the beliefs, behaviours and attitudes of social peers makes a difference to mothers' feeding decisions in developed country settings is justified by extensive evidence (Hoddinott and Pill, 1999; Scott and Mostyn, 2003; McFadden and Tool, 2006; McInnes et al, 2013). Women who are encouraged to breastfeed by key social network members are more likely to start and continue for longer (Avery et al, 2009) and, in the UK, women who have friends who have breastfed are more likely to breastfeed their own baby (McAndrew et al, 2012). Negative or mixed messages from partners, family, friends and health professionals can undermine breastfeeding decisions (McInnes et al, 2013; Larsen et al, 2008). Furthermore, feeding intention and breastfeeding self-efficacy have been found to be inter-related with social support (Meedyia et al, 2010; Brown, 2013).

Peer support interventions are intended to '*extend natural embedded social networks and complement professional health services*' (Dennis, 2003, p.322). In her concept analysis of peer support interventions delivered in a health care setting Dennis defined this form of intervention as '*the provision of emotional, appraisal and informational assistance by a created social network member who possesses experiential knowledge of a specific behaviour or stressor and similar characteristics as the target population*' (p.329). In her review of UK-based BFPS interventions, Dykes (2005) describes the breastfeeding peer support schemes she includes as '*recruiting a group of local women, who have breast fed their babies, to undertake a short programme of training ... who are then engaged in supporting breastfeeding women within their local communities in a range of ways and via a number of access points.*' Dennis points out that a continuum runs between professional support and lay support and that peer supporters working across different interventions have different levels of training and are integrated to different extents with existing systems of care, while Dykes's review potentially encompasses interventions that are not directly related to professional care-giving or to an existing care pathway. Both definitions leave room for considerable variation in intervention form and in theoretical underpinnings.

Peer support is a notoriously under-theorised intervention form (Turner, 1999); broadly, several theoretical concepts operating at the level of the relationship between the individual and the peer are considered to be relevant. In particular, the notion that information will be more credible and be more acceptable if the recipient perceives the giver as similar to themselves is conceptualised by *The Principle of Homophily* (McPherson et al. 2001), while *Social Learning Theory* (Bandura, 1986) suggests that individuals compare themselves with others who occupy a social role to which the individual aspires and learn through mechanisms of observation, imitation and modelling. The *Theory of Social Support* (Barnes, 1954; Cassel, 1976) provides a framework for explaining the ways in which social networks help individuals manage stressful events; though different forms of intervention will tend to emphasise different aspects of social support. Four types of social support have been distinguished (House, 1981): *informational support* involves advice and suggestions that the person supported can use to solve problems; *emotional support* comes from sharing life experiences, and providing empathy,

love and care, built on relationships of trust; *Instrumental support* consists of providing tangible aid and services, and *appraisal support* facilitates self-evaluation through constructive feedback. Intervention theorists also distinguish between *perceived support*, the sense a mother has that the help will be there if she needs it, and *received support*, the help that occurs as a direct result of interaction (Dennis, 2002).

The evidence base for BFPS is mixed. A Cochrane review of 'additional support' (provided by professionals, peer supporters or both) based on 57 trials, including 37 from high income countries found that any extra support (irrespective of provider) had a positive effect on breastfeeding duration rates (Renfrew et al. 2012). Interventions tended to be more effective when delivered in areas with higher background initiation rates, delivered face-to-face, offered proactively, offered on an on-going basis, and when tailored to the needs of the target population (Renfrew et al, 2012). Similar findings of effectiveness, and characteristics of effective support are also reported in a recent Cochrane review to compare extra support for healthy breastfeeding mothers of healthy term babies compared with usual maternity care (McFadden et al, 2017). A systematic review including 11 randomised controlled trials (RCTs) of BFPS that started in the antenatal period, found that interventions targeting women intending to breastfeed were more likely to lead to increases in breastfeeding initiation rates compared to universal BFPS interventions (Ingram et al, 2010). A systematic review of 17 RCTs, including a meta-regression of 15 RCTs, concluded that BFPS interventions improved breastfeeding maintenance in low or middle income countries, but had less impact in high-income countries and were ineffective in the UK (Jolly et al, 2012). The less intensive interventions contained within the review (<5 planned contacts) had no impact on breastfeeding duration and interventions that combined antenatal and postnatal contact tended to be ineffective, while postnatal-only interventions were associated with improved breastfeeding durations. Further experimental studies to assess the effectiveness of BFPS in high-income countries have been recommended (Jolly et al, 2012; Hoddinott et al, 2011).

Challenged by mixed evidence from systematic reviews and concerned about the potential for inconsistent definition of BFPS, two of the authors (GT and HT) carried out a scoping review of RCT BFPS study papers to identify ways in which interpretation from the experimental evidence base for BFPS might be improved (Thomson and Trickey, 2013). This scoping review indicated high rates of implementation failure among experimental studies and suggested that intervention designs were varied and complicated in ways that category-based analysis in systematic reviews had failed to fully address. Furthermore, the discussion sections of several study papers hinted at complex interactions between health professionals, peers and mothers that may have influenced outcomes. Given this evidence of complexity, the authors recommended that realist principles should be applied to enhance the potential for the evidence base to inform intervention design.

Realist approaches to evaluation and evidence synthesis are based on an understanding that it is not meaningful to try to separate out complex interventions, such as peer support, from their delivery contexts (Pawson et al, 2005). Realist evaluators look for interactions among the setting's resources (for example, interactions between people, their physical environment, their funding context and existing policy context, with a focus on observing the impact of new resources introduced or removed by the intervention) to identify 'generative mechanisms' (changes in people's feelings or beliefs caused by the

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introduction of the intervention) that lead them to act in ways that they would not otherwise have done (Wong et al, 2013, p.6). These relationships are described as Context-Mechanism-Outcome relationships; where the **C**ontext is the components of the existing setting plus the new resources provided by the intervention; the **M**echanism is the reasoning or response of the participants; leading to **O**utcomes, which are the intended and unintended consequences.

Realist reviewers draw on evidence from a variety of sources to build up their intervention cases and to identify important **CMO** interactions pertinent to the intervention studied. These include discussion sections of study papers, qualitative studies and process evaluations, as well as conversations with those responsible for designing, delivering or evaluating the intervention. A method of constant comparison between CMOs identified in different intervention settings is used to develop mid-range theories about how interventions do (or don't) work in different contexts and to draw transferable lessons. Realist reviewers frequently work forwards from identifying potential theories about how interventions do (or don't) work, to exploring the evidence to test identified theories across different contexts (Pawson et al, 2005). Principles of realist review are sometimes reverse-applied to articulate CMO relationships in intervention studies that have contributed to existing systematic reviews. For example, this approach has been used to enhance interpretation from experimental studies of school feeding programmes that had contributed to a Cochrane review (Greenhalgh et al, 2007).

The realist review presented in this paper was intended to inform intervention development and an experimental evaluation strategy for a UK-based one-to-one care-pathway BFPS intervention for mothers of full-term babies (Copeland et al, 2016). The intended intervention would be delivered via one-to-one contact between the peer supporter and the mother at points along her care pathway under experimental conditions. The research team wished to understand CMO relationships associated with one-to-one BFPS in experimental conditions delivered in developed country contexts. A realist review of community-based peer support interventions (breastfeeding peer support being one of the included forms of peer support) to increase health literacy and reduce health inequality (addressing a range of health issues) had been conducted (Harris et al, 2015). However, this realist review did not fully incorporate evidence from the one-to-one care pathway BFPS forms that had contributed to influential systematic reviews of experimental evidence base for BFPS discussed above. The research team anticipated that CMO relationships might operate differently in one-to-one delivery settings compared to group-based settings and also that different sorts of CMO relationships might emerge under experimental conditions.

To summarise the rationale for this review, the research team began with an understanding that existing systematic reviews were drawing together findings from an undertheorised intervention form. The team felt that an in-depth application of principles of realist review to the experimental evidence base would add valuable insights over and above those identified in the realist review of peer support interventions conducted by Harris *et al* (2015) and would inform design of one-to-one BFPS in the future. The review team therefore agreed to conduct a realist review with boundaries defined both by intervention form (one-to-one BFPS interventions) and by method of evaluation (experimental design). The team then worked iteratively to explore theories underpinning a set of intervention cases falling within the

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boundaries of the review, and to extract CMO relationships for one-to-one BFPS delivered under experimental conditions.

The aims of the review were agreed as follows:

1. To explore heterogeneity in theoretical underpinnings and in intervention design among one-to-one BFPS interventions;
2. To inform design decisions by identifying transferable lessons developed from cross-case comparison of context-mechanism-outcome (CMO) relationships; and,
3. To inform evaluation design by identifying CMO relationships associated with experimental conditions.

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Methodological approach

The steps for realist synthesis set out in Pawson *et al* (2004) were followed.

Scope. The review included BFPS interventions in experimental studies, published between the start of January 2000 and end of January 2016, which had breastfeeding (initiation, continuation or exclusivity) as the primary outcome among full term babies in developed country settings. Interventions were included if they primarily intended a one-to-one (peer-to-mother) model of support and excluded if the support was primarily intended to be group-based. The cut-off of year 2000 was chosen for pragmatic reasons to align with research team capacity. A decision was taken to prioritise more recently evaluated interventions, as the team believed these would have greater relevance to current delivery contexts.

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Evidence gathering. The unit of analysis for the review was the intervention case. Evidence gathering was conducted in two stages.

- A search for index studies (experimental study papers from which the case (intervention design) could be identified) was conducted using the following databases: ASSIA, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), Embase, ERIC, HMIC, Medline, Medline in process, Scopus, Social Services Abstracts, Sociological Abstracts and Web of Knowledge. To identify additional papers we searched Unicef UK Baby Friendly Initiative website, the following key journals *Breastfeeding Medicine*, *Journal of Human Lactation*, *Maternal and Child Nutrition*, *Midwifery* and two trial registers ClinicalTrials.com and metaRegister of Controlled Trials (mRCT). The search was limited to English-language only and publication years 2000-2016. Results of the screening process are reported using a PRISMA flow diagram (Figure 1).
- Intervention cases were then developed from the index study papers, drawing on process evaluations, qualitative studies, secondary analyses, intervention protocols, training manuals and correspondence with the study authors. Study paper reference lists and those of subsequently identified papers were scanned; supplementary searches conducted based on the name of the intervention and on the name of the lead author. Attempts were made to contact lead study authors where no process evaluation was available.

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Quality appraisal. Quality assessment of assembled case materials was conducted to assess suitability of each included case for realist review. Quality was considered compromised where the following were lacking: (i) a description of intervention theory, (ii) a description of intervention components, (iii) description of context (wider social infant feeding and health service), (iv) description of implementation, take-up and fidelity issues, (v) existence of process evaluation and (vi) congruence between measured outcomes and intervention theory.

Data extraction. The following data were extracted for each intervention case:

- **The intended intervention:** (a) The components: timing and setting, intended characteristics of peers and the intervention goals (initiation, continuation, exclusivity). (b) The target population: age, income, ethnicity and prior feeding intention, inclusion and exclusion criteria and timing of recruitment. (c) The intervention theory. Theory elicitation was approached from two directions. First, reviewers extracted all cited theories and explicit descriptions of theories of change (TOC). Second, we drew on the approach proposed by Leeuw et al (2003), starting with a process of looking for 'groups of relational statements about peer support that were used to describe, explain predict or control the intervention' (Harris *et al*, 2013, p.35), reconstructing theoretical assumptions by working backwards from descriptions of the intervention components or methods.
- **The delivery and usual care context:** location, infant feeding context (background rates), socio-economic context, existing policies and systems of care.
- **The intended experiment:** the main goal of the experiment, outcomes measured, type of experiment, study size and an assessment of risk of bias using Cochrane criteria (Higgins and Green, 2008).
- **Inferred CMO relationships:** Each intervention case was reviewed separately by two reviewers. Each reviewer produced descriptions of context-mechanism (CM) relationships that appeared to have contributed to outcomes (O). 'Outcomes' were consequences experienced by any actor with whom the intervention interacted – mother, peer, health professional, study manager, study researcher, etc – including formal outcomes (e.g. breastfeeding rates), intermediate outcomes (e.g. feeding intention; changes in knowledge, attitudes or beliefs), process outcomes (e.g. mother-peer contacts achieved; duration of contacts), secondary outcomes (e.g. experience, satisfaction), unintended outcomes (e.g. programme disengagement), and outcomes which tended to feedback into the intervention or intervention context (e.g. peer motivation; approval for continued funding). CMOs were developed drawing on outcome data, process evaluations, author inference and/or reviewer inference. For each CMO relationship described, the review team recorded the source and degree of inference (e.g. observed association, process evaluation findings, author's inference, reviewer's inference).

All review team members reviewed case material relating to at least two interventions; to ensure consistency one author (HT) reviewed all 15 intervention cases. Descriptive case tables were produced to facilitate comparison.

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Cross-case comparison, synthesis and lessons: A master list of CMO relationships was developed, enabling thematic grouping of sets of CMOs and cross-case comparisons. Sets of CMOs were grouped thematically. Drawing on the approach used by Harris et al (2013) we developed a set of statements to summarise emerging patterns and to inform future one-to-one BFPS intervention design in developed country settings. The team discussed the evidence (and counter-evidence) for a set of statements to inform future one-to-one BFPS intervention design in developed country settings.

Results

Fifteen intervention cases were identified from sixteen index experimental study papers, using the search strategy and eligibility criteria as described in **Figure 1**. Nine interventions were delivered in the USA, all associated with the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) (Chapman et al, 2004; Anderson et al, 2005; Gross et al, 2008; Yun et al, 2009; Di Meglio et al, 2009; Olson et al, 2010; Chapman et al, 2013; Reeder et al, 2014; Srinivas et al, 2015). Five papers related to UK-based interventions (McInnes et al, 2000; Graffy et al, 2004; Muirhead et al, 2006; McArthur et al, 2009; Jolly et al, 2012; Scott et al, 2016), and one intervention was delivered in Canada (Dennis et al, 2002).

[Figure 1: PRISMA Diagram – Identification of index experimental study papers, about here]

The index study papers

For the index study papers, intervention goals, outcome measures, implementation issues, observed effectiveness and experimental quality are presented in **Table 1**. Only six of the 15 BFPS experiments reported that the BFPS interventions were effective for increasing breastfeeding. Interventions were assigned a case number, as shown in **Table 1**, based on date of publication of the first associated experiment. Herein, case numbers are used to when referring to the interventions.

[Table 1 Index study papers associated with included intervention cases]

Twelve index experimental study papers (Cases 2-7, 10, 12-14) described Randomised Controlled Trials (RCTs). One intervention was evaluated using a quasi-experimental study design (Cases 1), while four intervention cases were natural experiments (Cases 8, 9, 11, 15). Applying Cochrane risk of bias criteria (Higgins and Green, 2008), the review team found that only three studies had low risk of bias (Cases 3, 5, 12). More than half the evaluations were at risk of selection bias (Cases 1, 2, 8-11, 15), attrition may have affected five evaluations (Cases 4, 6, 7, 9, 13) and the evaluation associated with Case 14 was at risk of detection bias. Implementation issues affected 11 of the 15 evaluations. Among the five UK intervention cases there were difficulties in achieving the intended number of contacts (Cases 1, 3, 7, 15) and in ensuring intervention fidelity (Cases 6, 7). Of the nine studies of US-based cases, four reported significant implementation problems (Cases 4, 12-14).

The quality of the cases

The case-based supplementary evidence-gathering process yielded additional contributing information pertaining to 12/15 cases. Fifteen full case descriptions were developed using the methods of data extraction described. The cases – based on collated information – varied in their suitability to contribute to realist review, as described in **Table 2**. Intervention theory was poorly specified in 13/15 intervention cases. It was possible to obtain a description of the intervention components for all but one intervention case (Cases 9). All the cases contained some description of the infant feeding context, however descriptions of the wider social and health service context were often incomplete. Information about implementation could not be obtained for Cases 8 and 9 and was incomplete for Cases 11 and 12.

Table 2: Quality Assessment for Realist Review about here

Heterogeneity and the problem being addressed

The interventions differed from one another in terms of the problem that was being addressed (**Table 1**, col 3; Goal). For all 15 interventions the 'problem' of low breastfeeding rates had been identified 'top-down' from a public health planning perspective with little or no target community involvement. In Case 1 an action-research approach was used to gain community level participation in intervention design, however, this was after the intervention focus on breastfeeding rates had been set. The 15 intervention cases addressed different types and scales of 'breastfeeding rate' problems and sought to overcome or address subsidiary problems; these included problems of maternal motivation, health inequality, complex needs, scarce resources, wider social norms and an unhelpful health care context.

Nine interventions aimed to increase initiation rates (Cases 1, 4-9, 11, 15); twelve sought to improve continuation rates (Cases 1-7, 10, 11, 13-15) measured at varying time points. Two interventions were intended to improve rates of *exclusive* breastfeeding (Cases 12-14). The scale of the 'problem' of low rates of breastfeeding varied. Case 1 was implemented against a backdrop of a breastfeeding continuation rates of around 10% at six weeks, while Cases 12 and 13 were delivered in the context of background initiation rates of 90% (the highest in the county of Oregon) to a low-income population of Latina – predominantly Puerto Rican – women.

Six interventions sought to increase rates regardless of pre-existing levels of motivation (Cases 1, 6-9, 13); Case 3 included women who were 'considering breastfeeding' but excluded women who had previously breastfed successfully; four studies included women who were (at least) 'considering breastfeeding' (Cases 4, 5, 12, 13); one study included women 'interested in participating' (Case 14); another included women who had already requested the intervention (Case 11); two were targeted to women who had initiated breastfeeding (Cases 2,10). Such variation implies different intended emphasis on persuading women to breastfeed, as opposed to affirming, enabling and facilitating.

Many interventions were interlinked with a wider agenda to reduce health inequalities. Only three intervention cases were not specifically located/targeted to address the needs of mothers experiencing social disadvantage (Cases 2, 3, 6); of these, two UK cases (3,6) were delivered to mothers living in areas with rates of social deprivation that were higher than the national average.

Heterogeneity in intervention theory and design

Given that the inclusion criteria specify a one-to-one model of BFPS, the interventions all had a narrow intended ecological reach; underpinned by (implicit) TOCs that anticipated that mothers would choose to breastfeed, continue for longer, or delay introduction of breastmilk substitutes, because *their own individual care pathways* for feeding were enhanced by the addition of one-to-one BFPS support. An implicit belief that mothers' goals and public health goals to some extent align appeared to underlie several included interventions, as indicated by the fact that the interventions (designed to meet a public health goal of increased breastfeeding rates) were sometimes super-imposed on philosophies of support-giving that were explicitly centred on the mothers own feeding goals. All training packages that were examined emphasised listening skills to some extent (Cases 3, 8, 9, 11, 13-15); breastfeeding counsellors used in Case 3 were trained to use a person-centred approach.

The emphasis on similarity between the mother and the peer varied among the interventions, as indicated in **Table 3**. Several cases selected peers on a locality basis, suggesting an intention to recruit from a similar social background (Cases 1, 4, 6-15). Six interventions attempted to individually-match mothers to peers by ethnicity or language (Cases 4, 8, 10, 12-14). Two interventions targeted to adolescents used adolescent peers (Cases 10, 15). The Case 13 intervention targeted to recent Spanish-speaking immigrants did match peers by first language. Case 12 targeted to overweight or obese mothers did not select overweight or obese peers.

[Table 3: Adherence to the principle of homophily - about here]

Interventions differed considerably according to indicators of peer professionalisation, as indicated in **Table 4**. At one extreme, Case 3 peers were trained to University Diploma level while, at the other, Case 2 peers received only two hours orientation. Cases 4, 5, 7-9 and 11-15 peers were employed or managed by health care professionals, Cases 4, 5, 7 and 12 peers provided support in a health care setting. Not all the interventions were equally well embedded in existing health services. Several settings had prior experience of BFPS (Cases 5, 11-13), in other settings the intervention was funded for the lifetime of the evaluation only (Cases 1, 3-8, 13,14).

[Table 4: Professionalisation and integration - about here]

Social Learning Theory was explicitly cited in relation to Case 15. Cases 1 and 14 explicitly referred to social influence or role modelling as a concept underpinning intervention design. Published articles relating to Cases 4, 5 and 8 referred to peer supporters as role models.

Different relationships with different aspects of social support could be inferred from intervention design. *Informational support* seems to have been intended through antenatal contact in Cases 1, 3, 7, 12 and 13 and was used to address specific feeding-related beliefs in Case 12. *Emotional support* was indicated by emphasis on 'listening skills' in all available training materials (Cases 3, 8, 9, 10,11 and 13); material for eight intervention cases (Cases 1, 2, 4-6, 10-12) made explicit mention of an intention for the peer to develop a *trusting relationship*. Case 12 referred to peers drawing on motivational

interviewing techniques, a form of *appraisal support*. Several US cases emphasised hands-on *instrumental support* to establish breastfeeding (Cases 4, 5, 12) and Case 3 peers were trained to observe feeds and help solve breastfeeding problems. Case 3, 4, 5 and 12 peers were intended to facilitate access to aids, including breast pumps, slings and nipple shields.

Comparison across interventions indicated considerable heterogeneity in the timing, frequency, intensity and setting for contacts, as shown in **Table 5**. This may reflect different underpinning beliefs about the importance of building relationships and continuity of care, but are likely to have also been influenced by resource considerations, time constraints, logistical or safety issues, and existing service configurations.

[Table 5: Intended contacts - about here]

Design opportunities and weak points

Context-Mechanism, Context-Outcome, Mechanism-Outcome and Context-Mechanism-Outcome relationships were extracted from the materials collated for each intervention case. There is not space here to reproduce a full set of CMO interactions for each of the 15 cases. However, an example extraction sheet, illustrating how extracted interaction were evidenced for Case 1, is provided in **Figure 2**. Further supplementary material relating to CMO extractions for each intervention case is available from the authors on request.

[Figure 2: Example Case Description and extraction of CMO relationships, about here]

Alongside the process of data extraction a master list of CMO statements was developed to facilitate cross-case comparison. This mater list formed the basis of propositional statements, describing mid-range theories about how one-to-one BFPS interventions might be expected to operate in different contexts towards different kinds of outcomes (**Figure 3**).

[Figure 3: About here]

In the process of iterating between the case extraction sheets, the master list and an emerging set of propositional statements, the review team observed that sets of mechanisms and emerging mid-range theories could themselves be usefully thematically grouped according to the ecological level at which the interaction took place. The research team also noted that these thematic categories reflected the presence of cumulative CMO relationships, whereby the outcome from C-M interactions occurring at one ecological level influence the context for the next set of CMO interactions and thereby effecting the likelihood of mechanisms at lower ecological levels being triggered.

This observation was used to develop a diagram describing areas that should be considered in future design work, based on a loose temporal sequence of effects. This diagram is presented in **Figure 4**. Mechanisms on the left-hand side of the diagram, which operate at higher ecological levels, influence

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Having given this point consideration we have taken a decision to include an example extraction sheet (for Case 1) as an additional Figure. As well as explaining the process we think this may be a helpful template for other realist reviewers. The extraction sheet indicates which CMOs were extracted for Case 1 and the evidence base on which that extraction was made.

We have also included an offer to provide further information about extraction for other intervention cases on request.

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the context for potential mechanisms in the next category, moving to the right. The categories identified were:

1. Congruence with local feeding norms;
2. Congruence with the existing health care pathway;
3. Peer accessibility;
4. Peer qualities;
5. Interactions inside the peer-mother relationship;
6. Within-intervention feedback relating to the activity of peers; and,
7. Legacy feedback.

The main relationships between the categories are indicated by the arrows.

[Figure 4: One-to-one BFPS: cross-case analysis by ecological level, temporal sequencing, stages of design, about here]

Congruence with local feeding norms

In contexts where most babies are fed with formula milk beyond the early weeks (as in the UK) low-dose BFPS interventions that use antenatal intervention to educate and persuade, risk being viewed as irrelevant by mothers who simply do not want to breastfeed (Cases 1, 6), while low-dose BFPS interventions to improve continuation rates may be insufficient to encourage mothers to use the help at the point when they are deciding to discontinue (Cases 3, 7). Target populations that have multiple competing needs arising from complex personal circumstances may not view the BFPS intervention as a priority, for example low-income adolescent mothers (Case 10) or recent immigrants (Case 12). Quasi-experimental studies relating to two US WIC-based interventions showed improved initiation rates in a general population of mothers (Cases 8, 9), however there was insufficient contextual information available to draw transferrable lessons about the interaction between the intervention and the wider context in these cases.

(i) Congruence with the existing health care pathway

Poor referral pathways (Cases 6, 15) and understaffing (Case 4) led to delayed postnatal contact; in settings where many mothers stop breastfeeding soon after the birth severely compromised the intervention (Case 6). Referral to BFPS was more difficult to achieve with respect to highly transient populations (Case 12). Interventions that were well-embedded within the setting and which were associated with a more professionalised BFPS service, tended to experience fewer implementation problems. Where managers had prior experience of employing peer supporters (Cases 5, 8, 9) sometimes to the extent that BFPS referral was already seen as part of usual care (Case 11) this may have meant that health professionals already perceived peers as part of the team, with tested referral pathways in place. Case 8 and 9 BFPS interventions were funded across clinic areas in anticipation of new restrictions on provision of formula milk to WIC clients resulting from congressional legislation -

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this may have meant the intervention had credibility among health professionals and WIC managers, ameliorating integration issues. There is evidence from Case 9 that where peers already held some other position within the WIC agency at the start of the intervention this led to improved initiation rates. Case 9 also found that when Lactation Consultants were incorporated as part of the intervention team initiation rates were higher; these individuals may have acted as champions for BFPS within the setting and provided a source of ongoing supervision and support for peers.

Where health professionals did not consider the breastfeeding support provided by peer supporters to be valuable or important mothers tended to receive mixed-messages (Cases 1, 6). Discontinuity could also be reinforced by misaligned policies such as routine in-hospital supplementation with formula milk (Cases 1, 12, 13) or provision of free formula milk to the target population (Cases 12, 13), while a pre-existing Baby Friendly setting was thought to improve goal alignment in Case 5.

(ii) Peer Accessibility

Two dimensions of 'accessibility' emerged as important to successful delivery of BFPS; these were *practical accessibility* – is the help accessible at critical points? – and *emotional accessibility* – does the mother feel inclined to make use of the available help?

Inaccessibility in the days after the birth affected several interventions which were intended to provide postnatal support to enable breastfeeding continuation. In some cases, proactive contact in the period soon after the birth was not a planned part of the intervention (Cases 1, 3) in other cases contacts were planned but were often not in practice delivered (Cases 4, 6, 7, 13, 15). For many mothers, anticipation that BFPS might become available further down the line was not enough to them to overcome early feeding challenges. The combination of in-hospital instrumental ('hands on') help and affirmational support in the immediate post-birth period may have led to improved initiation rates in Case 4. Cases 5 and 15 suggest that receiving an intensive (daily) dose of support via a schedule of planned contacts soon after the birth may cause some mothers to feel that their decision to breastfeed was valued and affirmed, so that they continued to breastfeed for longer than they otherwise would have done. However, there are also indications that in both these cases (5,15) the motivation to continue was temporary and extrinsic – primarily maintained by continued contact with the peer – the improvements in breastfeeding rates were not maintained as the support from the peer began to tail away.

Several studies indicated that mothers face powerful social and emotional barriers to help-seeking. The finding from Case 3 that reactive postnatal support was not taken up by a quarter of mothers and that many mothers discontinued breastfeeding without contacting the breastfeeding counsellor contradicts the notion, derived from a person-centred counselling approach, that supporter '*should do nothing to impose herself on the client*' (Seel and Seel, 1990) because this will undermine her experience of being in control. At first glance, Case 2 – a successful telephone support BFPS intervention, in which the schedule of support is agreed in conversation with the mother – appears to suggest reactive support can be effective. However, the Case 2 BFPS intervention was 'negotiated proactively' as opposed to 'reactive' – mothers who had already initiated breastfeeding were contacted soon after the birth with a schedule of contacts agreed between the peer and the mother. This time point for an offer of ongoing support seemed to be acceptable for mothers. Case 2 mothers almost never took up the invitation to

contact the counsellor for additional support but tended to rely on the agreed schedule, with the consequence that some mothers wished the peer had contacted them more often, despite knowing they were free to contact the peer.

(iii) Peer Qualities

The principle of homophily did not operate consistently as a mechanism for triggering mothers to use the intervention or change their behaviour. Case 2 peers did indicate that there were times when they would have felt more comfortable if they had been socially matched to mothers. Case 3 study authors suggested that socio-economic differences between the breastfeeding counsellors and the mothers they supported may have led lower income mothers to feel more reticent about help seeking; however, this supposition is difficult to disentangle from the fact that Case 3 support was offered reactively. It may simply be that reactive support is more likely to be used by middle-class mothers. Prioritising peer selection according to the principle of homophily undermined the Case 10 intervention. In this case peers, like the women they supported, had 'multiple competing priorities, sparse social supports and responsibilities' and experienced the intervention as burdensome and challenging.

Ensuring that peers shared specific characteristics that directly affect access to support or feeding outcomes in the target population did seem to be helpful. For example, African-American peers deployed through Case 8 were aware of and able to empathise with culturally specific privacy concerns of African-American mothers. Similarly, in Case 13, mothers from a transient Spanish-speaking population who tended not to contact the Lactation Consultant tended to feel comfortable with Spanish-speaking peers, so that Spanish-speaking women were more likely to receive all the planned calls and more likely to receive additional calls. In contrast, Case 12 participants faced additional barriers to breastfeeding related to body size. This intervention did not use peers who were (or had been) overweight while breastfeeding; this may have made it difficult for them to understand or empathise with the additional challenges arising from countervailing biological mechanisms including lactogenesis, mechanical mechanisms to do with attachment and positioning, or mechanisms relating to embarrassment and body image.

The impact of training on the quality of interactions is unclear. Case 2 peers, who received only two hours training tended to build successful relationships with their clients; the extensive training that Case 3 and Case 4 peers received did help them to overcome accessibility barriers. In contrast, integration seemed to help peers overcome emotional barriers to making contact with mothers and helped them to feel valued team members with a recognised role (Cases 5, 11). Where BFPS was poorly integrated peers sometimes lacked confidence to working with less motivated clients (Cases 1, 2). Case 10 peers did not feel socially confident to make 'cold calls', so that relationships failed to develop. The 'volunteer' status of Case 3 peers may have presented an additional barrier to support seeking; mothers 'may have felt unsure' about how much help it was reasonable to ask for.

(iv) Inside the peer-mother relationship

Emotional support from peers was consistently valued (Cases 1, 2, 3, 6, 10, 11, 14); mothers also valued feeling affirmed in their decision to breastfeed (Case 1, 6, 10). Case 14 mothers tended to feel

more able to meet their own breastfeeding goals as a consequence of the support. Mothers and peers often felt the contacts were instrumental in enabling specific breastfeeding challenges to be overcome (Cases 2, 3, 11). There is some evidence from Cases 2 and 11 that a perception that support is available if needed (rather than the content of the peer contact) can sometimes provide a 'buffering effect', giving mothers the confidence to keep going and overcome challenges. The sense that additional attention is being paid by the peer supporter may also help mothers to respond more rapidly to signs that their baby is not well (Case 12).

Longer-term mother-peer relationships tended to be experienced positively (Cases 2, 11, 14); these provided mothers with opportunities to appraise their feeding decisions on an ongoing basis (Cases 2, 11) and sometimes resulted in the development of high levels of trust (Cases 2, 11). However, long-term intervention was not essential to the development of supportive relationships, short-term BFPS also could be experienced positively by those made use of the help (Case 3). Good relationships developed in cases where peers were selected to be similar to the target community as well as in cases where peers and mothers had different social backgrounds.

Antenatal informational support in Cases 1, 3 and 6 did cause some mothers to change specific feeding-related intentions and beliefs; first time mothers may be particularly receptive to antenatal messages (Case 6). However, changes in understanding or intention achieved through antenatal contact did not consistently translate into changes in feeding behaviour down the line (Cases 1, 3). In contexts where breastfeeding was unusual, intensive support from peers around the time of the birth did seem to provide additional extrinsic motivation to breastfeed (Cases 6, 12) though once the peer was absent this appeared to be insufficient to overcome countervailing messages from the mothers' immediate social network.

(v) Peers and within-intervention feedback

Peers are motivated when they feel their work is valued and feel demoralised when they feel they are not being used or appreciated. In consequence, peers tend to be more responsive to mothers who actively seek their support and convey their appreciation (Cases 1, 3, 14) and disengage when mothers do not respond to offers of help or decide to formula feed their babies (Case 1, 2, 13, 14). Over time there is a tendency for interventions to focus resources towards mothers who are more motivated – those who would, in any case, have been more likely to continue (Cases 1, 3, 14). This tendency is highlighted by Case 1 in which peers adapted the intervention goals to focus on enabling informed choice rather than persuading.

Lone working or working in conditions where there was little opportunity to meet with other peer supporters tended to exacerbate feelings of de-motivation (Case 2, 13), while the opportunity to meet socially or for ongoing training tended to improve peers' sense of engagement (Cases 1, 10).

(vii) Legacy feedback

The intervention case materials tended to focus on short-term study period effects. Only a subset of interventions continued beyond the study period (Cases 5, 8, 9, 11, 15); the impact of short-term weakly embedded interventions on the wider health care context and community setting is unknown. Some

legacy benefits were gleaned from the case materials. BFPS sometimes led to peers gaining skills and confidence from training, purposive activity and positive feedback (Cases 1-3, 10). More broadly, community activism stimulated by peer training may lead to contextual changes at the community level (Case 1), changed perceptions of health care professionals (Case 1) and higher expectations of support for breastfeeding among mothers (Case 14). However, these kinds of changes tended not to be formally evaluated and it is not possible to say whether they were sustained.

Findings relating to the experimental context

Many interventions were temporary, implemented explicitly for experimental study in contexts with no prior experience of BFPS being delivered alongside standard care (Case 1, 3, 4, 5, 7, 10, 13, 14). These interventions tended to be poorly embedded with unclear referral relationships and low levels of acceptance and co-operation from health care staff. Intervention-group only delivery sometimes undermined credibility among health professionals who do not see the intervention as 'standard' to care and may have led to displacement and compensating efforts directed to the control population (Cases 3, 7). Unanticipated logistical issues associated with intended modes of delivery sometimes occurred, but it cannot be stated whether feasibility testing would have ameliorated these (Case 1, 4, 6, 7, 10, 12-14). The effect of an intervention 'bedding in' is demonstrated most clearly by Case 15 – only 4% of eligible women accessed the intervention during the first month, compared to 61% during the final month. Intervention cases delivered in settings that were already familiar with BFPS did not experience issues with intervention delivery or fidelity to the same extent (Cases 11, 12). Experimental conditions may also result in a Hawthorne effect for BFPS (Case 13).

Discussion

Peer support for breastfeeding is recommended to increase breastfeeding rates (WHO, 2003; NICE 2005, 2008). Findings from experimental studies of BFPS in developed countries yield mixed results. Adding a realist lens to the existing experimental evidence base highlights heterogeneity among studied BFPS interventions and has confirmed that intervention designs are frequently under-theorised. Through extraction of CMO interactions from 15 studied intervention cases we identified seven areas for focus to inform future intervention design. The seven areas are (i) congruence with local infant feeding norms, (ii) integration with the existing system of health care, (iii) overcoming practical and emotional barriers to access, (iv) ensuring friendly, competent and proactive peers, (v) facilitating authentic peer-mother interactions, (vi) motivating peers to ensure positive within-intervention amplification, and (vii) ensuring positive legacy and maintenance of gains. **We anticipate that drawing on the associated evidence-based statements – Figure 3 – and adopting the staged thinking tool – Figure 4 – will help planners to develop more robustly theorised interventions.**

Within the relatively narrow inclusion criteria of one-to-one care pathway forms of BFPS intervention, delivered in developed country settings, to mothers of full-term babies, this review has found considerable heterogeneity in: the type and scale of feeding 'problems' that were addressed, the specific intervention components that were employed, the wider delivery context and background social

norms. Characteristics of 'peers' selected to deliver the 15 included interventions varied in degree of compliance with the principle of homophily and according to the extent to which professionalisation and integration with existing services was intended. Descriptions of intervention theory were frequently absent from the intervention case materials. The Theory of Social support was referred to explicitly in the literature relating to two intervention cases and appeared to be implied as an underpinning theory more broadly. However, different configurations of intervention components suggested differences of emphasis on informational, emotional, instrumental or appraisal among the included interventions (House 1981).

While interpersonal TOCs will clearly be fundamental to an intervention that is centred on a peer-mother relationship, the findings of this review indicate strongly that BFPS intervention design should incorporate theories (and associated intended mechanisms for change) operating at higher ecological levels. As Jagosh (2012) has noted, CMO configurations are often embedded inside one another or temporally ordered so that an outcome from on CMO interaction becomes the context for the next CMO interaction. This is the case for one-to-one BFPS interventions which rely on a chain of mechanisms firing in sequence and integration with the care pathway, as described in **Figure 2**. Failure to consider interactions between the intervention and upstream context influences at the intervention design stage appears to be in part responsible for high rates of implementation failure among studied BFPS interventions. This finding highlights the need for those designing and evaluating complex interventions to consider such interventions as interruptions to wider complex adaptive systems (Hawe et al, 2009; Fletcher et al, 2016).

Our findings are similar to those of Harris et al (2015) in terms of the importance of cultural-specific support and allowing sufficient time and opportunities to facilitate meaningful peer-recipient relationships. While Harris's work emphasises the bottom-up processes required to negotiate and co-design peer support provision, our review offers more concrete insights into how one-to-one breastfeeding peer support should be operationalised – for professionals, peers and recipients. Our review confirms findings from qualitative research that background feeding norms and behaviours interact with BFPS interventions in important ways and that the strength of countervailing mechanisms among mothers who had not themselves previously been considering breastfeeding and who are living in areas with very low background breastfeeding rates may be very difficult to overcome (McInnes, 2013).

The tendency among peers to modify interventions protocols and to direct time and emotional energy towards mothers who are most appreciative of their support is understandable. It's worth also considering whether peers are not also enacting a rational distribution of their resources by directing their energies in the direction in which they perceive they are making the greatest difference and avoiding wasting resources where it is not possible to make a difference. This consideration raises questions about the appropriate goals for BFPS intervention in areas with high background formula feeding rates.

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The review confirmed findings from Harris et al (2015) that peer support interventions often rely on support from health professionals. BFPS interventions inserted into service contexts in which managers and maternity staff are ambivalent about breastfeeding, where in-hospital formula milk supplementation rates are high and where health professionals themselves lack the knowledge and skills to enable breastfeeding are unlikely to be delivered as intended, or be effective. Even where BFPS is congruent with an existing service agenda, further work is needed to embed the intervention and establish effective referral pathways. Aiken and Thomson (2012) found that integration can be improved through processes that emphasise collaboration, including improving visibility of peers in a health professional setting, joint-training, opportunities for mutual feedback between peer supporters and health professionals, shared access to systems and records, and paid co-ordination of peers. However, this review also suggested that integration barriers were often context-specific. From a design perspective, it may be more fruitful to specify a stage of identifying and overcoming context-specific barriers to integration, incorporating processes that have been found to improve integration, rather specifying a one-size fits all approach.

Help needs to be timely – this does not imply a one-size-fits-all approach to specifying points for intervention, but rather means ensuring that contacts anticipate 'pivotal points' for changes feeding behavior in the target population, along the lines discussed by Hoddinott et al (2012). In a UK context, where unplanned drop-off in breastfeeding in first two days is common (McAndrew, 2010) this means proactive contact soon after the birth is required. Proactive support need not mean untailored support, a *negotiated proactive* approach may enable a mother to progressively adjust a schedule of contacts to meet her needs (Dennis, 2002). However, a negotiated model needs to take account of the clear finding from this review that women of all backgrounds experience significant emotional barriers to contacting peer supporters for help; the review disconfirms any notion that mothers will be empowered by reactive BFPS support because they feel in charge of the relationship.

The review confirmed that mothers value warm emotionally supportive relationships (Schmied et al, 2011); however, it was not possible to identify any aspects of training or ways of delivering the support (e.g. face-to-face/ telephone; long-term/ short-term) that were consistently associated with the kinds of relationships that mothers appreciated. It is perhaps surprising that a context of socially similar peers did not consistently emerge as an important trigger for change mechanisms. It's possible that an upstream priority of ensuring interventions are accessible may have masked additional benefits arising from perceived similarity in our CMO analysis. Alternatively, it may be that the 'like me' qualities of the peer are less important in care pathway BFPS models, where the peer's role may be perceived as being close to that of an auxiliary health care worker. A further surprise, the sense either on the part of the peers or on the part of the mothers that the BFPS intervention delivered specialised breastfeeding expertise did not consistently emerge as an important mechanism for effective intervention. Again, this may be because of a masking impact of upstream considerations, it may be that that social support is a more important trigger for change, or it may be that the peer's own level of expertise is less important than her ability to facilitate access to expertise from elsewhere within the referral pathway.

The review identified ways in which an experimental context may make it more likely that mechanisms associated with implementation failure will be triggered. **The findings affirm the need to understand interventions as interruptions to complex systems (Hawe et al, 2009), as well as the need to take a co-production approach to intervention development, including the development of a theoretical rationale and the intended mechanisms via which positive outcomes will be realised, and accounting for context in evaluation are crucial components of intervention design and intervention, (Bonell et al., 2015).** The need to integrate realist principles (Fletcher et al. 2016) and process evaluations (Moore et al, 2015) into randomised controlled trials ('realist RCTs') to enable evaluations of complex interventions to answer questions about what works, for whom and under what circumstances is also underlined. The thinking tool and statements provide an evidence-based guide to BFPS intervention development; they do not supersede a need for future evaluation.

Commented [HT16]: Drafting has been improved

A key limitation of this review is that we have used information drawn only from cases that have been associated with an experimental study. A broader range of one-to-one BFPS intervention cases that have been studied using alternative research designs, e.g. non-experimental, qualitative, might have added depth to our findings. A further limitation relates to the variable quality of included cases. Only four cases included a process evaluation and we were not successful in contacting all the study authors to elicit further information. Where process studies did exist, intended mechanisms for change were often lacking so that the process evaluation could not effectively ascertain whether these mechanisms had been triggered. Description of the pre-intervention context was weak for several cases. Two cases lacked a detailed description of the components of the intervention. We recommended that full details of context and mechanisms are included in the reporting of experimental studies so that clear implications can be identified.

Commented [HT17]: We have amended this part of the discussion to reflect the comments made by Reviewer 3.

The focus on one-to-one BFPS in this review limits applicability of lessons. Harris et al (2015) make a distinction between peer support interventions that are underpinned by a top-down public-health epistemological stance and those underpinned by community-based participatory approaches to agenda setting. As the majority of interventions were driven up a top-down public health agenda, this reflects a bias towards authoritarian forms in the experimental literature about peer support more generally (O'Mara-Eves, 2013). The public health agenda driven, one-to-one 'care pathway' BFPS interventions that predominate the systematic review evidence, represent a subset of existing BFPS intervention types (Trickey, 2013). In practice, in the UK and elsewhere, BFPS is often delivered in group settings (Dykes, 2005).

Finally, this realist review of BFPS interventions needs to be considered in terms of its potential contribution to the broader public health policy objective of bringing about sustained change in infant feeding norms in developed country settings. The inclusion criteria for this review means that evidence presented is based on BFPS interventions that – however well or poorly embedded into their varied contexts – are primarily focused on changing the behaviour of individual mothers. A consensus is now building around an understanding that interventions operating at the individual level alone are unlikely to achieve sustained change in breastfeeding rates; that wider social, structural and service constraints should now be the focus of public health policy (Rollins et al, 2016; Baby Friendly UK, 2016). **Behaviour**

Commented [HT18]: Amended to take account of comments from Reviewer 1.

change theories have become more complex, enabling those designing interventions to consider many contributing factors which influence how people behave. For example, The Behaviour Change Wheel (Mitchie et al., 2011) highlights three essential components: capability (psychological and physical), motivation (autonomic and reflective) and opportunities (social, physical). The next layer of the wheel details nine intervention functions (e.g. training, environmental restructure, modelling, education) aimed at addressing deficits in one or more of the essential components. The final circle of the wheel are seven categories of policy that could enable those interventions to occur (e.g. service provision, fiscal measures, guidelines, communication/marketing). There is a need to understand the interactions between these levels (Dyson et al, 2006; Labbock, 2008; Trickey, 2016; Rollins et al, 2016) and, at present we lack a unifying theory that would allow us to translating this understanding into a prescription as regards the sequence in which influences should be addressed. The place of intermediate outcomes – for example, changes in wider service context, changes in attitudes, changes in beliefs, changes in intentions – on a pathway to community or society-level norms is under-theorised.

The absence of any over-arching TOC means that it is difficult for intervention planners to target BFPS interventions to maximum benefit. If the policy focus is communities with low breastfeeding rates, should BFPS focus on encouraging more women to initiate breastfeeding or on enabling more women to continue? Should the emphasis be on breastfeeding rates or on positive experiences and changing attitudes? In the medium-term commissioners will need answers to these broader questions. In the meantime, we recommend that intervention planners draw on our stages of design model for BFPS in conjunction with taking a context-specific participatory approach to agenda-setting, so that local level TOCs can be developed and appropriately evaluated.

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